Journal of Diabetes Research

Psychological Aspects Related to Diabetes Mellitus

Guest Editors: Nitin Gupta, Sanjay Kumar Bhadada, Viral N. Shah, and S. K. Mattoo

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Editorial

Psychological Aspects Related to Diabetes Mellitus

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The prevalence of diabetes has shown an exponential worldwide rise in recent years [1]. Poor glycemic control results in long-term micro/macrovascular complications, and thus most diabetes organizations recommended good glycemic control (defined as A1c less than 7%) to prevent these complications. However, management of diabetes requires lifelong daily adherence to dietary and exercise plans, frequent blood glucose monitoring, and adherence to medications. This results in higher risk for reduced physical, emotional, and social well-being (in terms of quality of life) among people with diabetes.

Over the decades, there has been a burgeoning research interest in the psychological aspects related to diabetes. Numerous evidences suggest the important role of psychosocial factors in diabetes self-management. Psychosocial problems can result in nonadherence to medications, poor quality of life, and lack of interest in managing disease resulting in poor glycemic control and long-term complications. In this regard, therefore, the American Diabetes Association (ADA) and various other diabetes organizations recommend psychosocial assessment of people with diabetes to improve diabetes related health outcomes [2]. In keeping with the quite broad and complex nature of diabetes, the research issues are numerous and varied. This special issue is in no way different. When the publishers and the editorial team had jointly envisaged this theme (and special issue) a year back, we had not anticipated the interest it would generate. An overwhelming number of submissions were received for this issue within a short span of just six months, after undergoing an extremely rigorous process of in-house and external peer review.

Various aspects related to diabetes have been reported in this special issue of the journal, namely, study of preventive factors, etiology, quality of life (QOL), clinical and psychosocial correlates, comorbidity, adherence issues, management (both self-intervention and external intervention based), and cultural issues.

The aforementioned psychological factors can influence the self-management of diabetes. In this issue, E. J. Dill et al. studied the effect of psychosocial factors such as psychological distress, coping skills, and family support on a weight loss program for the prevention of diabetes among 3135 American Indians and Alaska Natives. They demonstrated that psychosocial factors influence weight loss. It may be possible that addressing psychosocial factors might increase the success of diabetes prevention strategies.

Studies by M. M. A. Eilander et al. and M. P. Günther et al. demonstrated that behavior problems and psychosomatic factors are associated with glycemic control (reflected by A1c) in children and adolescent with type 1 diabetes (T1D). M. S. D'Souza et al. have studied determinants of the quality of life (QOL) among 300 adults with type 2 diabetes (T2D) from Oman. They showed that QOL is linked with self-management strategies; additionally management and knowledge of diabetes were higher in females. L. C. Jones et al. showed that 20% of 246 community-dwelling older adults (≥65 years) with T2D had depressive symptoms, with positive association between higher level of diabetes distress and depression. They conclude that if interventions are targeted at reducing the diabetes related distress and additional health complications arising out of diabetes, then one may be able to reduce depressive symptoms in patients with diabetes.

In a study by L. Wisting et al., they showed that eating disorder psychopathology and illness perception were important contributors to metabolic (glycemic) control in females with T1D. Studies from three different continents support the recommendations of the ADA that evaluation of psychosocial factors should be a part of all diabetes clinic visits [2], in order to improve diabetes related outcomes and QOL in these patients.

Significant research is being undertaken to understand the etiology of diabetes and diabetes prevention. The success of longitudinal epidemiologic studies lies with participant retention in such studies. B. Lernmark et al. have analyzed the factors associated with participant dropout in a large multinational TEDDY (The Environmental Determinants of Diabetes in the Young) study aimed at characterizing environmental factors causing T1D in children. Demanding research protocol, frequent blood draws, overwhelming research information, and time constraints were common factors related to participant dropout. The results so obtained made them advice caution regarding use of painful procedures, time required for participation, and assessment of study satisfaction. Thus, one can see that participation (and conversely withdrawal) from trials by patients with diabetes potential (and their families) can be influenced by various psychosocial factors.

Keeping in view the inherent nature of the disease and its long-term management, coupled with the individualistic and autonomous pattern of living in the West [3], which is now being increasingly seen in the Eastern/traditional countries [3, 4], self-management of diabetes assumes importance of significant proportions. In this regard, studies are available in this issue, which have examined this concept using differing research methodologies.

A.-R. Abubakari et al. studied role of various factors to explain adherence to self-management recommendations among over hundred people with poorly controlled diabetes by administering various questionnaires. They determined that the "illness perceptions" and "self-efficacy beliefs" of such patients were important predictors of their self-management behaviors and could potentially guide effective interventions.

M. Hofmann et al. specifically focus on adults with T2D and attempt to measure the impact of an internet-based, self-management intervention ("HeLP-Diabetes") by mixed-methodology. The qualitative and quantitative data so generated demonstrated that the interventions positively impact both psychological and behavioral outcomes in these patients. However, it is necessary to bear in mind that the sample comprised only 19 participants.

The write-up by A. Jones et al. is, strictly speaking, not a research study but a "practical guide" for diabetes healthcare providers on the processes and techniques required for establishing a "working alliance" with patients having diabetes in order to enhance their self-management and positively influence their treatment outcome in relation to psychological and somatic aspects of the illness.

Recently, there has been focus in creating semiautomatic insulin delivery system (artificial pancreas, AP) to improve glycemic control and prevent long-term diabetes related complications, especially in patients with T1D [5]. However, the success of the AP lies in not only creating devices but also understanding factors associated with its acceptance. Apart from self-management, psychological aspects tend to be associated with any form of intervention for diabetes [6]. Hence, it is pertinent that this issue carries studies highlighting this key aspect too. C. Ziegler et al. studied the parameters of fear, satisfaction, and acceptance of AP system among patients with T1D. They demonstrated that the AP system was associated with reduced hypoglycemia worries and increased satisfaction in patients with T1D. However, this study was limited by small number of patients with T1D and was conducted over a very short duration of only 4 days.

With increasing advances in technology, patients with diabetes tend to access information regarding the illness and interventions online more frequently [7]. In another study from Netherlands, Y. Roelofsen et al. have investigated clinical and psychological characteristics between users and nonusers of an online platform. Over 600 patients with T2D were evaluated, and it was seen that patients who accessed the online platform had more favourable psychological characteristics (higher quality of life, better well-being, lesser distress, and better medication adherence). Hence, patients with poorer psychological profile tended to be more "unreached." This study does have significant implications for not only planning interventions, but also reaching out to these patients.

Lastly, the impact of culture cannot be emphasized enough; it tends to influence personalities, behaviors, illnesses, and so forth [8]. Hence, the article by N. R. Patel et al. on the migrant British South Asians is quite topical and pertinent. Not only do they focus on this ethnic group (which has a disproportionately high prevalence of diabetes) in a Western country (i.e., UK), but also another cultural variable is studied in detail that is "impact of travel back to the East." There is a qualitative study on 44 participants with both types of DM being interviewed cross-sectionally. They concluded that despite living in the UK, social networks in the East were very important for both information and support.

The World Health Organization has pledged to build awareness towards the global epidemic of diabetes [9]. To this end, assimilating information on the psychological aspects of diabetes in a comprehensive and scientifically critical manner shall be a step in right direction. Mainstream focus and interest in research and clinical aspects of diabetes have invariably centered around the physical aspects/complications. It is probably an opportune moment to provide the same focus and intensity to the psychological aspects too. Hence, understanding the pertinent psychological aspects related to diabetes is essential [6].

In a recent review in the World Journal of Diabetes, Chew et al. [6] have highlighted the need for more research to understand various individual (read as "psychological") factors, cross-disciplinary working, and international collaboration. As editors of this special issue, we could not agree more with this. Additionally ADA, in the position statement, has highlighted the key role of team approach and collaborative care interventions [2].

We hope that this "special issue" shall stimulate the readers into not only furthering research on diabetes and related psychosocial aspects, but also developing service delivery models and higher standards of clinical care using a multidisciplinary team based integrated liaison model approach.

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Viral N. Shah
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Research Article

Sociodemographic and Clinical Predictors of Self-Management among People with Poorly Controlled Type 1 and Type 2 Diabetes: The Role of Illness Perceptions and Self-Efficacy

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Self-management is critical if people with diabetes are to minimise their risk of macrovascular and microvascular complications, yet adherence to self-management recommendations is suboptimal. Understanding the predictors of optimal diabetes self-management in specific populations is needed to inform effective interventions. This study investigated the role of demographic and clinical characteristics, illness perceptions, and self-efficacy in explaining adherence to self-management recommendations among people with poorly controlled diabetes in North West of England. Illness perceptions and self-efficacy data were collected using validated questionnaires and clinical data were obtained from hospital records. Correlations were used to investigate bivariate relationships between independent variables and self-management, and multiple regression techniques were used to determine demographic and psychosocial predictors of self-management. Various demographic and clinical characteristics were associated with adherence to self-management recommendations. In particular, employment status explained 11% of the variation in adherence to foot care whilst diabetes treatment category explained 9% of exercise and 21% of the variations in SMBG recommendations. Also, 22% and 8% of the variations in overall self-management were explained by illness perceptions and self-efficacy beliefs, respectively. Illness perceptions and self-efficacy beliefs of people with poorly controlled diabetes are important predictors of their self-management behaviours and could potentially guide effective interventions.

1. Introduction

Diabetes is a complex chronic condition with serious physical, psychological, and clinical complications for individuals affected [1]. Irrespective of the type of diabetes, appropriate self-management is critical if individuals with the condition are to minimise their risk of diabetes complications and ensure improved health outcomes overall. Key areas of the diabetes self-management regime include significant behavioural and lifestyle changes such as meal and dietary planning, daily regulation of physical activity, appropriate use of recommended medication, and, where applicable, monitoring and interpretation of blood glucose and use of its results to inform decisions such as adjusting medications, diet, and physical activity levels [2]. There is evidence that adherence to supportive but often complex self-management plans in diabetes is suboptimal [3, 4] which raises questions about potential predictors of effective self-management, which have particular importance for people whose diabetes presents as poorly controlled.

In addition to the drastic behavioural and lifestyle changes required following diagnosis with diabetes, uncertainties about the future and, indeed, thoughts and/or experiences of the acute and chronic complications associated with the condition often lead to severe coping and other psychosocial problems for individuals affected.

Thus, promoting effective self-management requires that patients are equipped with a repertoire of relevant knowledge and skills through appropriate self-management education and support systems [2, 5]. Specifically, individuals with diabetes need a clear understanding of the tasks involved in self-management, a practical appreciation of how to perform each self-management task on daily basis, some of which could be complex, and the ability to determine when and under what circumstances to undertake a particular self-management task, as well as decision-making and problem-solving skills [6, 7]. Even with these skills, adherence to self-management recommendations is influenced by several other factors including (but not limited to) personal and sociodemographic characteristics, individual's own perceptions and expectations about the given illness, and their perceived confidence in relation to whether or not they are able to perform the given self-management task (concept of self-efficacy) [8–10].

Self-efficacy is a cognitive theory that was put forward in the 1970s by Bandura [11]. The concept asserts that individuals' level of confidence in relation to their ability to perform a given task such as a specific health behaviour is an important determinant of whether or not they initiate and engage in that behaviour. Because of its potential to influence the desired health outcomes, the concept of self-efficacy is of great interest to researchers, health providers, and promoters in search of theoretical frameworks to anchor and guide policy and practice. Particularly, improvements in self-efficacy of patients have been used as a mechanism to enhance behaviour change and improve adherence to chronic disease self-management recommendations, including those for diabetes [6, 12, 13]. Indeed, self-management interventions developed with self-efficacy as the underpinning theoretical framework have shown promise, albeit inconclusive. For instance, Lorig and Holman [6] observed that self-efficacy on its own significantly influences the health status of people with long-term conditions. Specifically they found that self-efficacy levels at baseline as well as changes in self-efficacy achieved through self-management intervention significantly predicted health status. Recently, others have also reported modest to strong relationships between self-efficacy and self-management behaviours among adults with type 2 diabetes [14, 15] and adolescents with type 1 diabetes [9, 16]. In spite of the plethora of evidence on the relationship between self-efficacy and self-management, the majority of studies have been conducted in the general diabetes population, regardless of patient demographics and diabetes control outcomes. Thus, it is not clear if such a relationship will exist in a sample exclusively drawn from a population with poorly controlled diabetes.

In addition to self-efficacy, another cognitive framework useful for explaining health-related behaviour choices of individuals and perhaps populations is the illness representation model. This concept is based on the common-sense model of illness representation which evolved from the work of Howard Leventhal and colleagues' investigating impact of fear messages on individuals' inclination to perform recommended health behaviour [17]. They observed that a health threatening stimulus provoked, simultaneously, the search for both emotional and cognitive representations of the health threat among their study participants. Leventhal noted that the parallel processing of the cognitive and emotional representations of the threat served to generate strategies and coping plans with which to eliminate the threat. Much of research on this framework has been on patient samples; however, in principle, a health threat (stimulus) could result from experiencing symptoms of an illness, being diagnosed with an illness, or being potentially at risk of illness. Illness representations could emerge from three types of information: "lay" knowledge already possessed by an individual, authoritative information obtained from external sources (e.g., doctor and book), and personal experience, whether current or previous, including outcomes of that experience. It is contended that an individual's representations of an illness are based on their personal perceptions and/or experiences of the condition or other illness and should not necessarily be expected to conform to existing medical facts about the given illness [18, 19].

Research has reliably shown that an individual represents an illness along five cognitive dimensions [17]: identity, the label and symptoms associated with the illness; consequences, the individual's perception of how the illness might affect their lives and any likely outcome; Control, the individual's perception of the level of control or influence they have over the course of the illness, including its cure or treatment; timeline, the length of time individuals perceive their illness will last (short-term or long-term); and Cause, individuals' beliefs about what caused the illness. The emotional representation component indicates patients' attitude or state of mind in response to the diagnosis or health threat (e.g., fear, anxiety, or distress). Illness representations have been found to significantly influence individual's lifestyle and behaviour choices, and the concept has subsequently been employed as an effective mechanism for improving behaviour change and other health outcomes [20–22]. Among people with diabetes, illness representation has been reported to predict adherence to recommended self-management behaviours, as well as objective clinical outcomes, particularly glycaemic control levels [23–26]. However, what is not clear is whether the concept of illness representation is universal in terms of the demographic and clinical profile of the patient population studied. This is important if effective packages to support coping and self-management of diabetes are to be put forward by clinicians.

This study examined whether patient characteristics, patients' diabetes specific self-efficacy, or patients' illness representations would significantly influence self-management behaviours of predominantly poorly controlled type 1 and type 2 diabetes (from this point, type 1 and type 2 diabetes will be referred to as diabetes, unless otherwise specified) patients managed in acute trusts. We specifically aimed at addressing 2 research questions. First, we sought to investigate which sociodemographic and disease characteristics are likely to influence diabetes specific self-efficacy, illness representation, and self-management among individuals with poorly controlled diabetes. Then we determined whether self-efficacy and illness representations influence the degree of adherence to self-management recommendations among the study population.

2. Materials and Methods

2.1. Study Participants and Procedures. This study was part of a larger study that investigated the influence of work-related factors on diabetes self-management. Thus, names and addresses of potentially working adults (aged 25–65 years) with diabetes were obtained from databases of two NHS hospital trusts in the North West of England. Individuals who did not have a record of severe mental (such as severe depression) or cognitive disorder (such as dementia) and could provide consent were contacted by post and invited to participate in the study. Study packs containing invitation letter, consent form, participant information sheet, stamped self-addressed return envelope, and study questionnaires were sent to potential participants. The invitation letter asked patients to read the information sheet and if they agree to participate in the study, sign the consent forms, complete the questionnaires, and return them to the researchers in the stamped envelope provided. After three weeks from the date of postage, reminder letters and another pack of questionnaires were sent to patients who did not respond. Participant recruitment took place between July 2013 and November 2013.

Relevant data were collected using a demographic and disease characteristics questionnaire, the brief Illness Perceptions Questionnaire (IPQ) [27], the Summary of Diabetes Self-care Activities (SDSCA) questionnaire [28], and the Perceived Diabetes Self-Management Scale (PDSMS) [29].

Recent (last 6 months, if not last 12 months) data on glycaemic control (HbA1c), diabetes complication status (microvascular), and comorbidities were obtained from participants' medical records. Ethical approval was granted by the North East-Newcastle & North Tyneside committee 1.

2.2. Study Questionnaires. The brief IPQ [27] is a nine-item summarised and quick to administer version of the full illness perception questionnaires [30, 31] used for assessing individuals' cognitive and emotional representations of an illness such as diabetes. The first eight items of the questionnaire examine patient's perceptions of the timelines, consequences, identity (symptom load), coherence (or understanding), and emotions, each scored on a scale of 0 to 10. The ninth item asks patients to rank in order of importance the 3 factors that they believe to have caused their illness (in this case, diabetes). Overall, high scores on the brief IPQ indicate a more threatening or serious view of the illness, whereas low scores reflect more benign view. Psychometric properties of the instrument have been evaluated using a wide range of patient populations including people with myocardial infarction, asthma, and diabetes. Six-week test-retest reliability for individual components of the measure, as determined by Pearson correlation coefficient, ranged between 0.42 and 0.75 and items of the brief IPQ correlated sufficiently with equivalent component items of the full IPQ-R (ranging from 0.32 to 0.63), indicating good concurrent validity. Further, various elements of the brief IPQ have been found to significantly predict a range of health outcomes including attendance at rehabilitation classes, time of return to work, and quality of life among MI patients [27].

The SDSCA is a self-report measure and asks patients to indicate how many of the last seven days they fulfilled dietary, exercise, self-monitoring of blood glucose (SMBG), and foot care recommendations as advised by their diabetes health care team (scored on a scale of 0 days–7 days). The revised SDSCA used in this study consists of 11 carefully selected core items which demonstrated sound psychometric properties (internal consistency, predictive validity, and no ceiling/floor effect) from seven previously published studies [28]. Of the 11 items of the SDSCA, four are for diet, two are for exercise, two are for SMBG, two are for foot care, and one is for smoking. In consonance with the number of days in a week, each item (except smoking) is scored on a scale of zero (participant has not performed the task in the last seven days) to seven (participant has performed the task every day in the past seven days). The item for smoking is binary (Yes/No response) and asks whether participants smoked cigarette during the past seven days. In this study, the scores for specific dimension of self-management, diet, exercise, SMBG, and foot care, were obtained from the average scores of all relevant items combined. Scores for overall adherence to self-management (overall self-management) were computed by taking the average of diet, exercise, SMBG, and foot care. The smoking item was not included in computing the dimension-specific or the overall self-management scores.

The PDSMS [29] is an 8-item likert-type questionnaire which was developed from the generic Perceived Medical-Condition Self-Management Scale [32] for use with both type 1 and type 2 diabetes populations. If fully completed, total scores for the PDSMS range from 8 to 40 with high scores indicating greater confidence in the individual's ability to self-manage their diabetes. Psychometric evaluation analyses showed reasonable correlations between responses to the PDSMS and SDSCA and demographic characteristics, demonstrating sufficient evidence of construct validity. The PDSMS also showed good internal consistency (Cronbach's alpha = 0.83) among the mixed type 1 and type 2 diabetes patient sample.

2.3. Statistical Methods. Data analyses were conducted using the Statistical Package for Social Sciences (SPSS version 20, IBM Corp.). Initial analyses were performed to investigate normality and other assumptions of parametric statistical tests where required. Bivariate correlations (Pearson's correlation coefficient (r) for continuous variables, Spearman's rho (P) for ordinal and continuous variables that were not normally distributed, or point biserial (r_{pb}) for dichotomous variables; see Table 1) were produced to examine univariate relationships between dependent and independent variables. Two methods of multiple regressions were used. First, stepwise regressions were used to determine which sociodemographic characteristics best predict psychosocial dependent variables (illness perceptions and self-efficacy) and

Table 1: Bivariate relationships between sociodemographic and disease characteristic variables and psychosocial dependent variables.

Variable	IP score	PDSMS score	Diet SMG	Exercise SMG	SMBG	Foot SMG	Overall SMG
Age	−0.03	−0.02	0.03	−0.12	−0.01	0.24^{*}	0.08
Sex$_{\text{pb}}$	0.04	−0.10	0.12	0.03	0.18^{*}	0.02	0.16
Marital status$_{\rho}$	0.16	−0.12	−0.14	−0.16	−0.07	−0.01	−0.11
Educational qualification$_{\rho}$	−0.16	0.16	−0.09	0.12	−0.01	0.10	−0.02
Ethnicity	0.01	0.03	0.09	0.05	−0.05	0.22^{*}	0.12
Employment status$_{\rho}$	0.23^{*}	−0.09	−0.04	-0.20^{*}	−0.04	0.08	0.01
Diabetes type$_{\rho}$	0.19^{*}	-0.20^{*}	0.06	-0.23^{*}	-0.26^{**}	0.13	−0.09
Diabetes treatment type$_{\rho}$	0.21^{*}	−0.08	0.05	−0.14	0.39^{***}	0.07	0.12
Duration since diagnosis	−0.18	0.19^{*}	−0.01	0.05	0.33^{***}	0.13	0.18
BMI status$_{\rho}$	0.21^{*}	−0.13	−0.08	−0.19	−0.16	0.15	−0.10
HbA1c (%) categories$_{\rho}$	−0.12	0.18	−0.18	0.22^{*}	0.07	0.04	0.10
BP status$_{\text{pb}}$	0.07	−0.01	0.12	−0.01	−0.09	0.15	0.02
Retinopathy status$_{\text{pb}}$	−0.01	0.03	−0.07	−0.04	0.11	0.07	0.07
Neuropathy status$_{\text{pb}}$	0.24^{*}	−0.14	−0.11	-0.20^{*}	−0.08	0.13	−0.09
Nephropathy status$_{\text{pb}}$	0.14	−0.06	0.10	0.09	−0.04	0.05	0.12
IP score			−0.16	−0.13	−0.01	0.04	−0.17
PDSMS score			−0.16	0.19^{*}	0.10	0.17	0.29^{**}

ρ, spearman's rho; pb, point biserial correlation coefficient; all other correlation coefficients are Pearson's correlation coefficients.
$^{*}p$ value ≤ 0.05; $^{**}p$ value ≤ 0.01; $^{***}p$ value ≤ 0.001.
IP, illness perception; PDSMS, Perceived Diabetes Self-Management Scale; SMG, self-management; SMBG, self-monitoring of blood glucose.

adherence to self-management recommendations. Finally, the enter method was used to determine the extent to which illness perceptions or self-efficacy predicts adherence to self-management recommendations in the study population. Independent variables were entered irrespective of the strength of the relationship in the bivariate correlations.

Based on relevant parameters of the main study, a minimum of 340 participants were required to achieve a precision of 0.05 at 95% confidence interval, assuming 1 in 3 diabetes patients in the working-age range was in employment. However, a minimum sample size of 128 is sufficient for the analysis presented in this paper (see details in Section 3.2.2).

People with diabetes are not a homogenous group and some questions of the SDSCA may not be relevant for some specific groups. For instance, SMBG may not be recommended for some patients, particularly individuals on oral hypoglycaemic agents. Thus, prior to completing the SDSCA, participants were asked to indicate (Yes/No/Not applicable) whether they have ever been advised by their diabetes healthcare team to perform any of the recommended self-management tasks since diagnosis. Responses to this preliminary question were then used to adjust for all analysis involving the SDSCA.

3. Results and Discussions

3.1. Results

3.1.1. Demographic and Disease Characteristics of Study Participants. A hundred and twenty-three individuals with diabetes (51% type 2) participated in the study. Just over half (51%) of participants were male and nearly all participants (96%) considered their ethnicity as white British. About a quarter of participants (24%) had university level educational qualification and most (80%) were employed or self-employed. On average, participants were 50 years old (mean age: 50.24; SD = 10.84), had been diagnosed with diabetes for 16 years (mean duration since diagnosis = 15.97 years; SD = 10.62), and were on average obese as indicted by the mean BMI = 31.76 (SD = 6.90). As expected of an exclusively poorly controlled sample, average percentage HbA1c was 44.39 (SD = 14.22). Prevalence of diabetes related comorbidity and complications were also high in the studied population with over 80% of participants having blood pressure levels considered either prehypertensive or hypertensive. Also, half of participants had diabetic retinopathy, slightly more than one in five (21%) had diabetic neuropathy, and 11% were diagnosed with nephropathy.

3.1.2. Associations between Sociodemographic and Disease Characteristic Variables and Psychosocial Dependent Variables. Bivariate correlations between demographic/disease characteristics and individual components of illness representations showed scores of significant relationships. Notably, high educational attainment was associated with perception of greater personal control ($P = 0.21$, p value < 0.05) and less concern about their illness ($P = -0.22$, p value < 0.05). Participants with type 1 diabetes tended to perceive their diabetes as long-term ($r = -0.26$, p value < 0.01) and had perceptions of greater personal control ($r = -0.29$, p value $<$ 0.01), greater treatment control ($r = -0.31$, p value < 0.01), and greater understanding or illness coherence ($r = -0.21$,

p value < 0.05). As a surrogate marker of illness severity, being on a more complex treatment regimen was associated with experiencing greater number of symptoms ($P = 0.35$, p value < 0.001). Longer duration since diagnosis was significantly correlated with perceiving diabetes as long-term condition ($r = 0.28$, p value < 0.01) and perceptions of greater personal control ($r = 0.21$, p value < 0.05), treatment control ($r = 0.20$, p value < 0.05), and greater understanding or coherence about diabetes ($r = 0.30$, p value < 0.01). High BMI was associated with greater worries (concern) about diabetes ($P = 0.22$, p value < 0.05), presence of neuropathy was associated with perception of less treatment effectiveness ($r = -0.29$, p value < 0.01), and presence of nephropathy was associated with perceptions of greater consequences ($r = 0.20$, p value < 0.05) as a result of diabetes.

In terms of overall illness perception score, the univariate relationships (see Table 1 column 2) indicate that, compared to the unemployed/retired, participants who were employed had more threatening representations about their diabetes (see interpretation of brief IPQ in Section 2.2). Also having type 2 diabetes, being on a more complex treatment regimen, having higher BMI, and having neuropathy were associated with a more threatening view of diabetes.

As shown in Table 2, a raft of significant relationships between demographic/disease characteristics and illness perceptions were observed in the multivariate regression analyses. Demographic/disease characteristics explained 12% of the variations in consequences, 56% of timeline, 38% of personal control, 27% of treatment control, 17% of identity (symptom load), 15% of concern, 14% of illness coherence, and 9% of emotional representations among study participants. A key demographic variable which predicted variations in specific components of illness perceptions was educational achievement. Compared with the lowest educational attainment (primary/secondary education), college/sixth form graduates were less likely to represent their diabetes as long-term ($B = -0.50$; 95% CI, -0.77–-0.24; p value ≤ 0.001) and graduates from university/graduate were more likely to report greater personal control of their diabetes ($B = 1.30$; 95% CI, 0.29–2.30; p value ≤ 0.01), whereas graduates from polytechnic were more likely to perceive their diabetes with greater number of symptoms ($B = -2.44$; 95% CI, -4.72–-0.15; p value ≤ 0.05). In relation to disease or clinical variables, treatment regimen, duration since diagnosis, microvascular complication status, type of diabetes, BMI, and percentage HbA1c significantly contributed to a range of specific illness representations. Diabetes treatment category emerged as a significant predictor for most specific components of illness perceptions. Specifically, there were significant variations in consequences ($B = 1.34$; 95% CI, 0.20–2.48; p value ≤ 0.05), timeline ($B = -0.67$; 95% CI, -1.04–-0.30; p value ≤ 0.001), personal control ($B = 1.56$; 95% CI, 0.12–3.00; p value ≤ 0.05), identity (number of symptoms experienced) ($B = 1.86$; 95% CI, 0.67–3.05; p value ≤ 0.01), and concern ($B = -1.86$; 95% CI, -2.81–-0.90 p value ≤ 0.001) between participants on one hypoglycaemic tablet compared to people on more complex or advanced treatment regimens (≥2 hypoglycaemic tablets, insulin, or diabetic tablets and insulin). Longer duration since diagnosis was associated with longer timeline perceptions ($B = 0.02$; 95% CI, 0.01–0.03; p value ≤ 0.01), greater understanding (coherence) about diabetes ($B = 0.06$; 95% CI, 0.02–0.11; p value ≤ 0.01), and lower negative emotional response ($B = -0.09$; 95% CI, -0.15–-0.03; p value ≤ 0.01).

Employment status, diabetes type, diabetes treatment category, BMI, and neuropathy status significantly contributed to the overall illness perception scores. The multivariate relationships between demographic/disease characteristics and overall illness perception as shown in Table 2 (row (ix)) indicate that diabetes treatment category (1 diabetic tablet versus diabetic tablets and insulin), nephropathy status, duration since diagnosis, percentage HbA1c, and BMI significantly contributed to variations in illness representation in the study sample. Together, these variables explained 34% of the variation in overall illness representation among the study participants.

Diabetes type and duration since diagnosis significantly correlated with self-efficacy scores in univariate analyses (Table 1). Having type 1 diabetes and longer duration since diagnosis was associated with higher confidence in patients' ability to self-manage their diabetes. In the regression analysis (see part (2) of Table 2), neuropathy status, duration since diagnosis, and percentage HbA1c each contributed significantly in predicting patients' perceived confidence (self-efficacy). The three variables together explained 23% of the variation in self-efficacy among the study participants.

3.1.3. Associations between Sociodemographic/Disease Characteristic Variables and Adherence to Self-Management Recommendation. A number of sociodemographic/disease characteristic variables significantly influenced participants' self-management behaviours in the univariate analysis as captured in Table 1. Older age was associated with greater adherence to foot self-management and being female was associated with greater frequency of SMBG. Consistent with general expectations, participants with type 1 diabetes, those with more complex treatment regimens and longer duration since diagnosis, were also associated with higher frequency of SMBG. Further, employment status, diabetes type, percentage HbA1c, and neuropathy status were also associated with adherence to exercise recommendations. The multivariate analyses to determine which demographic/disease characteristics predict self-management behaviours showed that only diabetes treatment category and employment status significantly contributed to variations in self-management behaviours. As seen in Table 2 part (3), diabetes treatment category explained small but significant proportions of the variations in participants' adherence to exercise (9%), SMBG (21%), and overall self-management (7%) whilst employment status explained 11% of the variation in adherence to foot care recommendations.

3.1.4. Associations between (a) Illness Representations and Self-Management Behaviours and (b) Self-Efficacy for Diabetes Self-Management and Self-Management Behaviours. Multivariate relationships between illness representation scores and measured diabetes self-management behaviours are shown in

Table 2: Predicting illness perceptions, self-efficacy, and adherence to self-management recommendations from sociodemographic and disease characteristics.

Predictor variable	*B* (SE)	95% CI	*p* value	β	R^2
(1) *Predicting illness perceptions from demographic/disease characteristics*					
(i) Consequences and demographic/disease characteristics			$<0.01^{**}$		0.12
Constant	2.88 (0.41)	0.88–4.89	$\leq 0.01^{**}$		
Nephropathy status	2.54 (1.03)	0.48–4.59	0.02^{*}	0.254	
diabetic tablets + insulin versus 1 diabetic tablet	1.34 (0.57)	0.20–2.48	0.02^{*}	0.242	
HbA1c (%)	0.04 (0.02)	0.00–0.08	0.04^{*}	0.212	
(ii) Timeline and demographic/disease characteristics			<0.001		0.56
Constant	9.78 (0.13)	9.55–10.05	$<0.001^{***}$		
≥2 diabetic tablets versus 1 diabetic tablet	−0.67 (0.19)	−1.04–−0.30	0.001^{***}	−0.34	
Primary/secondary versus college/sixth form	−0.50 (0.13)	−0.77–−0.24	$<0.001^{***}$	−0.36	
Duration since diagnosis	0.02 (0.01)	0.01–0.03	$<0.01^{**}$	0.29	
(iii) Personal control and demographic/disease characteristics			$<0.001^{***}$		0.38
Constant	12.79 (1.16)	10.48–15.11	$<0.001^{***}$		
Diabetes type	−2.78 (0.51)	−3.78–−1.79	$<0.001^{***}$	−0.56	
HbA1c (%)	−0.07 (0.02)	−0.10–−0.04	$<0.001^{***}$	−0.39	
Primary/secondary versus university/graduate	1.30 (0.51)	0.29–2.30	0.01^{**}	0.23	
≥2 diabetic tablets versus 1 diabetic tablet	1.56 (0.73)	0.12–3.00	0.03^{*}	0.21	
(iv) Treatment control and demographic/disease characteristics			$<0.001^{***}$		0.27
Constant	13.00 (1.17)	10.68–15.33	$<0.001^{***}$		
Diabetes type	−1.73 (0.49)	−2.70–−0.75	0.001^{***}	−0.36	
HbA1c (%)	−0.05 (0.02)	−0.09–−0.02	$<0.01^{**}$	−0.30	
Neuropathy status	−1.47 (0.59)	−2.64–−0.30	0.01^{**}	−0.25	
(v) Identity and demographic/disease characteristics			$\leq 0.001^{***}$		0.17
Constant	4.63 (0.42)	3.79–5.17	$<0.001^{***}$		
diabetic tablets and insulin versus 1 diabetic tablet	1.86 (0.60)	0.67–3.05	$<0.01^{**}$	0.32	
Primary/secondary versus polytechnic	−2.44 (1.15)	−4.72–−0.15	0.04^{*}	−0.22	
(vi) Concern and demographic/disease characteristics			$<0.001^{***}$		0.15
Constant	8.22 (0.29)	7.65–8.79	$<0.001^{***}$		
insulin versus 1 diabetic tablet	−1.86 (0.48)	−2.81–−0.90	$<0.001^{***}$	−0.39	
(vii) Illness coherence and demographic/disease characteristics			$<0.01^{**}$		0.14
Constant	5.82 (0.50)	4.83–6.81	$<0.001^{***}$		
Duration since diagnosis	0.06 (0.02)	0.02–0.11	$<0.01^{**}$	0.30	
Sex	1.05 (0.46)	0.14–1.96	0.02^{*}	0.24	
(viii) Emotional response and demographic/disease characteristics			$<0.01^{**}$		0.09
Constant	6.67 (0.60)	5.48–7.86	$<0.001^{***}$		
Duration since diagnosis	−0.09	−0.15–−0.03	$<0.01^{**}$	−0.30	
(ix) Overall IP score and demographic/disease characteristics			$<0.001^{***}$		0.34
Constant	14.21	−3.09–31.51	0.11		
diabetic tablets and insulin versus 1 diabetic tablet	6.82 (2.22)	2.40–11.23	$<0.01^{**}$	0.29	
Nephropathy status	10.98 (3.87)	3.27–18.70	$<0.01^{**}$	2.84	
Duration since diagnosis	−0.21 (0.11)	−0.42–0.00	0.06	−0.19	
HbA1c (%)	0.27 (0.09)	0.10–0.44	$<0.01^{**}$	0.32	
BMI	0.48 (0.19)	0.11–0.86	0.01^{**}	0.27	
(2) *Predicting PDSMS scores from demographic/disease characteristics*			**$<0.001^{***}$**		**0.23**
Constant	31.87 (2.56)	26.77–36.98	$<0.001^{***}$		
Neuropathy status	−5.17 (1.63)	−8.42–−1.92	$<0.01^{**}$	−0.32	
Duration since diagnosis	0.17 (0.06)	0.05–0.29	$<0.01^{**}$	0.29	
HbA1c (%)	−0.14 (0.05)	−0.24–−0.03	0.01^{**}	−0.26	

Table 2: Continued.

Predictor variable	B (SE)	95% CI	p value	β	R^2
(3) *Which demographic/disease characteristics best predict adherence to self-management recommendations*?					
(i) Diet/meal planning recommendations and demographic/disease characteristics					
No variable entered into the equation (no variable significantly predicted diet)					
(ii) Exercise recommendations and demographic/disease characteristics			**$<0.01^{**}$**		**0.09**
Constant	2.21 (0.31)	1.59–2.83	$<0.001^{***}$		
Insulin versus 1 diabetic tablet	1.47 (0.52)	0.44–2.50	0.01^{**}	0.31	
(iii) Blood testing recommendations and demographic/disease characteristics					0.21
Constant	5.17 (0.27)	4.63–5.71	$<0.001^{***}$		
≥2 diabetic tablets versus 1 diabetic tablet	−3.49 (0.75)	−4.97–−2.00	$<0.001^{***}$	−0.46	
(iv) Foot care recommendations and demographic/disease characteristics			**$<0.01^{**}$**		**0.11**
Constant	2.53 (0.26)	2.02–3.05	$<0.001^{***}$		
Employed versus not in work due to long-term illness/disability	2.32 (0.75)	0.82–3.81	$<0.01^{***}$	0.32	
(v) Overall SMG recommendations and demographic/disease characteristics			0.02^{*}		0.07
Constant	3.79 (0.15)	3.50–4.10	$<0.001^{***}$		
≥2 diabetic tablets versus 1 diabetic tablet	−0.99 (0.42)	−1.83–−0.16	0.02^{*}	−0.26	

$^{*}p$ value ≤ 0.05; $^{**}p$ value ≤ 0.01; $^{***}p$ value ≤ 0.001.

Table 3 part (1). The results suggest that illness representations explain significant proportions of the variations in adherence to SMBG (14%), feet care (18%), and overall self-management (22%). Specifically longer timeline representations of diabetes were associated with greater frequency of SMBG ($B = 0.66$; 95% CI, 0.07–1.25; p value < 0.05). Greater sense of personal control ($B = 0.25$; 95% CI, 0.04–0.46; p value < 0.05) and illness coherence ($B = 0.28$; 95% CI, 0.06–0.49; p value < 0.01) was associated with better adherence to feet care. In addition, greater perception of illness coherence ($B = 0.19$; 95% CI, 0.08–0.31; p value < 0.001) was associated with higher adherence to overall self-management recommendations.

Results for relationships between self-efficacy for managing diabetes and self-reported adherence to self-management recommendations (as in Table 3 part (2)) indicate that self-efficacy is a predictor of patients' adherence to diabetes self-management recommendations. This is particularly significant for overall self-management in which self-efficacy explained 8% of the variation in self-management among the participants.

3.2. Discussion

3.2.1. Summary of Findings. This study investigated clinico-sociodemographic and psychosocial predictors of self-management behaviours among individuals with poorly controlled diabetes receiving care at two acute trusts in North West of England. In accordance with our research questions, the findings suggest that participants who were employed had more threatening representations about their diabetes compared with less economically active (unemployed/retired) participants.

Participants with adverse or advanced clinical outcomes, complex treatment regimen, being diagnosed with nephropathy, high hbA1c, and high BMI, were more likely to have threatening representations about their diabetes.

Compared to participants with type 2 diabetes, individuals with type 1 diabetes expressed higher confidence in their ability to self-manage their diabetes. Three clinical indicators contributed significantly in predicting participants' self-efficacy for diabetes self-management, duration since diagnosis, neuropathy status, and HbA1c. Participants who have been diagnosed with diabetes for a longer duration perceived greater confidence in self-managing their diabetes, whereas participants who have been diagnosed with neuropathy and those with higher HbA1c perceived lower confidence in their ability to self-manage the condition. Type of diabetes, neuropathy status, duration since diagnosis, and HbA1c were also confirmed as significant predictors of self-efficacy for self-management of diabetes in multiple regression analyses.

A range of demographic (particularly, educational attainment) and disease (treatment category, duration since diagnosis, microvascular complication status, type of diabetes, BMI, and HbA1c) characteristics contributed significantly in predicting patients' representations about their diabetes.

A variety of demographic and disease characteristic variables were significantly associated with participants' self-management behaviours. In particular, treatment category

Table 3: Predicting adherence to recommended self-management behaviours from psychosocial variables (illness perceptions or self-management-related self-efficacy).

Predictor variable	B (SE)	95% CI	p-value	β	R^2
(1) *Predicting self-management from illness perceptions*					
Diet recommendations and illness perceptions			**0.07***		**0.13**
Constant	5.43 (2.05)	1.37–9.48	0.01**		
Consequences	0.04 (0.08)	−0.13–0.21	0.65	0.06	
Timeline	−0.26 (0.20)	−0.64–0.13	0.19	−0.13	
Personal control	0.01 (0.08)	−0.15–0.17	0.93	0.01	
Treatment control	0.03 (0.09)	−0.15–0.17	0.73	0.04	
Identity	−0.10 (0.07)	−0.24–0.03	0.13	−0.16	
Concern	−0.06 (0.08)	−0.22–0.09	0.42	−0.09	
Understand	0.21 (0.08)	0.05–0.37	0.01**	0.27	
Emotional response	0.07 (0.07)	−0.07–0.21	0.33	0.12	
Exercise recommendations and illness perceptions			**0.14**		**0.11**
Constant	4.27 (2.76)	1.21–9.75	0.13		
Consequences	0.02 (0.12)	−0.23–0.26	0.90	0.02	
Timeline	−0.36 (0.26)	−0.88–0.16	0.18	−0.13	
Personal control	−0.09 (0.12)	−0.33–0.14	0.43	−0.10	
Treatment control	0.29 (0.13)	0.02–0.56	0.03*	0.27	
Identity	−0.16 (0.09)	−0.35–0.02	0.08	−0.19	
Concern	−0.08 (0.11)	−0.30–0.15	0.50	−0.08	
Understand	0.05 (0.11)	−0.17–0.27	0.65	0.05	
Emotional response	0.17 (0.10)	−0.03–0.36	0.09	0.22	
SMBG recommendations and illness perceptions			**0.04***		**0.14**
Constant	−4.77 (3.11)	−10.94–1.40	0.13		
Consequences	0.10 (0.13)	−0.15–0.36	0.42	0.11	
Timeline	0.66 (0.30)	0.07–1.25	0.03*	0.20	
Personal control	−0.04 (0.13)	−0.29–0.21	0.75	−0.04	
Treatment control	0.22 (0.15)	−0.08–0.51	0.15	0.18	
Identity	0.15 (0.10)	−0.05–0.35	0.15	0.15	
Concern	−0.19 (0.12)	−0.43–0.05	0.11	−0.18	
Understand	0.15 (0.12)	−0.10–0.39	0.24	0.12	
Emotional response	0.05 (0.11)	−0.16–0.27	0.62	0.06	
Foot care recommendations and illness perceptions			**0.01****		**0.18**
Constant	3.52 (2.73)	−1.90–8.94	0.20		
Consequences	0.15 (0.11)	−0.07–0.38	0.17	0.18	
Timeline	−0.39 (0.26)	−0.91–0.12	0.13	−0.14	
Personal control	0.25 (0.11)	0.04–0.46	0.02*	0.25	
Treatment control	−0.17 (0.13)	−0.42–0.07	0.17	−0.17	
Identity	0.09 (0.09)	−0.08–0.26	0.31	0.10	
Concern	−0.09 (0.10)	−0.29–0.12	0.41	−0.09	
Understand	0.28 (0.11)	0.06–0.49	≤0.01**	0.26	
Emotional response	0.06 (0.09)	−0.12–0.25	0.50	0.08	
Overall self-management recommendations and illness perceptions			**0.003****		**0.22**
Constant	1.93 (1.44)	−0.92–4.79	0.18		
Consequences	0.03 (0.07)	−0.10–0.16	0.66	0.06	
Timeline	−0.06 (0.14)	−0.33–0.21	0.65	−0.04	
Personal control	0.02 (0.06)	−0.10–0.15	0.71	0.04	
Treatment control	0.10 (0.07)	−0.05–0.24	0.18	0.16	
Identity	−0.05 (0.05)	−0.15–0.05	0.30	−0.11	
Concern	−0.07 (0.06)	−0.18–0.05	0.30	−0.13	
Understand	0.19 (0.06)	0.08–0.31	≤0.001***	0.33	
Emotional response	0.10 (0.05)	−0.001–0.20	0.05*	0.23	

Table 3: Continued.

Predictor variable	B (SE)	95% CI	p-value	β	R^2
(2) *Predicting self-management recommendations from self-efficacy (PDSMS score)*					
Diet recommendations and PDSMS score					**0.03**
Constant	3.50 (0.58)	2.35–4.65	$<0.001^{***}$		
Diabetes self-efficacy	0.04 (0.02)	−0.001–0.08	0.05^{*}	0.18	
Exercise recommendations and PDSMS score					**0.03**
Constant	0.88 (0.93)	−0.96–2.73	0.34		
Diabetes self-efficacy	0.06 (0.03)	−0.00–0.13	0.05^{*}	0.19	
SMBG recommendations and PDSMS score					**0.01**
Constant	3.46 (1.06)	1.36–5.56	0.001^{***}		
Diabetes self-efficacy	0.04 (0.04)	−0.04–0.12	0.29	0.10	
Foot care recommendations and PDSMS score					**0.03**
Constant	1.28 (0.94)	−0.58–3.14	0.18		
Diabetes self-efficacy	0.06 (0.03)	−0.01–0.13	0.07	0.17	
Overall SMG recommendations and PDSMS score					**0.08**
Constant	2.23 (0.48)	1.27–3.18	$<0.001^{***}$		
Diabetes self-efficacy	0.05 (0.02)	0.02–0.09	$<0.01^{**}$	0.29	

$^{*}p$ value ≤ 0.05; $^{**}p$ value ≤ 0.01; $^{***}p$ value ≤ 0.001.

significantly explained participants' degree of adherence to exercise (9%), SMBG (21%), and overall self-management (7%) recommendations.

Finally, both illness representations and self-efficacy for diabetes self-management were significant predictors of participants' self-management behaviours. Illness representations explained 14% of adherence to SMBG, 18% of adherence to foot care, and 22% of overall self-management recommendations. Self-efficacy beliefs explained 3% each of adherence to diet and exercise and 8% of overall self-management recommendations.

3.2.2. Discussion of Findings. The gender distribution of the sample reflects the slight differences in the overall prevalence of diabetes in men (6.3%) and women (5.3%) in England (33) and the age distribution of the sample is consistent with the mixed sample of younger type 1 diabetes patients (mean age: 45.10; SD = 12.03) and older type 2 participants (mean age: 55.05; SD = 7.03).

The finding that illness representations predict self-management behaviours of this poorly controlled diabetes population shows that the Leventhal's common sense model of illness representation is fairly robust in explaining patients' thoughts and reflections in their attempt to cope with a health condition such as diabetes [33]. It also shows the concept is applicable to a wide range of patients with diabetes, irrespective of their demographic, cultural, or clinical profile [9, 10, 24, 25]. Similar observations have been shown in studies of other illness groups too. For example, a meta-analysis examining the significance of illness perceptions on attendance at cardiac rehabilitation following acute myocardial infarction reported small but significant effect sizes of the relationships between the two variables [21]. In relation to specific components of the illness perception schema, meta-analysis of the results found that greater perception of identity or symptom load ($r = 0.13$; p value = 0.004), consequences ($r = 0.08$, p value = 0.012), and cure/control ($r = 0.119$, p value < 0.001) were significantly associated with attendance at cardiac rehabilitation [21].

The fact that longer duration since diagnosis was associated with longer timeline perceptions, greater understanding (coherence) about diabetes and lower negative emotional response is encouraging and reflects a situation where patients have come to terms with the reality about their condition and therefore doing their best to comprehend and potentially confront the illness rather than allow themselves to be weighed down by negative emotions.

Although somewhat expected, the finding that self-efficacy significantly explains variations in adherence to self-management behaviours is of immense practical importance. Indeed, self-efficacy is a social cognitive concept which has behavioural underpinnings including the motivation for the individual to activate and persist on the behaviour even in the face of difficulties, albeit depending on the magnitude and strength of the efficacy expectations [11]. In part, self-efficacy is driven by an individual's expectations that behaving in a particular way will yield benefits and/or avert difficulties in the future. The motivation to initiate and sustain behaviour could also be activated through the mechanism of goal setting and attainment, self-initiated or otherwise [34].

Our findings on self-efficacy and self-management behaviours concur with the large body of literature which consistently demonstrates associations between self-efficacy and health-related behaviours. For example, in an ethnically diverse, low income population with type 2 diabetes, Sarkar and colleagues reported significant association between self-efficacy and adherence to dietary, exercise, SMBG, and foot care recommendations [35]. The associations observed in their study persisted after adjusting for relevant clinical and demographic variables. More recently, Walker and others also reported moderately significant associations between participants' adherence to diet, exercise, foot care, and SMBG among low income and minority ethnic populations with diabetes, both in univariate and multivariate (but not foot care) analyses [15]. Indeed as found in our study others [15, 35] have also shown significant associations between self-efficacy and clinical disease outcomes such as HbA1c.

Interestingly, both psychological measures (the brief IPQ and the PDSMS) identified persons with type 1 diabetes and having been diagnosed with diabetes for a longer duration to be associated with higher perceived confidence. On the contrary, presence of neuropathy and high HbA1c were associated with lower perceived confidence in managing diabetes. Unfortunately, the cross-sectional nature of this study does not permit us to make inferences about temporality of these relationships. For instance, it is unclear whether individuals are likely to become less confident after failing to bring their HbA1c under control or developing diabetic complications or vice versa. Nevertheless, this finding is useful and could guide the identification of patients who may benefit from self-efficacy related interventions.

Our findings show that sociodemographic and disease characteristics (mostly in the univariate analyses, but also a few in the multivariate analyses) influenced adherence to self-management recommendations in different ways. Exploring such variations further could be useful for targeting and tailoring self-management interventions to specific population groups [36, 37].

In terms of its implications for practice, the pivotal role of self-efficacy in predicting or acting as a catalyst for motivating the individual in the performance of a given task, including health behaviour, implies that the concept could be used to guide behaviour change and diabetes control intervention in our study population, as has been demonstrated in other populations with diabetes [12, 14]. As explained by Bandura [11] the magnitude and intensity of self-efficacy possessed by an individual could vary for different areas or aspects of behaviour; it is therefore possible to identify any deficiencies in an individual and work towards augmenting them through the provision of targeted skill training and education [38]. This approach could potentially work for poorly controlled patients such as the participants in our study.

An obvious implication of the findings in relation to illness representation is that illness representation in general could be used as a framework to guide interventions aiming at promoting appropriate self-management behaviours among individuals with poorly controlled diabetes. Particularly, interventions enhancing appropriate timeline, personal control, and illness coherence components of the illness perception schema could be useful. On the flip side, it is also possible to use the illness perception concept as a screening tool for identifying patients who, because of their illness representations, are potentially less likely to adhere to self-management recommendations and subsequently working to alter these perceptions [20, 39].

This study has some limitations which should be considered in the interpretation of its findings. First, the small sample size of the study ($n = 123$) means there is potential for type II error. For example, considering the sample size calculation based on the $50 + 8k$ (k = number of predictors) rule for multiple regression analysis [40], we would have required at least 128 complete responses for the multiple regression analysis between self-management and the eight components of illness representation. It is therefore likely that our analyses failed to detect some associations. Secondly, the participant information sheet for the main study explained that the study was investigating work-related factors on diabetes self-management. Invitation letters and study packs were accordingly sent to all patients in the working age range (25–65) as the hospital records did not contain this information. Indeed, some patients returned questionnaires uncompleted, some with notes explaining that they are not in employment. It would therefore be misleading to present statistics for response rates in this report. Also, data for both predictor and outcome variables were collected at a single time point (cross-sectional design). Cross-sectional studies have several limitations, including the fact that we are unable to infer causality and direction of effect in the associations reported in this study. Further, data were collected using postal questionnaires and some clinical data obtained from routine hospital records. Both postal questionnaires and routine data have their inherent limitations too. Nonetheless, the findings from this small scale study are of critical importance and further studies investigating the applicability of illness representations and self-efficacy frameworks and their practical underpinnings on the behaviour of exclusively poorly controlled individuals with diabetes are warranted.

4. Conclusions

The concept of self-management is about helping patients assume the day-to-day control of their illness with some support from healthcare professionals. Thus we call for more studies aimed at understanding the potential barriers and promoters of self-management and good clinical control of diabetes in predominantly poorly controlled diabetes populations such as our study sample, using psychological constructs such as those used in this study. Different forms of reaching out to patients of varying ages and clinical and demographic profiles including digital platforms which could be tailored to the circumstances of individuals may be appropriate.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Research Article

"I'm Managing My Diabetes between Two Worlds": Beliefs and Experiences of Diabetes Management in British South Asians on Holiday in the East—A Qualitative Study

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Background. Diabetes is disproportionately high among British South Asians compared to the general UK population. Whilst the migrant British South Asians group has received most attention on research related to diabetes management, little consideration has been given to impact of travel back to the East. This study aimed to explore the role of social networks and beliefs about diabetes in British South Asians, to better understand their management behaviours whilst holidaying in the East. *Methods*. Semistructured interviews were conducted in Greater Manchester. Forty-four participants were recruited using random and purposive sampling techniques. Interviews were analysed thematically using a constant comparison approach. *Results*. Migrant British South Asians expressed a strong preference to be in a hot climate; they felt they had a healthier lifestyle in the East and often altered or abandoned their diabetes medication. Information acquisition on diabetes and availability of social networks in the East was valued. *Conclusion*. Social networks in the East are a valued source of information and support for diabetes. The lack of adherence to medication whilst abroad suggests that some migrant British South Asians have a poor understanding of diabetes. Future research needs to explore whether patients are seeking professional advice on diabetes management prior to their extended holiday.

1. Introduction

Diabetes is a life-long chronic and progressive condition affecting 3.2 million people in the UK, and 90% of people have type 2 diabetes (T2D) [1]. T2D and its associated complications are disproportionately high among British South Asians compared to the general UK population [2]. The onset of T2D is related to genetic predisposition, poor diet, obesity, and physical inactivity; additional factors such as cultural health beliefs, language difficulties, and access to healthcare service have also been suggested to influence the higher incidence of T2D in British South Asians [3]. Migration from the Indian subcontinent (e.g., Indian, Pakistani, Bangladeshi, and Sri Lankan) has been associated with the onset of T2D in British South Asians due to changes in lifestyle and diet [4–6] as well as the stresses of adapting to the UK and the emotional upheaval of leaving the Indian subcontinent [7, 8].

Diabetes self-management is vital and has been stated as one of the most challenging regimes of any chronic illness due to the extensive number of tasks involved in managing blood sugar levels and reducing the risks of serious complication including hypertension, stroke, kidney failure, heart disease, and neuropathy [3]. However, studies with migrant British South Asians have found this group to have poor knowledge and understanding of the seriousness of diabetes [9], lower perceived awareness of its complications, poor knowledge about diet, and poor adherence to medication [10] resulting in poor diabetes outcomes [11]. Similar findings in terms of knowledge and attitudes of diabetes have also been reported in South Asians residing in the East [12, 13].

Culturally sensitive diabetes education programmes designed to improve self-management in this population have had limited success in improving diabetes outcomes [14]. Whilst the migrant British South Asian group has received most attention in the literature on research related to incidence of diabetes and its management [15], very little consideration has been given to the effects of migration on diabetes management in this population [4], particularly with regard to whether their beliefs and behaviours concerning diabetes change when they travel back to the Indian subcontinent for extended holidays. The need to provide education to British South Asians on aspects of travel abroad and adhering to medication was outlined in a review by Hawthorne et al. (1993) [16]. This is potentially important as it is common for migrant British South Asians in the UK to travel to the East regularly, especially during the UK winter months to escape the cold weather. Thus, there is a possibility that people make changes to their diabetes regimen during their stay in the East and may not be aware of the importance of continuing to manage their diabetes whilst travelling and holidaying in the Indian subcontinent. In addition, people will often stay with family or friends in the East; therefore, it is also important to consider the changes in people's social context for diabetes management, as there is an increasing recognition that social networks (e.g., strong family ties and friends) contribute to diabetes management as well as providing practical and emotional support to the work individuals with diabetes undertake for their diabetes [17, 18]. Social networks also have the potential to shape beliefs, attitudes, and information acquisition for diabetes [19–22] and it is likely that management practices and lifestyle behaviours whilst holidaying in the East may be influenced by this context.

To date, the advice on travelling and diabetes provides general information on the precautions people should take in terms of diet and medication supplies [23] and the impact of jet lag, time zone differences, which may affect adherence to medication and thus blood glucose levels [24]. However, there is lack of advice for British South Asians with diabetes on the importance of adhering to the diabetes regimen when holidaying in the East for an extended period of time, and it is not clear whether patients actually consult or seek advice from their GP or Practice Nurse (PN) about their intentions and/or plans to travel abroad for long periods of time. This could usefully be addressed in consultation with a GP and/or PN as most patients are managed and supported by primary care in the UK.

In the study reported here, we exploreself-reported beliefs and practices of diabetes management in British South Asians, to better understand their management behaviours whilst holidaying in the East. Data was collected within the context of a broader study around diabetes management and social networks.

2. Methods

This study was conducted as part of National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC), Long Term Conditions (LTC) programme, and ethical approval was granted through this programme of research (Reference 10/H1008/1 09130).

British South Asian adults with type 1 diabetes (T1D) or T2D, living in Greater Manchester, were recruited using two methods of sampling; 30 participants were recruited using random sampling of 22 GP registers and additional 14 participants were recruited using purposive sampling to obtain a broader sample of participants from community groups (mosques, temples, religious classes, exercise groups, and Muslim day centres). Interviews were conducted with participants in a location of their choice, mainly their own homes.

Semistructured face-to-face interviews were conducted with participants between March 2010 and July 2011. The interviews lasted between 30 and 90 minutes and were audio recorded with consent. The length of an interview is known to vary depending on the topic, researcher, and participant [25]. A topic guide was developed by the gaps identified from the literature in this field (as mentioned in the Introduction) and through discussion with the research team to explore a range of beliefs and practices concerning diabetes management including fasting, diet, and use of self-management resources, medication, and support from social networks.

Data collection and analysis were iterative with modification of the topic guide as analysis progressed.

One interview was conducted in Hindi by the first author (Neesha Patel). A professional interpreter, independent of the project, provided language support for Urdu speaking respondents whose first language was not English ($n = 9$). On other occasions, where this was requested, members of patients' families sometimes helped with interpretation. In two interviews, a Diabetes Asian Link worker was present to provide language support. All respondents were reimbursed £15 for their time.

3. Data Analysis

Initially open coding was used to analyse the transcripts and, through comparison of these codes, categories and themes were identified. Thereafter, data were analysed thematically using a constant comparison approach [26]. Themes were developed independently by all authors and then agreed on through discussion. Field notes and written memos were used to help develop interpretations during analysis. Data collection was continued until category saturation was achieved in that interviews continued until no new themes emerged from the data. Atlas.ti6 software was used to store and manage the data.

Table 1: Demographics.

	n (%)
	44
Male	23 (52)
Female	21 (48)
Age, years (SD = 12.5, range)	61 (32–84)
Diabetes	
T1D	5 (11)
T2D (*n* = 7 on insulin)	39 (91)
Duration of diabetes	
0 to 5 years	11 (25)
5 to 10 years	16 (36)
10 years+	17 (39)
Marital status	
Married or in civil partnership	38 (86)
Other	6 (14)
Subethnic groups	
Indian	22 (50)
Pakistani	18 (41)
Bangladeshi	3 (7)
Other (Nepalese)	1 (2)
Education	
No qualifications	19 (44)
1 to 4 O levels	3 (7)
A levels	1 (2)
Other qualifications	4 (9)
NVQ	3 (7)
Professional qualifications	5 (11)
First degree	5 (11)
Higher degree	4 (9)
Born in the UK or migrated to UK	
British born South Asians	4 (9)
British migrant South Asians	40 (91)

4. Results

Forty-four people were interviewed. Table 1 shows the demographic characteristics of the participants studied. The majority of South Asian participants with T2D in this study were migrants from the Indian subcontinent. Thus, the data in this section relates mainly to this group, along with reference to UK born South Asians where appropriate.

Data is presented in three main themes: social networks, *differing roles and opportunities for social support from networks* "back home," beliefs about diet and diabetes management, and limited role for GP/practice.

Data is presented to illustrate the themes, and participants are identified by their diabetes type, gender, and method of recruitment with an asterisk to indicate a participant has been quoted more than once.

4.1. Social Networks, Differing Roles and Opportunities for Social Support from Networks "Back Home". The availability of family members in the East seemed to have an important role in providing more care and facilitating dietary behaviours.

> *She can't take care of herself much down here [UK] because my brother is always at work, I am at my place, my sisters are always at college or busy so she is always on her own but Pakistan she has her dad, brothers and sisters and their kids. [Community participant 6, Pakistani, female, T2D]*
>
> *P: When I came back from Pakistan I was healthier than I was here (in the UK) and I felt much better because my sister-in law goes to the park for a walk for 2 hours…when she comes home she will eat. I copied her and I felt much better. [Participant 326, Pakistani, female, T2D]*

The families abroad were also an important source of information for diabetes and would often provide information on diet and foods, and participants seem to value and follow the advice, which was believed to be beneficial to diabetes:

> *lots of people in the family have it so they used to tell me try this and that to reduce my sugar levels, e.g. karela juice but it's very bitter and all day I can taste it in my throat which I didn't like. (Community participant 27, Pakistani, female, T2D)*
>
> *I: Do people give advice you advice on how to manage diabetes?*
>
> *P: Yeah that's always in the family*
>
> *I: It is different type of advice in Pakistan compared to the advice you get from people here [in the UK)?*
>
> *P: Yeah it's the same advice like; they tell you what's good for you and what's not for diabetes. Like sometimes you learn about foods that are good for your diabetes, like certain vegetables. [Participant 81, Pakistani, male, T2D]*

In addition to receiving information and advice from family members in the East, some participants also described receiving advice from external sources in the UK.

> *I: When you're there (in the East) do people give you advice on your diabetes?*
>
> *P: Some of my friends know about diabetes and if they are not around then I go to the doctors.*
>
> *I: What kind of things do they tell you to do?*
>
> *P: To be careful about the sweet things that I have and diet.*
>
> *I: So what about here in the UK do people tell you that here?*

> *P: No no-one in the family but Asian Link Worker, doctor and nurses tell me and when I go to the mosque to pray other people that have diabetes they talk about it and they all give different reasons. (Community participant 5, Bangladeshi, Male, T2D)*

4.2. Beliefs about Diet and Diabetes Management. Compared to UK born South Asians, it was more common for migrant British South Asians to travel "back home" (India, Pakistan, or Bangladesh) for a prolonged period of time (six to eight weeks or more). However, going "back home" was reported to have a positive influence on diabetes management, mainly attributed to the healing effects of being with family and the hot weather conditions in the East.

Many of the migrant British South Asian participants with T2D believed that their diet was much healthier "back home" due to the availability and daily consumption of more fruit and vegetables.

> *P: You get fresh fruit and vegetables every day, they come to the house with a cart every day or there are markets nearby too but it's fresh every day. (Participant 401, Indian, male, T2D)*

The foods in the East were also believed to be fresher and easier to access compared to the West, where participants often described using frozen foods rather than going to the supermarket every day to buy fresh foods.

> *Daughter: Here you cannot get fresh vegetables; there [Pakistan] you can so she has fresh stuff all the time. Here whatever is in the freezer she will take it out and cook it? She gets a lot of fresh fruit and vegetables from there. So there is a big difference with how she deals with things here and how she does it there. There she is healthier so she is active down there, fresh fruit is always better, so she takes care of herself down there.*

Participants described walking more with family members and adapting to their family's comparatively healthier lifestyle whilst on holiday in the East, compared to when they are back in the UK.

> *P: You can't get out and enjoy and you don't have the freedom to go out and do things like go for walks for a start but err everybody gets a bit low in the winter times. . .I would like to live in India for 6 months and here for 6 months. [Participant 7, Indian male, T2D]*

Holidaying "back home" seemed to give a sense of freedom and motivation to engage in healthy behaviours and live a healthy lifestyle.

> *P: Whenever I go India. . .you feel like going out and you're not restricted to do anything, whereas, as soon as you come here, you're in front of the box (TV) twenty four seven and that's your life now. [Participant 332, Indian, male, T2D]*

> *P: Here (in the UK) most of the time its damp and raining we stay indoors and do not move much but in Pakistan you go out more and walk more, the sun is out and you sweat and you have less health problems. [Participant 398, Pakistani, female, T2D]*

Apart from reporting having a healthier diet in the East, a majority of participants described how the hot weather provided more opportunities to sweat in the heat. Participants reported the belief that sweating (i.e., benefit of holidaying in a hot climate, rather than sweating due to physical activity/exertion) helped to eliminate excess sugar and impurities from the blood to improve diabetes control.

> *P: The heat and sweat. . .when you sweat the sugar levels stays in control. (Participant 296, Pakistani, male, T2D)*
>
> *P: When I go there (East), I sweat it out all my impurities, you're just sweating it out. (Community participant 26, Indian, female, T2D)*

The meaning of a holiday in the East for some participants was also to have a "break" from their medication for diabetes. For instance, some participants described stopping their diabetes medication or altering their medication regime whilst on holiday "back home."

> *I: Did you take all your medication with you?*
>
> *P: I think I didn't need it*
>
> *I: So you stopped taking it?*
>
> *P: Yeah because I didn't need to take it because my sugar levels were in very good control. (Participant 296, Pakistani, male, T2D)*
>
> *P: Every time I've been it's in July when it's hot and I like hot weather. Everybody keeps saying how I can cope with the heat but I like it. . .I never take any medicine when I am there. . .for 6 or 7 weeks that I am there, I never take. (Community participant 27, Pakistani, female, T2D)*

Compared to when they are in the UK, some participants strongly believed that their diabetes was cured or had disappeared whilst being "back home" in the East.

> *P: When I go there my diabetes is gone. . .I feel good but when I come back it's gone higher. (Community participant 42, Pakistani, female, T2D)*

On return to the UK, participants described being less active due to poor weather conditions, especially in the winter. For some participants, the lack of exercise in the West was also related to poor mobility and health.

> *P: I used to go walking but I've got knee problem and sometimes foot problem. I think these days because of the weather I feel worse. . .the doctor told me I need vitamin D and has given me tablets to take. [Participant 326, Pakistani, female]*

> *P: I don't do enough exercise here (West) because the climate is different from Bangladesh errm…the glucose stays in the blood and the cholesterol is higher which it normally wouldn't be in Bangladesh…because I don't do any form of exercise (in the West). I don't sweat it off that's what I think. [Participant 5, Bangladeshi, male, T2D]*

There were tensions between participants having knowledge about the importance of exercise for diabetes and being self-aware of the little time they actually spent exercising in the UK and the effect this may be having on their diabetes.

A small number of participants with T1D described the difficulties of managing their diabetes when holidaying in the East. One of the main difficulties was travelling with insulin and not being able to store it at the correct temperatures.

> *P: These days in Pakistan it's terrible conditions, no electricity for about 8 hours…so in the summer it's very difficult and because I take insulin I have nowhere to store it when the electricity goes. It's supposed to be stored between 2-8c and sometimes it can take up to 16 hours for the electricity to come back…the problem is the fridge won't work which means the efficacy of my insulin will reduce…and I get sick there. [Participant 313, Pakistani, male, T1D]*

For a small number of UK born South Asians ($n = 4$), adapting to the diet in the East was a strong concern and one participant in particular described being reluctant to try any of the food or drink tap water whilst on holiday in Pakistan due to fears of becoming ill.

> *P: As far as the diet goes, it's nil and void, basically…when we got there, I bought a fridge…the water's not very good there, so I bought bottled water, …if you eat from there (Pakistan), your stomach is going to go so, basically, I just instructed my wife to get…you know, beans and get loads of potatoes and stuff like that and just ate chips and beans for a fortnight. [Participant 398, Pakistani, male, T1D]*

4.3. Limited Role Perceived for GPs/Practice. Participants described the role of the GP in supporting the management of diabetes as limited to prescribing medication and suggested they attended the GP only in response to invitation from the practice for routine check-ups and vaccinations.

> *P: GP doesn't do anything just prescribes medication that's it. In all these years I hardly go to the doctors…I am on repeat prescription and my daughter rings the surgery and she just picks up the prescription. I just go for my vitamin or flu injections when they write to me. [Participant 393, Pakistani, male, T2D]*

> *P: GP doesn't explain anything they just give medicine. [Participant 364, Nepalese, Male, T2D]*

There was a tension between having more frequent contact with the PN for their diabetes care and believing that the GP was the best person to seek information from for diabetes. Participants described receiving very little information and support about diabetes when they consulted their GP and suggested this may be due to the GP being pressured for time.

> *P: The doctor just prescribes my medicines. [Participant 95, Indian, Female, T2D]*

> *P: I don't get much advice from my GP, I just get my tablets and that's it (big laugh)…you can't blame them because they are seeing so many patients a day, they haven't got the time to spend 20 minutes or half an hour to talk and tell you things….people do listen to the GP, its coming from the horses' mouth you know….we rely on the GP for information. I mean I listen to my doctor. [Community participant 5, Indian, male, T2D]*

The limited access to information and support from the preferred source, which was the GP, resulted in GPs being perceived as having a limited role around prescribing and social networks including GPs aboard being at the forefront of new information related to diabetes.

> *P: My family and friends can support me when there are new developments, like my cousin called me last week to inform me about new insulin which you only have to take once and told me to ask my GP…the GP doesn't have enough time but the nurse has more time and she is very helpful. My GP in Pakistan I talk to him and get advice over the phone about my diabetes. [Participant 313, Pakistani, male, T2D]*

This participant described help-seeking from GP whilst abroad, but few other participants reported this.

Overall, there seemed to be some disappointment and dissatisfaction expressed by some of the participants with regards to the care they received from their GP for their diabetes. Even those participants who expressed satisfaction with the care they received from the PN wanted more information and support from their GP for their diabetes.

5. Discussion

5.1. Summary. This is the first qualitative study in the UK to explore beliefs and practices of diabetes management in migrant British South Asians, whilst spending extended holidays in their native country. The main findings of this study show migrant British South Asians express a preference to be in a hot climate and change their diabetes management practices either by altering or abandoning their diabetes medication. The study findings also inform on the perceived role of the GP for diabetes care in the UK as being limited and the differences in the support received for diabetes management from social networks abroad in the East compared to the UK. The families abroad were an important source of information for diabetes, and their availability facilitated in participants taking up more exercise and eating a healthier diet until they return back to the UK.

5.2. Comparisons with Previous Literature. The existing literature reports on the impact of South Asians migrating from the East on factors such as genetics, diet, lifestyle, and psychological wellbeing, with implications for the onset and management of diabetes in the West. In the present study, participants' social context appeared to influence their beliefs about medication, as being back in a hot climate was believed to improve diabetes control or cure diabetes temporarily due to sweating in the heat. Studies conducted to assess knowledge and attitudes of diabetes with South Asian patients residing in the East have reported similar findings. In their Knowledge, Attitude, and Practice (KAP) survey with 238 diabetes patients, Shah et al. (2009) found that 63% had poor knowledge of diabetes and the importance of lifestyle modification, whilst 39% believed that diabetes could be cured. Low levels of literacy were also a common barrier to diabetes management [13]. Choudhury et al. (2014) [12] used a KAP survey to assess insulin use in 358 diabetes patients in tertiary care hospitals in India. Higher educational and socioeconomic status was associated with better understanding of insulin use and complications related to diabetes. Although a longer duration of diabetes was associated with better knowledge, 45% believed that food therapies (bitter gourd) could be used to control blood sugar levels.

The influence of beliefs and cultural practices has been shown to impede with diabetes management in this group [27]. However, in their study with British Bangladeshi men with diabetes, Greenhalgh et al. (1998) [28] showed that this group of men held strong beliefs about the benefits of sweating in the East for diabetes control and related the absence of sweating due to poor weather conditions in the West as one of the causes of diabetes. Our study findings extend on this work as the lack of adherence to medication whilst in the East suggests that participants in our study may have a poor understanding of the potential consequences of stopping or altering their medication for a long period of time. Other studies have shown the importance of personal models (*i.e., patient's beliefs about treatment effectiveness*) in diabetes [29, 30]; however, in the present study, the social context and location in which the participants manage their diabetes (i.e., in the company of family members with diabetes in the East) seemed to have a greater impact on treatment beliefs and self-management behaviours. In addition, participants appeared to have their own Explanatory Models (*i.e., interpretations of illness and treatment from different sources*) [31] of diabetes in the East which they seemed to carefully observe whilst on holiday, as well as drawing on the knowledge and practices of others (e.g., social networks) to make sense of their own diabetes in this social context. This context also seemed to provide an important lens through which participants chose to manage their diabetes whilst on holiday.

Research on the role of social networks has highlighted the importance of the support received from personal networks for illness management [18], particularly, the actions, practical, and emotional support that members of peoples' personal networks undertake [21]. For example, access to different types of network members has been found to provide access to a range of resources [32] and information [18]. However, the finding of our study extends the previous research and theorising about people being embedded in a "single" social network and the tensions between these, into a new area of "multiple networks" for diabetes management. The participants in our study appear to have two different and largely independent social networks, one in the East and one in the West, and their management behaviours, attitudes, and the support they receive differ between these networks. Whether people changed their self-management behaviours when in the East as a result of social network influences or a result of different opportunities (e.g., availability of fresh food and warmer weather) is unknown.

Other authors have also highlighted the importance of contextual influences in shaping individuals' health and wellbeing [33, 34], particularly in the South Asian group [19]. For example, the finding that participants make positive lifestyle changes such as walking and eating healthier foods with the family, compared to when they are in the UK, suggests that they were able to engage in self-care behaviours collectively with family members whilst in the East. However, participants struggled to engage in these behaviours independently when they returned back to the UK, with the climate, availability of fresh foods, and mobility being stated as barriers. The self-categorisation theory [35] provides a plausible interpretation for this finding in that the social context seemed to provide participants with motive and opportunities to compare their behaviour with others [35, 36]. Thus, the way in which participants perceived themselves in the East and the West seemed to have implications for both diabetes-related beliefs and management behaviours. In addition, the tensions between the dissatisfaction of the care received from their GP (UK) for their diabetes may explain why participants turn to their social networks for support and information [18, 27].

5.3. Strengths and Limitations. The analysis was undertaken in an interdisciplinary team (with expertise in psychology, health services research, and primary care), which increases trustworthiness of the analysis [37]. The interview guide contained a range of topics related to diabetes management and social networks and holidaying in the East was one of a number of topics explored.

There are limitations to the present study. Although recruitment took place in several areas of Greater Manchester to target an adult population from various subethnic South Asian groups, backgrounds, and age to increase sample variety, most participants were first generation immigrants, from deprived communities, with T2D, whose first language was not English, and some were illiterate in their native language. The migrant status may have also been a key factor in shaping the knowledge, belief, and attitudes towards diabetes. Therefore, it can be argued that this sample may not sufficiently reflect the more-educated sections of the South Asian community, British born South Asians, and patients with T1D as 90% of the sample had T2D, and we believe that our findings primarily relate to this group. We did not collect specific information on socioeconomic status. However, T2D remains as a significant problem in South Asian people from lower socioeconomic backgrounds and warrants research. A professional interpreter, Diabetes Asian

Link worker, and the participants' family members facilitated some of the interviews. This may have influenced the data in that the interviewees' responses may not have been captured accurately, as the interpreters may have found it easier to summarise the respondents' answers to the questions asked, rather than interpret each answer in verbatim [38].

5.4. Implications for Policy and Practice. The social context and the support received from social networks whilst holidaying in the East had an influence on beliefs and behaviours related to diabetes management. This suggests that this patient group appear to have a poor understanding of the importance of adhering to diabetes medication when holidaying in the East. Culturally tailored, community-based diabetes management programmes may facilitate and increase motivation to engage in a healthy lifestyle and better manage diabetes on return to the UK [39].

Current policy guidelines on diabetes management do not inform on pretravel advice/education for patients or provide guidance on altering patients' diabetes medication during travel, apart from the importance of adhering to medication for positive clinical and health outcomes [40]. Of the limited information available on travel and diabetes, patients are advised to seek care and information on diet and medication before travel [23, 41] to minimize fluctuations in glucose control and reduce other travel related risks [42]. Of the few studies available on diabetes management during travel, most are on travel-related problems in people with T1D [24, 43]. Given that the migrant British South Asians in this study indicated a high regard for holidaying in the East, tailored pretravel education for patients and their social networks may inform them on the importance of diabetes management and seeking pretravel advice before going to the East. Health care practitioners in primary care may also benefit from training and skills into the beliefs held about diabetes in migrant British South Asians and the changes independently made to their diabetes regimen in order to help improve adherence to medication whilst on holiday and reduce potential future complications and healthcare costs including medication wastage and mortality.

6. Conclusion

Holidaying in the East is an important social and cultural tradition for the migrant British South Asian population. The availability of social networks in the East and the information received on diabetes (diet and exercise) from networks seemed to be valued and resulted in participants engaging in a healthier lifestyle during their stay. However, the informed decision to refrain and/or alter their diabetes medication due to the belief that diabetes disappears in the East, as a result in the change in climate providing the opportunity to sweat and eliminate excess sugar from the body, suggests that some migrant British South Asians have a poor understanding of diabetes and the importance of adhering to medication.

Future research needs to explore whether patients are seeking professional advice on how to manage their diabetes whilst on an extended holiday. This will help to inform pretravel diabetes education resources for patients and their social networks to reduce potential future complications of diabetes and healthcare costs to the NHS.

Disclaimer

The views expressed in this paper are those of the authors and not necessarily those of the NHS, NIHR, or the Department of Health.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Research Article

Low Self-Confidence and Diabetes Mismanagement in Youth with Type 1 Diabetes Mediate the Relationship between Behavioral Problems and Elevated HbA1c

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Introduction. Previous studies indicated an association between behavior problems (internalizing, externalizing) and glycemic control (HbA1c) in youth with type 1 diabetes (T1D). The aim of this study is to examine if this association is mediated by self-confidence and mismanagement of diabetes. *Methods*. Problem behavior was assessed with the Strengths and Difficulties Questionnaire. Mediating variables were assessed using the Confidence in Diabetes Self-Care-Youth and Diabetes Mismanagement Questionnaire. HbA1c was derived from hospital charts. Bootstrap mediation analysis for multiple mediation was utilized. *Results*. 88 youths with T1D, age 11–15 y, participated. The relation between both overall problem behavior and externalizing behavior problems and HbA1c was mediated through *confidence in diabetes self-care* and *mismanagement* ($a_1b_1 + a_2b_2$ *path*; point estimate = 0.50 BCa CI 95% 0.25–0.85; $a_1b_1 + a_2b_2$ *path*; point estimate = 0.73 BCa CI 95% 0.36–1.25). *Conclusions*. Increased problem behavior in youth with T1D is associated with elevated HbA1c and mediated by low self-confidence and diabetes mismanagement. Screening for problem behavior and mismanagement and assisting young patients in building confidence seem indicated to optimize glycemic control.

1. Introduction

Adolescence is characterized by major biological and psychosocial changes, which interact in complex ways. This is particularly true for youth with type 1 diabetes (T1D) and probably explains the fact that youth with diabetes have the poorest glycemic control of all age groups, with less than 15% of adolescents with type T1D reaching Hemoglobin A1c (HbA1c) levels below target [1–5]. On top of the hormonal changes that negatively affect blood glucose control, adolescents with T1D have an increased risk of developing depression, anxiety, and disturbed eating behaviors, relative to healthy youth. These problems typically occur in mid-adolescence [6] and result in poor glycemic control [7–11]. Externalizing behavior problems (e.g., attention and disruptive behavior complaints) are associated with decreased glycemic control as well [12–15]. Although behavior problems at diagnosis do not seem to impact lifelong poor glycemic control [16], they have been found to be directly associated with hyperglycemia [15]. Adolescents showing external problem behavior seem to be generally unresponsive to punishment, are often impulsive, and have concentration problems [17]. Problematic behavior, both internal and external, frequently coincides with low self-efficacy beliefs, low self-esteem, dysfunctional coping mechanisms, and increased risk taking behavior, all complicating daily self-management of diabetes [17]. Self-efficacy beliefs, for example, low self-confidence, and diabetes mismanagement are likely to mediate the relationship between behavior problems and poor glycemic outcomes, but this hypothesis has not been previously tested.

Using baseline data of multicenter cohort DINO study (diabetes in development) that examines the complex interaction between biological and psychosocial development during adolescence [18], we examined whether overall, external, and internal problem behavior are associated with glycemic control and whether this relationship is mediated by confidence in diabetes self-care and mismanagement.

2. Materials and Methods

2.1. Participants. Youth aged 8 to 15 treated ($N = 598$) in 5 pediatric diabetes centers in Netherlands were invited to participate in the DINO study. The participating centers provide secondary and tertiary clinical care to children and adolescents with T1D in their region and can be considered representative of youth with T1D in Netherlands. Exclusion criteria were mental retardation, diabetes other than type 1, and diagnosis less than 6 months prior to the start of the study. Written informed consent was obtained from all parents and adolescents 12 years and older. Participants completed an online survey. In view of their age, 8–11-year-olds completed a shorter survey than participants 11 years and older. Data from the latter survey were used for the study reported in this paper. In total, 151 children and adolescents (25.3%) agreed to participate, of whom 100 were ≥11 years.

The DINO study was approved by the Medical Ethical Committee of VU University Medical Center.

2.2. Measures. Problem behavior was assessed using the Strengths and Difficulties Questionnaire (SDQ). SDQ [19, 20] captures emotional and behavioral functioning and contains 25 items, rated on a 3-point Likert scale (e.g., "Other people my age generally like me"). The SDQ comprises five scales: emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and prosocial behavior. The overall score of problem behavior (range 0–40) can be divided into external (range 0–20) and internal (range 0–20) problem behavior. Cronbach's α was 0.70 on the overall scale [19, 20], in the current study 0.60. Higher scores indicate more problematic behavior; scores ≤ 13 are considered normal.

Confidence in diabetes self-care was assessed using an adapted adolescent version of the Confidence in Diabetes Self-Care Scale (CIDS) [21]. The original adult version of the CIDS consists of 20 items on a 5-point Likert scale, Cronbach's $\alpha = 0.86$ [21]. The adapted youth version consists of 12 items (e.g., "I believe I can check my blood glucose at least 2 times a day"): 10 of the original questionnaire, 2 items combined to 1 (original questions 2 and 20), and 1 additional item regarding alternations in blood glucose. Cronbach's α of the CIDS-Youth in the current study was 0.79. Higher scores represent higher diabetes self-confidence (range 12–60).

Mismanagement in diabetes self-care was assessed using an adapted version of the mismanagement scale [22]. The original version consists of 10 items of which 3 items were used and 1 was adjusted. The recall period was changed from 10 days to the past week. Answers are given on a 5-point Likert scale (e.g., "In the past 7 days, how often did you miss shots/did not bolus?"). Cronbach's α of the original version is 0.74 and 0.60, respectively [22]. Cronbach's α of the adapted version in the current study was 0.47. Higher scores indicate more mismanagement (range 4–16).

Table 1: Characteristics of participating adolescents.

Boys (N/%)	45 (51.1)
Age (yrs)	12.9 ± 1.2
HbA1c	64.3 mmol/mol (8.0%) ± 11.5 mmol/mol
Age diabetes onset	7.1 ± 3.8
Diabetes duration (yrs)	5.8 ± 3.8
Pump/injections (%)	80.7/19.3 ≥ 4 per day
Traditional family composition (%)	83
SDQ overall problem behavior (0–40)	8.6 ± 4.3
SDQ external problem behavior (0–20)	4.9 ± 2.8
SDQ internal problem behavior (0–20)	3.7 ± 2.8
CIDS-Youth (12–60)	51.2 ± 5.3
Mismanagement (4–16)	6.4 ± 2.0

Data are means ± SD, unless otherwise indicated.

Demographic and diabetes related data were derived from hospital charts during the same period as the completion of the survey. HbA1c was used as a marker of *glycemic control* over the past 8–12 weeks, with recommended target < 7.5%, 58 mmol/mol [23].

2.3. Analyses. t-tests and chi-square tests were applied in order to examine differences in HbA1c, age, and gender between responding and nonresponding adolescents. To examine whether there was a relationship between problem behavior (overall, external, and internal) and glycemic control and whether this relationship is mediated by confidence in diabetes self-care and diabetes mismanagement, bootstrap mediation analysis for multiple mediation through the Indirect Macro was applied [24, 25], correcting for age and gender. Since we chose to use more than one possible mediator, this method was considered more appropriate than traditional models [24, 26–28]. Analyses were performed with a bootstrap of 5000 resamples, in which random samples based on the original data are generated. A 95% confidence interval (CI) was calculated [25].

3. Results

A total of 88 adolescents (45 boys) completed the online survey (88.0% of the 100 youths ≥ 11 y), mean age 12.9 (±1.2) years with a mean disease duration of almost 6 years. Baseline characteristics are shown in Table 1. There were no differences in HbA1c, age, and gender between responders and nonresponders. Thirteen adolescents (14.8%) reported problem behavior above the normal range (overall problem

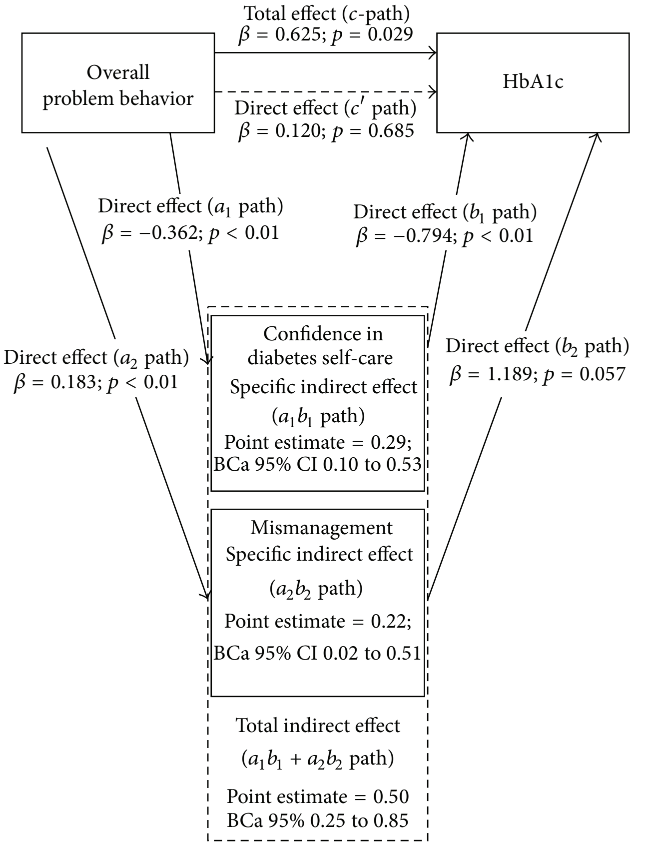

Figure 1: Graphic representation of the multiple mediation model of the associations between overall problem behavior and glycemic control with confidence in diabetes self-care and mismanagement of diabetes self-care. 5000 resamples were calculated while using the bootstrap method [24].

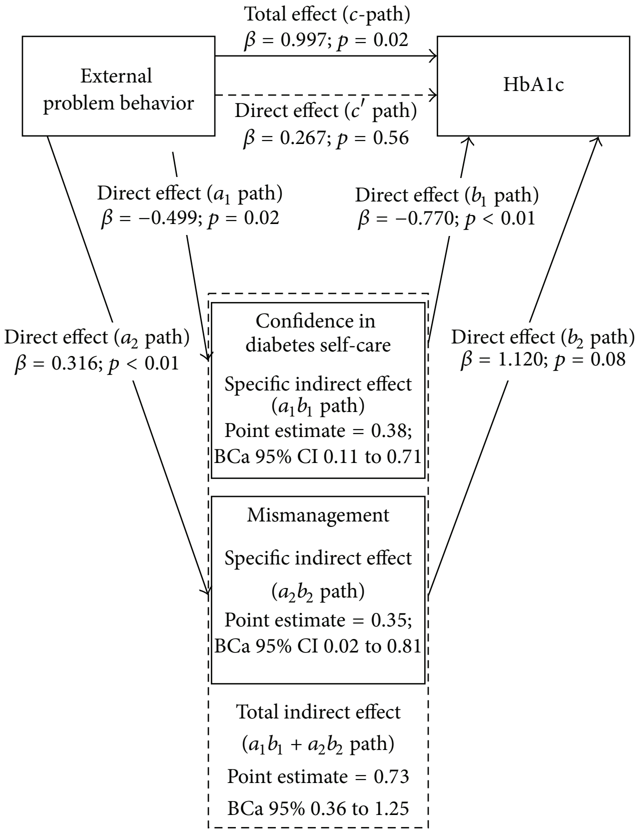

Figure 2: Graphic representation of the multiple mediation model of the associations between external problem behavior and glycemic control. 5000 resamples were calculated while using the bootstrap method [24].

behavior score > 13). Almost three-quarters of adolescents (72.7%) had HbA1c levels above target.

3.1. Overall Problem Behavior. Figure 1 shows the multiple mediation model of the associations between *overall problem behavior* and glycemic control. A significant total effect (c-path) was found between overall problem behavior and glycemic control ($\beta = 0.625$, $p = 0.029$), indicating that higher overall problem behavior scores are associated with higher HbA1c. Mediation analysis showed that this relationship was mediated by confidence in diabetes self-care and mismanagement as the indirect effect was significant ($a_1b_1 + a_2b_2$ *path* point estimate = 0.50, BCa 95% 0.25 to 0.85) and the direct effect (c' path) was not anymore ($\beta = 0.120$, $p = 0.685$). Increased overall problem behavior was associated with higher confidence in diabetes self-care (a_1 path $\beta = -0.362$, $p < 0.01$) and worse self-care of diabetes (a_2 path $\beta = 0.183$, $p < 0.01$). Lower confidence in diabetes self-care was associated with higher HbA1c (b_1 path $\beta = -0.794$, $p < 0.01$). The association between mismanagement of diabetes and higher HbA1c was borderline significant (b_2 path $\beta = 1.189$, $p = 0.057$).

3.2. External Problem Behavior. Figure 2 shows the multiple mediation model of the associations between *external problem behavior* and glycemic control. A significant total effect (c-path) was found between external problem behavior and glycemic control ($\beta = 1.00$, $p = 0.02$): increased external problem behavior was associated with higher HbA1c. Again, multiple mediation analysis showed that this relationship was mediated by confidence in diabetes self-care and mismanagement as the indirect effect ($a_1b_1 + a_2b_2$ *path* point estimate = 0.73, BCa 95% 0.36 to 1.25) was significant and the direct effect (c' path $\beta = 0.27$, $p = 0.56$) was not anymore. Increased external problem behavior was associated with low confidence in diabetes self-care (a_1 path $\beta = -0.49$, $p = 0.02$) and worse self-management of diabetes (a_2 path $\beta = 0.32$, $p < 0.01$). Low confidence in diabetes self-care and worse self-management of diabetes were both associated with higher HbA1c; however the latter was not significant (b_1 path $\beta = -0.77$, $p < 0.01$; b_2 path $\beta = 1.12$, $p = 0.08$).

3.3. Internal Problem Behavior. Figure 3 shows the multiple mediation model of the associations between *internal problem behavior* and glycemic control. In contrast to the overall and external problem behavior, the total effect between internal problem behavior and glycemic control was not

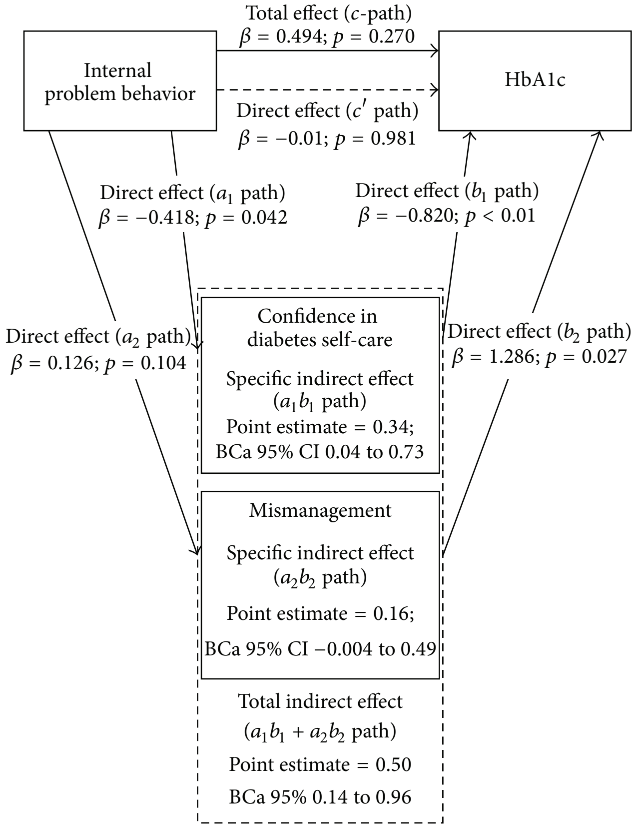

Figure 3: Graphic representation of the multiple mediation model of the associations between internal problem behavior and glycemic control. 5000 resamples were calculated while using the bootstrap method [24].

significant (c-path $\beta = 0.494$, $p = 0.270$). However, multiple mediation analysis did show a significant mediation by confidence in diabetes self-care and mismanagement as the indirect effect was significant ($a_1b_1 + a_2b_2$ *path* point estimate = 0.50, BCa 95% 0.14 to 0.96). The association of the direct effect (c' path $\beta = -0.01$, $p = 0.981$) decreased as a result of this mediation. Increased internal problem behavior was associated with low confidence in diabetes self-care (a_1 path $\beta = -0.418$, $p = 0.042$), but not with worse self-management of diabetes (a_2 path $\beta = 0.126$, $p = 0.104$). Low confidence in diabetes self-care and worse self-management were both associated with a higher HbA1c (b_1 path $\beta = -0.820$, $p < 0.01$; b_2 path $\beta = 1.286$, $p = 0.027$).

4. Discussion

The aim of the present study in adolescents with T1D was to investigate whether there is a relationship between problem behavior and glycemic control and whether this relationship is mediated by low confidence in diabetes self-care and mismanagement of diabetes. Increased *overall* and *external* problem behavior were found to be associated with increased HbA1c and these relationships were mediated by confidence in diabetes self-care and self-management of diabetes. Interestingly no total effect was found between *internal* problem behavior and glycemic control, and the relationship between internal problem behavior and diabetes management was not significant; however, the indirect effect was significant. We should interpret these findings with caution, as the relationship could be dose-dependent: the risk of worsened illness management increases when internal problems get more serious [17]. The adolescents participating in our study reported somewhat less problematic behavior on all three SDQ scales (overall, external, and internal problem behavior) compared to the 11–16-year-old adolescents participating in SDQ validation study published in 2003 (overall $M = 8.6$ compared to 9.9, external $M = 4.9$ compared to 5.8, and internal $M = 3.7$ compared to 4.1) [19]. Our sample appears less problematic than previously reported in the literature where adolescents with T1D were found to have more problem behavior compared to healthy peers [7–10]. Possible explanations for this discrepancy could be that we included a slightly younger group compared to the SDQ validation study, a selection bias, or the fact that previous research was conducted a decade ago. Nevertheless, almost 15% of the adolescents in our study reported levels of problem behavior above the normal range. This underscores the clinical relevance of our proposed model.

The relationship between more behavior problems and suboptimal HbA1c levels has been demonstrated in other studies as well [12–14]. The present study confirms our hypothesis that this relationship is mediated by confidence and self-management of diabetes. More behavioral problems seem to decrease the adolescent's confidence in the management of their diabetes, in concordance with previous research [17]. The need to address psychosocial issues in pediatric diabetes care is recognized [29, 30]. Psychosocial well-being is an important outcome in and of itself but also has clear relevance to understanding problems in achieving satisfactory glycemic control [31, 32]. Timely detection and management of psychosocial issues, however, have been shown to be difficult in routine care, where time is limited and measurements of adolescents' physical health often have priority [33]. Our findings corroborate the clinical relevance of finding practical ways to ensure that assessment and management of behavioral problems in adolescents are in place.

4.1. Limitations. Although the current study contributes to enhancing our understanding of the complex interactions between psychosocial and biological developmental trajectories, some limitations should be taken into account. First, our study was cross-sectional and we cannot infer causality. The 12-year study of Northam et al. examined the relationship between problem behavior at diagnosis and longtime poor glycemic control but did not look at possible mediating pathways [16]. Future longitudinal research is planned to examine this relationship in more detail. Moreover, the relationship between the psychosocial development and diabetes outcomes is multifaceted. In the present study we only tested the contribution of a few of the factors involved and took

HbA1c as a marker for glycemic control. In addition, we may want to explore the momentary impact of behavior problems on blood glucose fluctuations which is likely to exist. Conversely, high and low blood glucose values can influence the adolescents' behavior, thereby creating a vicious cycle of events [34]. With regard to the measurements, we chose to administer the questionnaires via the internet, for pragmatic reasons. Also online administration of questionnaires is patient-friendly and more appealing to adolescents than traditional paper-and-pencil. We should acknowledge that we cannot validate that respondents have all filled in the online questionnaire without interference from others (e.g., parent, siblings); however, several studies have shown over the years that questionnaires completed via the internet are as reliable as paper-and-pencil [35, 36]. The internal consistency (Cronbach's α) of the adapted version of the mismanagement scale proved to be relatively low in our study ($\alpha = 0.47$). This may be due to the fact that management behaviors are relatively independent of one another or due to the small number of items, as the adapted version of the questionnaire consists of 4 rather than the 10 items in the original questionnaire. Psychometric validation of the scale warrants further research.

5. Conclusion

More problem behavior in adolescents with type 1 diabetes is associated with worsened glycemic control and this relationship is mediated by low confidence in diabetes self-care and poorer self-management of the diabetes. This finding has clinical implications. Psychosocial screening should include both internal problem behavior and external problem behavior. To assist adolescents in achieving better glycemic control, it would seem imperative to help them build their confidence and reduce diabetes mismanagement, for example, improving their self-care practices.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

Authors' Contribution

Minke M. A. Eilander conducted the design of the study, collected and researched data, and wrote the paper. Maartje de Wit conducted the design of the study and reviewed and edited the paper. Joost Rotteveel reviewed and edited the paper. Frank J. Snoek reviewed and edited the paper.

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Research Article

Metabolic Control and Illness Perceptions in Adolescents with Type 1 Diabetes

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Background. Disturbed eating behavior and psychosocial variables have been found to influence metabolic control, but little is known about how these variables interact or how they influence metabolic control, separately and combined. *Objective*. To explore associations between metabolic control (measured by HbA1c) and eating disorder psychopathology, coping strategies, illness perceptions, and insulin beliefs in adolescents with type 1 diabetes. *Methods*. A total of 105 patients (41.9% males) with type 1 diabetes (12–20 years) were interviewed with the Child Eating Disorder Examination. In addition, self-report psychosocial questionnaires were completed. Clinical data, including HbA1c, was obtained from the Norwegian Childhood Diabetes Registry. *Results*. Significant gender differences were demonstrated. Among females, HbA1c correlated significantly with eating restriction (.29, $p < .05$), the illness perception dimensions *consequences, personal control, coherence,* and *concern* (ranging from .33 to .48), and the coping strategy *ventilating negative feelings* (−.26, $p < .05$). Illness perception *personal control* contributed significantly to HbA1c in a regression model, explaining 23% of the variance among females (β .48, $p < .001$). None of the variables were significantly associated with HbA1c among males. *Conclusions*. Illness perceptions appear to be important contributors to metabolic control in females, but not males, with type 1 diabetes.

1. Introduction

Type 1 diabetes is a national and international health problem and priority, and Norway is amongst the highest incidence of type 1 diabetes in the world. The incidence in Norway has increased by 30% in the last 15 years, and the rate among Norwegian children was 32.5 per 100.000 person-years in 2012 [1]. Only one-third of young patients with type 1 diabetes in the Norwegian Childhood Diabetes Registry (NCDR) manage the target of Hemoglobin A1c (HbA1c, a measure of metabolic control) < 7.5% [2], which is the international target to minimize the risk of developing serious diabetes complications such as cerebrovascular and cardiovascular disease, retinopathy, neuropathy, and nephropathy [3]. Levels of HbA1c are found to predict early and late diabetes complications [4]. Also, childhood-onset type 1 diabetes is associated with increased mortality compared to healthy controls [5].

Type 1 diabetes appears to be a risk factor for the development of eating disorder behaviors. Disturbed eating patterns appear common and persistent in young women with type 1 diabetes, with prevalence rates more than twice those of nondiabetes populations [6, 7]. Although most studies focus on females, some researches suggest that males with type 1 diabetes may also have an elevated risk of developing disturbed eating behaviors [8]. The presence of eating pathology can severely impair metabolic control and advance the onset of long-term complications [9]. A core symptom of disturbed eating in type 1 diabetes is intentional insulin restriction to lose weight, an efficient weight loss strategy uniquely available to patients with type 1 diabetes and reported in up to about 35% of females [10, 11]. Insulin restriction is significantly associated with poorer metabolic control [12], and prior research has found that self-reported insulin restriction leads to a threefold increased risk of mortality at an 11-year follow-up [10].

In addition to disturbed eating behavior, other factors reported to be associated with metabolic control are psychosocial correlates such as illness perceptions [13], coping strategies [14], and insulin beliefs [15]. Illness perceptions refer to individual perceptions or beliefs about their illness and are found to be central to patient behavior in a variety of illnesses, including cancer [16], coronary heart disease [17], and chronic fatigue syndrome [18], as well as type 1 diabetes [19, 20]. Specifically, perceptions of control and consequences have been found to be significantly associated with metabolic control among adolescents and young adults [21]. Coping strategies refer to behaviors adopted to handle negative or stressful events and have been reported to be associated with metabolic control among adolescents and adults [14]. Finally, insulin beliefs refer to patients' beliefs about insulin and have been found to play an important role in adherence to treatment [13, 15] and diabetes control [22].

Although eating disorder psychopathology, coping strategies, illness perceptions, and insulin beliefs have shown to be independently associated with adherence to treatment and metabolic control in patients with type 1 diabetes, little is known about how these variables interact, and how they influence HbA1c, separately and combined. In addition, it is uncertain how these factors operate in males versus females. Increased knowledge may shed light on identifying targets for both assessment and treatment.

1.1. Aims of Study. This study aimed to investigate associations between HbA1c and eating disorder psychopathology, coping strategies, illness perceptions, and insulin beliefs in young males and females with type 1 diabetes and to assess the extent to which these variables explain the variance in HbA1c.

2. Materials and Methods

2.1. Participants and Procedure. The Norwegian Childhood Diabetes Registry (NCDR) is a nationwide, population-based registry, which includes all newly diagnosed children with diabetes since 1989. All pediatric departments in Norway perform and report the results of annual standardized examinations to NCDR. This cross-sectional study is part of a larger study of the NCDR. Of 850 eligible participants, 105 individuals (12%) with type 1 diabetes aged 12–20 years agreed to participate in a more extensive in-depth assessment, including a face-to-face interview.

Participants were compared to the background type 1 diabetes population in the NCDR, which has a completeness of 95% [1]. These groups did not differ on age, zBMI (age- and gender-adjusted body mass index), type 1 diabetes duration, number of consultations with the diabetes team, or number of consultations with dieticians. Participants were slightly older at onset of type 1 diabetes than nonparticipants (9.6 versus 8.8 years, $p < .05$), had somewhat lower HbA1c (8.6% (70 mmol/mol) versus 8.9% (74 mmol/mol), $p < .05$), and had fewer episodes of ketoacidosis (.02 versus .05, $p < .05$).

The participants were recruited from the NCDR between 2011 and 2012 and lived in rural and urban settings across all geographical regions of Norway. There were 44 (41.9%) males and 61 (58.1%) females. Male and female participants did not differ significantly on age (yrs), HbA1c, zBMI, age of onset, or duration of diabetes illness (yrs). The assessment was conducted at Oslo University Hospital or another location at the participants' choice (usually their home or school).

2.2. Ethical Aspects. The regional ethics committee approved the study. Written informed consent was obtained from all participants and their parents if the participant was below the age of 16 years.

2.3. Measures. The Child Eating Disorder Examination (ChEDE) [23] is a semistructured diagnostic interview that is considered the gold standard for assessing eating disorder psychopathology among children and adolescents. The ChEDE has been translated and validated in Norwegian and has demonstrated good psychometric properties [24]. The ChEDE consists of four subscales (restraint, eating concern, weight concern, and shape concern), in addition to a global score. The answers range from 0 to 6, and higher scores indicate higher degree of eating psychopathology. In line with Olmsted et al. [25], a diabetes-adapted version of the ChEDE was adopted to ensure that pathological scoring was due to weight and shape concerns and not only for controlling the diabetes. As such, any endorsement of items related to eating behavior or food (e.g., food rules and dietary restraint) was further queried to determine whether such behavior was attributable to medically indicated diabetes care or motivated by concerns about their weight and shape. Only attitudes or behaviors motivated by shape/weight concerns were rated. Additionally, after the section on bulimic episodes and overeating was completed, the patient was asked to estimate the percentage of episodes that were associated with a hypoglycemic/low blood sugar reaction. Finally, a separate item for insulin restriction was added, asking whether the patients ever reduced or omitted their insulin dose. If the patients responded affirmatively, they were asked why insulin was restricted. Interviews were conducted by two Masters-level psychologists (Line Wisting and Lasse Bang) who participated in training seminars for the administration of the ChEDE interview by its developer (Rachel Bryant-Waugh). Interrater reliability was assessed for subscales and global score totals and found to be good (composite intraclass correlations coefficient of .97).

Adolescent Coping Orientation for Problem Experiences (A-COPE) [26] is a measure of coping strategies and is translated and validated for use among Norwegian adolescents [27]. In addition to a total score indicating the degree of positive coping, the A-COPE consists of 34 items divided into five subscales: being social, seeking diversions, ventilating negative feelings, developing self-reliance, and solving family problems. Answers range from 1 to 5 (never, seldom, sometimes, often, and usually). Higher scores indicate a higher degree of positive coping on all items, after items 8, 10, 11, 15, 17, 18, 24, and 29 are reversed prior to analyses.

The Brief Illness Perception Questionnaire (BIPQ) [28] is a brief version of the Illness Perceptions Questionnaire (IPQ) [29] and Illness Perceptions Questionnaire-Revised (IPQ-R) [30] and is a valid and reliable measure of illness perceptions. It has been used in the context of a variety of illnesses, including type 1 diabetes. It consists of nine items, and each item assesses one dimension of illness perceptions: consequences, timeline, personal control, treatment control, identity, coherence, emotional representation, concern, and causation. Personal control, treatment control, and coherence are reversed in the analyses, indicating that a higher score on each of the items as well as the total score indicates more threatening/negative views of their diabetes.

The Beliefs about Medicines Questionnaire (BMQ) [31] is a measure of beliefs about medicines in general and one specific medicine (insulin in this study). It consists of four subscales: specific (insulin) necessity, specific concern, general necessity, and general overuse. Answers are ranged on a five-point Likert scale, ranging from 1 = strongly disagree to 5 = strongly agree. A Norwegian version has been translated and validated, demonstrating satisfactory psychometric properties [32]. The specific necessity and specific concern subscales are used in this study to measure participants' concerns regarding insulin and to what extent they perceive insulin to be necessary.

Clinical data were obtained from NCDR. HbA1c was determined for all participants by high-performance liquid chromatography (HPLC) (Tosoh G7; Tosoh Europe N.V., Belgium). All samples were analyzed in the same central laboratory and standardized according to the Diabetes Control and Complications Trial standards. The reference range was 4.0–6.0%; the analytical coefficient of variation was < 1%.

BMI was calculated based on weight and height (kg/m^2) and standardized to a z-score according to age and gender using the Centers for Disease Control and Prevention Growth Charts 2000, since the participants were primarily below 18 years (zBMI) [33].

2.4. Statistical Analyses. Associations between metabolic control, eating disorder psychopathology, illness perceptions, coping strategies, and insulin beliefs were assessed by means of Pearson's correlations ($p < .05$). Subsequent to the correlation analyses, standard multiple regression (enter) analyses were conducted in line with the backward elimination strategy described below, to investigate possible risk factors for HbA1c. The analyses were split by gender. Among females, and based on an alpha level of $p < .20$, the BIPQ subscales consequences, personal control, treatment control, identity, coherence, emotional representation, and concern were entered into the equation, in addition to the ACOPE subscale ventilating negative feelings and the ChEDE subscales restraint, eating concern, and weight concern. To avoid multicollinearity in the regression equation, shape concern was excluded due to a correlation with weight concern above .70. Intraclass correlation analysis was used to assess interrater reliability. Statistical analyses were conducted using PASW version 18 (SPSS IBM, NY, USA).

3. Results

3.1. Participant Characteristics. Mean age of the 105 participants was 15.7 years (SD: 1.8). For males ($n = 44$) and females ($n = 61$), mean age was 15.9 years (SD: 1.8) and 15.6 years (SD: 1.8), respectively. Mean age at onset of type 1 diabetes was 9.6 years (SD: 3.5) for the whole sample, 9.8 years (SD: 3.6) for males, and 9.5 years (SD: 3.5) for females. Mean type 1 diabetes duration for all participants was 5.7 years (SD: 3.7), for males 5.7 (SD: 3.6), and for females 5.7 (SD: 3.7). Regarding age- and gender-adjusted body mass index, mean zBMI was .4 (SD: .8) for the whole sample, .3 (SD: .8) for males, and .4 (SD: .9) for females. Mean HbA1c for the whole sample, males, and females was 8.6% (SD: 1.3), 8.4% (SD: 1.3), and 8.7% (SD: 1.3), respectively. There were no significant differences between males and females on any of the variables.

3.2. Correlations. Correlations between HbA1c and illness perceptions, eating disorder psychopathology, coping strategies, and insulin beliefs are presented in Table 1. The correlation analyses were split by gender to investigate gender differences. Among females, HbA1c correlated significantly at the $p < .05$ level with eating restriction (.29, $p < .05$), the illness perception dimensions consequences, personal control, coherence and concern (ranging from .33 to .48), and the coping strategy ventilating negative feelings (−.26, $p < .05$). HbA1c was not significantly associated with any of the variables among males.

3.3. Explained Variance in Metabolic Control. Among females, the BIPQ subscales consequences, personal control, treatment control, identity, coherence, emotional representation, and concern were entered into the regression equation, in addition to the ACOPE subscale ventilating negative feelings and the ChEDE subscales restraint, eating concern, and weight concern. This model explained 30% of the variance in HbA1c. After removing nonsignificant variables one by one, only the BIPQ *personal control* dimension remained

Table 1: Correlations between HbA1c and illness perceptions (BIPQ), eating disorder psychopathology (ChEDE), coping strategies (ACOPE), and insulin beliefs (BMQ).

	All	Females	Males
BIPQ consequences	$.277^{**}$	$.355^{**}$	.121
BIPQ timeline	.047	.055	−.006
BIPQ personal control	$.365^{**}$	$.484^{**}$	.106
BIPQ treatment control	.084	.158	−.091
BIPQ identity	.131	.220	−.133
BIPQ coherence	.155	$.328^{*}$	−.263
BIPQ emotional representations	.177	.219	.048
BIPQ concern	$.198^{*}$	$.340^{**}$	−.083
ChEDE eating restriction	$.265^{**}$	$.287^{*}$	.188
ChEDE shape concern	.135	.152	−.016
ChEDE weight concern	.191	.172	.205
ChEDE eating concern	.155	.180	−.044
ACOPE being social	.089	.061	.062
ACOPE seeking diversion	−.033	−.009	−.056
ACOPE ventilating negative feelings	−.163	$-.260^{*}$	.034
ACOPE developing self-reliance	−.121	−.135	−.128
ACOPE solving family problems	.089	−.031	.200
BMQ insulin necessity	.035	.080	−.129
BMQ insulin concern	.060	.060	−.016

Note. Significance level ∗ = <.05; ∗∗ = <.01.

significant (beta .48, $p < .001$), explaining 23% of the variance in HbA1c among females.

Among males, BIPQ coherence, ACOPE solving problems in the family, ChEDE restriction, ChEDE weight concern, and zBMI were entered into the regression model. This model explained 16.7% of the variance in HbA1c. However, no significant variables remained in the regression equation.

4. Discussion

This study investigated associations between HbA1c, eating disorder psychopathology, and psychosocial factors in adolescent females and males with type 1 diabetes. Potential risk factors for poor metabolic control were examined.

Significant gender differences were found in this study. Whereas no variables contributed significantly to the explained variance in HbA1c among males, the overall model including illness perceptions, coping strategies, and eating disorder psychopathology explained 30% of the variance in HbA1c among females. Following the backward elimination strategy, the illness perception *personal control* ("how much control do you feel you have over your diabetes?") was significantly associated with HbA1c, explaining 23% of the variance. The importance of illness perceptions to metabolic control is also reported in previous research. For example, in Griva et al.'s [34] study of adolescents and young adults (15–25 years) with type 1 diabetes, 30% of the variance in HbA1c was explained by control, consequences, and identity. However, they used the IPQ, which has later been revised (IPQ-R). The more recent IPQ-R and the BIPQ have divided control into personal control and treatment control [28]. The analyses were not separated by gender rendering a direct comparison to our findings difficult. Another study investigated 49 patients with type 1 diabetes above 16 years (mean age 43 years) and found that personal control and identity explained 15% of the variance in HbA1c when using the BIPQ; yet again, males and females were analyzed together. Despite methodological differences in measurement and demographics, however, the results of these studies appear generally consistent with our study. In contrast, McGrady et al. [20] examined illness perceptions as possible predictors of HbA1c in patients with type 1 diabetes (15–25 years) at two time points (baseline and after three months). Contrary to their hypotheses, illness perceptions did not account for significant variance in HbA1c at time 1 or time 2. A discrepancy in findings may be related to assessment differences, as they adopted the Diabetes Illness Representations Questionnaire (DIRQ) rather than a version of the IPQ.

The association between illness perceptions and HbA1c is also apparent when examining the correlation matrix. The BIPQ subscales *consequences*, *personal control*, *coherence,* and *concern* were associated with HbA1c in females (but not in males). More negative perceptions of their diabetes generally indicated higher levels of HbA1c. This is in line with a recent literature review investigating the relationship between illness perceptions and metabolic control across nine studies of adults with type 1 diabetes and type 2 diabetes [19]. Significant associations between HbA1c and the subscales identity, consequences, timeline, concern, and emotional representations were reported when analyzing the nine studies together. However, the associations are considerably weaker than those found among the adolescents in our study. In addition to different age groups and the fact that the review article had a mixed sample of patients with both type 1 diabetes and type 2 diabetes, the divergent results may relate to gender differences. Whereas the current study split the analyses by gender, the other studies investigated males and females together. All the abovementioned studies, including the current study, used some version of the Illness Perception Questionnaire (the Illness Perception Questionnaire, the Illness Perception Questionnaire-Revised, or the Brief Illness Perceptions Questionnaire), facilitating comparison of results. The association between illness perceptions and HbA1c suggests the importance of attention to patients' views and perceptions of their diabetes in clinical settings, especially among females.

HbA1c was associated with eating disorder psychopathology among females. More specifically, HbA1c was associated with the ChEDE subscale eating restriction, but not with the subscales eating concern, weight concern, or shape concern. This makes sense given that eating restriction is the only behavioral subscale of the ChEDE, whereas the remaining three subscales are cognitive. It is only disturbed eating behaviors, not cognitions, which can directly affect metabolic control. However, one might argue that cognitions often lead to specific behaviors, though only indirectly. To our knowledge, no studies have previously investigated the correlation between different ChEDE subscales and HbA1c.

However, a couple of studies have reported significant associations between eating pathology total scores and HbA1c with correlation coefficients of .25 [35] and .30 [36]. Both these studies using the self-completion measure the Diabetes Eating Problem Survey-Revised (DEPS-R), which is specifically designed to screen for eating pathology in diabetes. Although few studies have reported correlation coefficients between measures of eating pathology and HbA1c, previous studies have established poorer metabolic control in patients with concurrent type 1 diabetes and disturbed eating than in patients with type 1 diabetes only [9, 12], suggesting an association between these two variables. No significant correlation between HbA1c and eating disorder psychopathology was found among males in our study. This might be expected, since disturbed eating patterns are mostly found among females with type 1 diabetes [6, 7]. Eating disorder psychopathology was hypothesized to affect metabolic control, and in the regression analysis, eating restriction alone explains 8% of the variance in HbA1c in females (not in males). However, this significant effect disappeared when personal control was entered to the regression equation.

Coping strategies have previously been found to be associated with HbA1c [14, 37, 38]. In the current study, higher degree of ventilating negative feelings was associated with higher HbA1c among females. This is in line with previous research, suggesting that emotion-focused coping strategies are associated with poorer metabolic control among adolescents with type 1 diabetes [14]. However, active/problem-focused coping strategies previously shown to be associated with HbA1c in adolescents with type 1 diabetes [14, 37, 38] were not confirmed in this study. Assessment differences with a variety of measures and combination of measures used may account for this discrepancy of findings. In addition, none of these previous studies have separated the analyses by gender, which may complicate comparison of results across the studies.

Insulin beliefs and HbA1c were not found to be significantly associated in this study. Beliefs and perceptions about insulin have been associated with adherence to treatment [13, 15] and diabetes control [22]. However differences in terminology and assessment complicate the interpretation of results. Nevertheless, the importance of attitudes and beliefs about insulin has been emphasized clinically, suggesting that this should be investigated further.

Only one-third of patients in the NCDR manage the international target of HbA1c below 7.5%. This is consistent with international data [39]. Identifying contributing factors to HbA1c levels, and focusing on these clinically, is therefore important. The relevance of illness perceptions was demonstrated among females in this study, suggesting that patient's perceptions of their diabetes and its consequences could be worth addressing in diabetes clinics. In fact, interventions targeting illness perceptions in adults with only type 2 diabetes have successfully improved HbA1c [40], underlining the potential to improve health and minimize the risk of serious diabetes complications. Whether such interventions would yield similar results in adolescents with type 1 diabetes is unknown.

As described above, this study demonstrated several significant associations between psychosocial variables and HbA1c. Common to some of these is that they are relatively small (correlation ranging from .21 to .48). This could question the clinical relevance of the results. However, eating pathology and psychosocial variables explained 30% of the variance in HbA1c in our study, suggesting that such factors are clinically relevant in terms of reducing the risk of diabetes complications.

This study is the last of several studies that recruited patients from the Norwegian Childhood Diabetes Registry (NCDR) at the same time. After participating in previous large-scale studies, 850 patients were invited to participate in this further in-depth assessment of eating disorder psychopathology and psychosocial aspects. A subset of 105 patients agreed to this by actively returning a signed consent form via postal mail. Although only 12% of eligible participants represent a limitation of this study, it is strengthened by the collaboration with the NCDR that ensures clinical data on almost the entire population of young patients with type 1 diabetes in Norway. This enables comparison of participants to nonparticipants on various clinical and demographical data. In general, few significant differences were found between our participants and the nonparticipants, except for somewhat lower HbA1c levels and fewer episodes of diabetes ketoacidosis (see Materials and Methods). This might indicate that our subgroup is slightly healthier than the rest of the population, thereby implying a question of generalizability. Although the differences were relatively small, this might represent a limitation of the current study. The face-to-face assessment conducted with the semistructured diagnostic interview Child Eating Disorder Examination is a strength of this study. This interview is resource-demanding in terms of costs and time given the length of one to two hours.

A majority of existing studies are cross-sectional. These studies, including ours, are limited by their inability to establish causal relations. There is a need for long-term follow-up studies to longitudinally identify risk factors for poor metabolic control and track the development of these among adolescents with type 1 diabetes.

In summary, this study has documented gender differences in the associations between HbA1c, eating disorder psychopathology, illness perceptions, coping strategies, and insulin beliefs. Most important was the association between illness perceptions and HbA1c among females. These issues should be the subject of focus in diabetes clinics as they have shown to affect metabolic control, which is a crucial determinant of serious morbidity and mortality. Further research should investigate potential gender differences in both adolescents and adults. If our findings are replicated in other studies, it is crucial to establish interventions to deal with problematic illness perceptions in type 1 diabetes to improve metabolic control.

Conflict of Interests

The authors have no relevant conflict of interests to disclose.

Authors' Contribution

Line Wisting planned the study, collected data, analyzed the data, and wrote the paper. Lasse Bang collected data and contributed to the paper. Torild Skrivarhaug is the leader of the Norwegian Childhood Diabetes Registry (NCDR), contributed to the planning of the study, collected clinical data with the NCDR, and contributed to the paper. Knut Dahl-Jørgensen was one of the initiators of the NCDR and contributed to the planning of the study and to the paper. Henrik Natvig supervised Line Wisting and contributed to the data analyses and the paper. Bryan Lask supervised Line Wisting and contributed to the planning of the study and to the paper. Øyvind Rø supervised Line Wisting and contributed to the data analyses and the paper.

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Research Article

Correlates of Depressive Symptoms in Older Adults with Diabetes

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Investigators examined correlates of depressive symptoms within a sample of older adults with diabetes. Participants completed a structured telephone interview with measures including depressive symptoms, health conditions, cognitive function, and diabetes distress. Correlations and hierarchical linear regression models were utilized to examine bivariate and covariate-adjusted correlates of depressive symptoms. The sample included 246 community-dwelling adults with diabetes (≥65 years old). In bivariate analyses, African Americans, individuals with specific health issues (neuropathy, stroke, respiratory issues, arthritis, and cardiac issues), and those with higher levels of diabetes distress reported more depressive symptoms. Older age, higher education, more income, and better cognitive function were inversely associated with depressive symptoms. In the final covariate-adjusted regression model, stroke ($B = .22$, $p < .001$), cognitive function ($B = -.14$, $p < .01$), and higher levels of diabetes-related distress ($B = .49$, $p < .001$) each were uniquely associated with more depressive symptoms. Diabetes distress partially mediated the associations between cardiac issues and depressive symptoms and between cognitive function and depressive symptoms. Findings suggest that interventions targeted at helping older adults manage their diabetes-related distress and reducing the likelihood of experiencing additional health complications may reduce depressive symptoms within this population.

1. Introduction

The current impact of diabetes at individual and societal levels in the USA is substantial. According to the Centers for Disease Control and Prevention (CDC), approximately 29.1 million individuals in the USA (9.3% of the population) are currently living with diabetes [1]. The CDC estimates that 25.9% of Americans aging 65 or older have this chronic illness. On average, individuals with diabetes spend more than 2.3 times the amount in healthcare expenses than those without diabetes [1]. There is a clear need to do a better job of preventing diabetes at early ages as well as manage diabetes and comorbid conditions in older adults.

The combination of financial, physical, and mental demands due to living with a chronic illness such as diabetes can result in emotional distress and depressive symptoms. Due to the increasing prevalence of older individuals who are living with chronic illness, there is a need for researchers to investigate and better understand the various causes of depressive symptoms in this population. In order to reduce and better manage stressors, one must first have a general understanding of how stressors in the context of chronic illness are processed both emotionally and physically.

1.1. Biopsychosocial Model. In 1977, George Engel proposed the biopsychosocial cultural model (later shortened to "biopsychosocial model" for the sake of brevity). Engel proposed this model under the hypothesis that to provide a basis for understanding what influences the trajectory of a disease (for treatment and prevention purposes) we must not only examine the biological factors affecting the individual, but also examine the social context in which that individual lives [2]. With this theory, the fields of medicine and research gained a better understanding of the relationships between suffering, disease, and illness as well as a clearer understanding of an individual's subjective experience and the influence it can have on diagnoses, health outcomes, and overall healthcare [3]. It is with an understanding of the biopsychosocial model that researchers of the current study sought to examine depressive symptoms and diabetes distress in a sample of older adults living with diabetes.

1.2. Stressors and Mental Health. The relationship between the presence of health conditions such as stroke, cardiovascular disease, respiratory issues, arthritis, and neuropathy and individuals reporting depressive symptoms has been well documented [4–7]. Previous research also suggests that experiencing the pain of neuropathy coupled with the possible decrease in independence may have a negative impact on mood [8]. For individuals who are coping with the effects of a stroke and are also dealing with cognitive function difficulties that often follow a stroke, in addition to the day-to-day management of their diabetes, psychological distress may be exacerbated [9]. It has also been proposed that respiratory issues, such as asthma, and negative moods have a mutually potentiating relationship [10]. It appears that an individual's heart health and the ability to control chronic health issues are very closely related to mood problems [11]. Furthermore, depressive symptoms are more prevalent in older individuals who experience arthritic pain [12]. In addition to the relationship with health conditions, the prevalence of depressive symptoms seems to be considerably higher among older individuals who are of lower educational attainment, are female, and/or are minorities [13–15].

1.2.1. Cognitive Function, Diabetes, and Depressive Symptoms. Depressive symptoms are often exhibited at the onset or during the early manifestations of cognitive decline and dementia [16, 17]. Decline in cognitive function is an issue particularly important for older individuals who experience diabetes. For example, in a longitudinal study of 624 community-dwelling older adults, it was found that having diabetes predicted cognitive decline, particularly among individuals with less frequent physician visits and African Americans who reported higher levels of perceived discrimination [18].

1.2.2. The Role of Diabetes Distress. Diabetes distress is the term used to describe the emotional strains that are commonly associated with living with diabetes. Fisher and colleagues examined associations between major depression, depressive symptoms, diabetes distress, and glycemic control [19]. Diabetes distress was found to differ from both clinical depression and depressive symptoms so far as it was more closely tied to poorer glycemic control and disease management. Their findings lend support to the idea that different methods of treatment focusing specifically on health-related distress may be particularly beneficial for improving depressive symptoms in this population [19, 20].

The purpose of this study was to examine correlates of depressive symptoms in older adults with diabetes and the extent to which diabetes distress may explain associations between depressive symptoms and factors that have been previously linked to these symptoms. It was hypothesized that older individuals with diabetes who reported additional adverse medical conditions would also report a higher number of depressive symptoms. Among older individuals living with diabetes, lower cognitive function was hypothesized to be associated with more depressive symptoms. Finally, reporting high levels of diabetes-related distress was hypothesized to be associated with high levels of depressive symptoms and to potentially explain associations between health, cognitive function, and depressive symptoms.

2. Methods

Data comes from the Diabetes and Aging Study of Health (DASH). The DASH sample included community-dwelling older adults in the Birmingham, Alabama area, as well as patients from a diabetes clinic at the University of Alabama at Birmingham (UAB). All participants were required to be 65 years of age or older and identified as having diabetes via either self-report or physician diagnosis. Community-dwelling participants were recruited from a commercially available list of older adults in the Birmingham metropolitan area that is maintained by the UAB Roybal Center for Translational Research on Aging and Mobility. Clinic participants were recruited from patients of one physician at the UAB Diabetes & Endocrinology Clinic. All participants were contacted via a mailed letter followed by telephone contact. African Americans were oversampled in order to fulfill DASH's overarching goal, examining racial disparities in mental health, cognitive function, and mobility outcomes in older adults with diabetes over time. Participants completed telephone interviews focused on diabetes-specific measures of health and psychosocial factors as well as performance-based cognitive testing.

2.1. Demographics. Demographic variables were gathered via self-report. Age, race, gender, years of education, marital status, and income were obtained. Income was measured in ordinal categories ranging from 1 (less than $5,000) to 9 ($100,000 or greater).

2.2. Health Problems. Health issues were assessed via self-report. A list of health issues that commonly occur in older adults was assessed, and participants reported if they had ever been told by a doctor/nurse that they have had various health conditions including neuropathy, stroke (or a "ministroke"/transient ischemic attack), respiratory issues (asthma, chronic bronchitis, or emphysema), arthritis, and cardiovascular problems (heart attack/myocardial infarction or congestive heart failure). Responses were coded as 0 (no) and 1 (yes).

2.3. Cognitive Functioning. Cognitive functioning was assessed using the modified Telephone Interview for Cognitive Status (TICS-M) which measures global cognitive status in older adults [21]. This is a 13-item modified and previously validated version of the Telephone Interview of Cognitive Status. The TICS-M includes four domains: orientation; registration/recent memory and delayed recall; attention/calculation; and semantic memory, comprehension, and repetition. The possible range of scores is 0 to 39, with a relatively higher proportion of the total score being allocated to the memory component [21]. A score of 20 or lower suggests cognitive impairment.

2.4. Depressive Symptoms. Mental health was assessed via the Geriatric Depression Scale-Short Form. This scale is comprised of 15 items which assess low moods and feelings of helplessness (common symptoms of depression) in the individual [22]. The potential range of this scale is from 0 to 15 and Cronbach's alpha is 0.85. A score of 5 or higher suggests elevated depressive symptoms [23].

2.5. Diabetes Distress. The scale used to measure diabetes-related emotional distress was a brief 2-item version [24] that was modified from the original 17-item Diabetes Distress Screening Scale (DDSS) [25]. For the DDSS2, participants were asked to rate how much the following items caused distress during the past month: "Feeling overwhelmed by the demands of living with diabetes," and "Feeling that I am often failing with my diabetes routine." Response options range from 1 (indicating the item was not a problem) to 6 (indicating that the item was a very serious problem). Cronbach's alpha for the two items was 0.79. A summary score was created for diabetes distress with a sum of 6 or greater corresponding to "moderate distress" and potentially identifying individuals who are at-risk for negative outcomes.

2.6. Analyses. Analyses were conducted using SAS V9.1.3 [26] and IBM SPSS Version 22 [27]. Bivariate correlations between depressive symptoms and variables of interest were examined. An initial regression model included demographic characteristics (age, gender, education, marital status, income, and race) as correlates of depressive symptoms. Subsequent models examined associations between depressive symptoms and variables categorized as potential problems for older adults with diabetes by adding health conditions (neuropathy, stroke, respiratory issues, arthritis, and cardiac issues), cognitive function, and diabetes distress in additional sequential models. In order to determine the contribution of additional variables to the regression model, an increment r-square test was assessed after each step.

3. Results

3.1. Participants. Descriptive characteristics for participants are presented in Table 1. There were 246 participants (172 community-based and 74 clinic-based ones), with 126 (51.44%) Caucasians, 110 (44.72%) African Americans (AA), and 10 "other" races (4.07%). There were 109 male participants (44.31%), and the average age was 73.35 years (range 65–90). Their self-reported time since diagnosis ranged from less than a year to 58 years, with an average of 16 years. In the 246 participants, the most frequent health condition was arthritis (71.54%). The average sample score on the TICS-M was 23.37 (SD = 5.59), slightly above the suggested cutoff for cognitive impairment of 21. Sixty-five participants (26.42%) scored 20 or less on the TICS-M, indicating that they experienced problems with cognitive function. In terms of diabetes-related distress, the average score on the DDSS2 was 3.85 (SD = 2.51). Forty-eight participants (19.51%) scored at or above the cut-off score of 6 indicating that they were experiencing moderate to severe distress. The average score for the sample on the GDS (cut-off score of 5 or higher for clinically significant symptoms) was 2.73 (SD = 2.96). Forty-three participants (17.48%) scored at or above this cutoff, indicating that they experienced an elevation in depressive symptoms.

Table 1: Sample characteristics on study variables.

	Mean (SD)	*N* (%)	Sample range
Depressive Symptoms	2.73 (2.96)		0–14
Age	73.35 (6.09)		65–90
Education	13.50 (2.65)		2–20
Income	5.05 (1.95)		1–9
Female gender		129 (52.44)	
Married		117 (47.56)	
Race			
Caucasian		126 (51.22)	
African American		110 (44.72)	
Other		10 (4.07)	
Neuropathy		109 (44.31)	
Stroke		14 (5.69)	
Respiratory issues		52 (21.14)	
Arthritis		176 (71.54)	
Cardiac issues		58 (23.58)	
Cognitive function	23.37 (5.59)		8–39
Diabetes distress	3.85 (2.51)		2–12

Correlations are presented in Table 2. These results indicated that African Americans reported more depressive symptoms than Caucasians ($r = .17$, $p < .01$). Participants who were older ($r = -.16$, $p = .01$) had higher income ($r = -.18$, $p < .001$), and more education ($r = -.22$, $p < .001$) reported fewer depressive symptoms. Regarding the specific health conditions of interest, people with neuropathy ($r = .21$, $p < .01$), stroke ($r = .36$, $p < .0001$), respiratory issues ($r = .20$, $p < .01$), arthritis ($r = .17$, $p < .05$), and cardiac issues ($r = .23$, $p < .001$) also experienced greater levels of depressive symptoms. Additionally, those within the sample who had better cognitive function ($r = -.27$, $p < .001$) reported fewer depressive symptoms.

Regarding correlations between diabetes distress and other variables of interest (Table 2), those individuals who experienced more depressive symptoms also experienced more diabetes distress ($r = .60$, $p < .0001$). Lower levels of diabetes distress were also seen in those with more years of education ($r = -.18$, $p < .01$), more income ($r = -.23$, $p < .001$), and married individuals ($r = -.13$, $p < .05$). African American participants indicated more diabetes distress than

Table 2: Correlations among depressive symptoms, demographic factors, health, and diabetes distress.

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)
(1) Depressive symptoms	1.00													
(2) Age	−.164 .010	1.00												
(3) Education	−.219 .001	.056 .383	1.00											
(4) Income	−.183 .004	−.093 .146	.529 <.001	1.00										
(5) Female gender	.047 .461	.164 .010	−.146 .022	−.389 <.001	1.00									
(6) Married	−.094 .141	−.133 .037	.100 .118	.473 <.001	−.397 <.001	1.00								
(7) African American race	.169 .008	−.141 .027	−.185 .004	−.383 <.001	.185 .004	−.234 <.001	1.00							
(8) Neuropathy	.210 <.001	.118 .066	−.057 .372	−.131 .039	.112 .079	−.161 .011	−.062 .336	1.00						
(9) Stroke	.356 <.001	−.176 .006	−.139 .029	−.006 .924	−.082 .199	.047 .462	−.009 .886	.099 .122	1.00					
(10) Respiratory issues	.200 .002	−.025 .702	−.015 .815	.013 .844	.054 .400	.065 .309	−.065 .309	.180 .005	.217 <.001	1.00				
(11) Arthritis	.174 .006	.091 .156	−.010 .874	−.058 .364	.229 <.001	−.103 .107	−.013 .843	.127 .046	.077 .228	.106 .100	1.00			
(12) Cardiac issues	.230 <.001	.054 .404	−.101 .113	−.132 .039	−.046 .470	.008 .901	−.076 .236	.102 .110	.194 .002	.135 .035	.032 .618	1.00		
(13) Cognitive function	−.266 <.001	−.066 .302	.323 <.001	.275 <.001	−.012 .852	.069 .282	−.324 <.001	−.060 .349	−.063 .323	−.027 .676	−.009 .888	−.043 .500	1.00	
(14) Diabetes distress	.598 <.001	−.122 .056	−.179 .005	−.227 <.001	.078 .225	−.133 .037	.190 .003	.157 .014	.127 .047	.062 .332	.100 .118	.170 .008	−.180 .005	1.00

Caucasians ($r = .19$, $p < .01$). Participants who experienced neuropathy ($r = .16$, $p = .01$) and cardiac issues ($r = .17$, $p < .01$) also reported greater levels of diabetes distress. Finally, those individuals with better cognitive function indicated that they had less diabetes distress ($r = -.18$, $p < .01$).

3.2. Hierarchical Regression Models. The association between demographic factors and depressive symptoms was initially examined (Table 3). There was a significant covariate-adjusted relationship between age and depressive symptoms, indicating that older age was associated with fewer depressive symptoms ($B = -.08$, $p < .05$). Additionally, the significant association between education and depressive symptoms indicated that being more educated was associated with fewer depressive symptoms ($B = -.17$, $p < .05$). None of the other demographic factors were significantly related to depressive symptoms in this covariate-adjusted model.

Adding health problems and cognitive function to the model accounted for a significant amount of variance above and beyond the variability accounted for by demographic variables alone: $R^2\Delta = .212$, $p < .001$ (Table 3, Model 2). In this model, the association between older age and fewer depressive symptoms remained significant. A number of health problems had unique associations with more depressive symptoms: neuropathy and arthritis: p's $< .05$; cardiac issues: $p < .01$; and stroke: $p < .0001$. Additionally, higher levels of cognitive function were associated with fewer depressive symptoms ($p < .01$).

In the final model, adding diabetes distress accounted for a significant amount of variance above and beyond the variability accounted for by demographic variables, health issues, and cognitive function: $R^2\Delta = .20$, $p < .001$ (Table 3, Model 3). Although diabetes distress and depressive symptoms were moderately correlated, an examination of the variance inflation factor (1.19) and tolerance (0.84) provided evidence that multicollinearity would not be a concern when interpreting the findings. Of the variables examined in the final model, stroke ($B = .20$, $p < .001$) and experiencing diabetes distress ($B = .49$, $p < .001$) had the strongest associations with depressive symptoms. The associations between neuropathy and depressive symptoms and between respiratory issues and depressive symptoms remained statistically significant. The relationship between cardiac issues and depressive symptoms was mediated by diabetes distress, and the relationship between cognition and depressive symptoms was partially mediated by diabetes distress. Individuals with cardiac issues and those with lower levels of cognitive function reported more diabetes distress, and higher levels of diabetes distress were, in turn, associated with reporting more depressive symptoms. The relationship between cardiac issues and cognitive function was reduced by 47.01% after adding diabetes distress to the model and the association

Table 3: Covariate-adjusted associations between depressive symptoms and demographics, health, and diabetes distress.

	Model 1			Model 2			Model 3		
	b	SE	*B*	*b*	SE	*B*	*b*	SE	*B*
Age	−.08	.03	−.16*	−.08	.03	−.16**	−.05	.02	−.09
Education	−.17	.08	−.16*	−.07	.08	−.07	−.04	.07	−.50
Income	−.09	.14	−.06	−.01	.12	−.01	−.05	.10	−.62
Female	−.07	.41	−.01	−.03	.38	.00	−.02	.32	−.94
Married	−.34	.44	−.06	−.35	.40	−.06	−.20	.33	−.03
Other races versus Caucasian	−.62	.95	−.04	−.57	.84	−.04	−1.35	.72	−.06
AA versus Caucasian	.45	.41	.08	.48	.39	.08	.11	.33	.02
Neuropathy				.82	.34	.14*	.47	.29	.08
Stroke				3.03	.75	.24***	2.79	.64	.22***
Respiratory issues				.65	.42	.09	.61	.35	.08
Arthritis				.87	.38	.13*	.59	.31	.09
Cardiac issues				1.06	.40	.15**	.56	.34	.08
Cognitive function				−.10	.03	−.19**	−.07	.03	−.14**
Diabetes distress							.58	.06	.49***

Notes. AA = African American; * $p < .05$, ** $p < .01$, and *** $p < .001$.

between cognitive function and depressive symptoms was reduced by 26.80%.

4. Discussion

This study was conducted to examine correlates of depressive symptoms in older adults living with diabetes. The sample consisted of older African American and Caucasian individuals diagnosed with diabetes prior to their participation in the study. The results yielded several findings that are consistent with previous literature, as well as new findings that may provide insight into potential ways to reduce depressive symptoms within the growing population of older individuals with diabetes.

It was hypothesized that individuals who reported adverse medical conditions in addition to a diabetes diagnosis would report a higher number of depressive symptoms. Results of this investigation revealed that individuals who had suffered a stroke reported substantially more depressive symptoms than those with no history of stroke. The association between stroke and depressive symptoms in older individuals with diabetes is important to discern, as previous studies indicate that many of the adverse effects of stroke are associated with elevated depressive symptoms [7, 28]. For example, stroke is one of the leading causes of permanent mobility limitation in the US, and mobility limitation has been shown to be associated with elevated depressive symptoms in older adults [29]. Stroke is also one of the leading causes of cognitive impairment. The relationship between stroke, depressive symptoms, and cognitive impairment is still unclear: many scientists are investigating whether poststroke depressive symptoms and cognitive impairment develop exclusive of one another or if there is a mutually potentiating relationship between the two. Regardless of causation, this interrelationship has important implications for older individuals with diabetes, as individuals who live with diabetes are at an increased risk of suffering both stroke and impaired cognition [9, 30, 31].

Our examination of cognitive function yielded results similar to those from the existing literature as well. It is quite common for researchers and healthcare professionals to see high levels of depressive symptoms in individuals with cognitive function impairments. Supporting a possible bidirectional relationship, high levels of depressive symptoms are also predictive of greater cognitive decline [31]. Analyses from the current study indicated that cognitive function has a significant association with depressive symptoms, where higher cognition is linked to lower depressive symptoms.

While the significant association between cognitive function and depressive symptoms is an interesting finding that should be further explored longitudinally in older adults with diabetes, the association became nonsignificant and was substantially reduced after addition of diabetes distress to the model. Thus, it is possible that worse cognitive function may be linked to depressive symptoms due to greater difficulty in managing diabetes.

The robust association between diabetes distress and depressive symptoms suggests the possibility that in this context the GDS is identifying individuals with elevated diabetes-specific distress rather than (or in addition to) symptoms of depression per se, though without the inclusion of a structured clinical interview for depression we can not confirm whether or not this is the case. The results are, however, similar to those found in Fisher and colleagues' study [19], in which it was determined that higher scores on the scale being used to measure depressive symptoms appeared to reflect diabetes-specific distress. This is an important finding regarding diabetes and depressive symptom research, as the majority of distress treatment methods are based on literature for the treatment of depression [19]. It is possible that individuals with diabetes are not receiving the appropriate type of treatment for their elevated depressive symptoms, which may appear to be similar to those seen in clinical depression but may be unique to having diabetes itself. It is also important to note that diabetes distress could potentially be modifiable, and, due to the high correlation between diabetes distress and depressive symptoms, it is feasible that these symptoms may be decreased by lowering diabetes distress.

A limitation of the current study is that much of the data were collected via self-report. However, we utilized a widely used screening measure for depressive symptoms in older adults as well as a validated performance-based measure of cognitive performance. While there were efforts to interview participants while they were in a quiet setting without distractions, this could not always be guaranteed. For any research study using telephone interviews, being distracted by something or someone nearby could affect both the participants' abilities to answer questions as accurately as possible and willingness to answer some of the questions in general. Additionally, the telephone-based interview did not allow for in-person A1C collection. Although participants were asked to indicate their latest A1C test result, a large portion of participants lacked knowledge of their result. Therefore, A1C was not used as a measure of diabetes control.

Because this study did not have access to medical records, an important question is whether self-report of diabetes is accurate. Prior studies have found that reliability of self-reported diabetes is very high compared to information from general practitioners as well as medical record data [32, 33]. In one of these studies, researchers reported that cognitive function measured with the Mini-Mental State Examination (MMSE) was not associated with poorer accuracy of reporting diabetes or other specific chronic diseases [32]. The main problem with diabetes self-reporting is with false-negatives (individuals with diabetes who do not report having diabetes) rather than false-positives [33]. However, in the current study, only individuals who reported having diabetes were included. Still, we did not have information on potentially important factors such as diabetes control or mental health history prior to diabetes diagnosis, which may be relevant to understanding depressive symptoms in older age. It should also be noted that information regarding family history of depression and comorbid substance use disorders were not gathered. Substance use disorder comorbidity, in particular, could directly affect diabetes control as well as depressive symptoms.

Due to the cross-sectional design of this analysis, it is impossible to determine causality or to investigate possible bidirectional associations between variables of interest. Lastly, results from this study are not necessarily generalizable to all individuals living with diabetes: the majority of the sample was from the greater Birmingham area in Alabama, and all participants were aware that they had diabetes. Thus, findings from this study may be generalizable only to those with knowledge of their diabetes status. Also relevant to generalizability, there was good representation of older African Americans, who are at greater risk of negative diabetes-related outcomes [34] and comprised 45% of the current sample.

5. Conclusion

The associations between adverse health issues and depressive symptoms as well as the association between poor cognitive function and depressive symptoms in older individuals with diabetes are worthy of further investigation. The findings from this study suggest that interventions targeted to help older adults properly manage their diabetes and reduce the likelihood of experiencing additional complications could possibly lead to a cost-effective option for healthcare professionals seeking the reduction of depressive symptoms. A common and low cost method for the reduction and management of distress in individuals living with diabetes seems to be education. Healthcare professionals can achieve this by providing the individual with knowledge regarding the health consequences of stress, teaching them various cognitive and behavioral skills to reduce physiological stress levels (e.g., recognition of major stressors in life, thought-stopping, and deep breathing), and educating them on better management of diabetes [35]. However, the extent to which lowered cognitive function influences the effectiveness of these educational programs in older adults with diabetes is not known.

Results from the current study may aid in the identification of older individuals living with diabetes who are at-risk for experiencing higher levels of depressive symptoms. The findings provide further evidence that having comorbid health issues may influence the presence of depressive symptoms. Given the higher rates of individuals living to older adulthood, many of whom are diagnosed with diabetes, interventions focused on diabetes distress could serve to aid a significant portion of the population in leading longer, healthier, and happier lives. These results are also important for clinicians and healthcare providers treating individuals with diabetes. These professionals should be educated about the myriad of issues and potential stressors that this population may face and how symptoms of distress and depression are manifested in order to ensure that proper treatment is given. While mood problems associated with diabetes may appear to be quite similar to those seen in clinical depression, healthcare providers and those living with diabetes alike should be aware of the possibility that these issues could be diabetes-specific and may need to be treated differently from the problems that are not unique to having diabetes. Given the interrelationship of cognitive impairment, depressive symptoms, and diabetes, further research is needed on intervention strategies for those with multiple problems in physical, cognitive, and psychological health.

Disclaimer

The content is solely the responsibility of the authors and does not necessarily represent the official views of NIA, NCATS, or the National Institutes of Health.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Research Article

Participant Experiences in the Environmental Determinants of Diabetes in the Young Study: Common Reasons for Withdrawing

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Background. To characterize participant reasons for withdrawing from a diabetes focused longitudinal clinical observational trial (TEDDY) during the first three study years. *Methods*. 8677 children were recruited into the TEDDY study. At participant withdrawal staff recorded any reason parents provided for withdrawal. Reasons were categorized into (1) family characteristics and (2) protocol reasons. Families who informed staff of their withdrawal were classified as active withdrawals (AW); families without a final contact were considered passive withdrawals (PW). *Results*. Withdrawal was highest during the first study year ($n = 1220$). Most families were AW ($n = 1549$; 73.4%). PW was more common in the United States ($n = 1001$; 37.8%) and among young mothers ($p = 0.001$). The most frequent protocol characteristic was blood draw (55%) and the most common family reason was not having enough time (66%). The blood draw was more common among female participants; being too busy was more common among males. Both reasons were associated with study satisfaction. *Conclusions*. Results suggest that, for families of children genetically at risk for diabetes, procedures that can be painful/frightening should be used with caution. Study procedures must also be considered for the demands placed on participants. Study satisfaction should be regularly assessed as an indicator of risk for withdrawal.

1. Introduction

The Environmental Determinants of Diabetes in the Young (TEDDY) study is a multicenter longitudinal clinical observational trial studying the natural history of the development of type 1 diabetes (T1DM) in children. Soon after birth, children were tested for HLA conferred genetic risk for T1DM. Children with the highest genetic risk were invited to participate in TEDDY. The purpose of the TEDDY study is to identify environmental factors that trigger autoimmunity and TIDM [1].

The success of longitudinal research studies, investigating important factors that contribute to T1DM, like TEDDY, is dependent upon study retention. It is important to investigate what study and psychosocial characteristics prompt families to leave a study in order to (1) implement possible preventive actions to increase retention and (2) design future longitudinal studies for this at-risk T1DM population in ways that enhance study retention. Although this topic is critical for the success of longitudinal trials, the extant literature is somewhat sparse. In fact, only 55% percent of pediatric trials report refusal or withdrawal reasons based on a recent literature review [2]. Previous work within more varied pediatric populations and interventional studies (e.g., T1DM, asthma, and obesity intervention trials) has suggested that a number of sociodemographic factors (e.g., older child age, minority status, and lower income) and psychological factors (e.g., greater depression and lower quality of life) were related to study withdrawal [3–6]. However, these findings from intervention studies in chronic illness populations may not be fully applicable to the TEDDY at-risk for T1DM population. Further, previous studies have tended to focus on existing characteristics of participants who do not complete a study rather than directly ascertaining reasons for withdrawal from the participants themselves.

A longitudinal study similar to the TEDDY study reported that logistical matters like blood sampling and lack of time were the reasons most often mentioned by families who withdrew [7]. In the TEDDY population, we have reported that characteristics of the study protocol, like blood draws, and family factors, like being too busy, were the primary reasons families did not join the study [8]. Study enrollment was associated with sociodemographic factors such as whether the child had a mother, father, and/or sibling with T1DM (first degree relative (FDR)), had an older mother, was a singleton, or had a sibling already enrolled in the study. Enrollment rates differed between the TEDDY countries, with a larger proportion of parents recruited from the European countries [8].

In other prior works, we identified predictors of withdrawal during the first year (up to the 15 months' visit) of TEDDY among families from the general population (GP) who had no immediate family member with T1DM [9]. Study withdrawal was more common if the mother was young, the father did not participate, or the study child was female. Also, mothers of children who withdrew were more likely to report smoking during pregnancy, abstaining from alcohol, and reducing their work hours or not working at all during pregnancy. Mothers who withdrew were also more likely to fail to complete items on study questionnaires and to underestimate their child's TIDM risk. Among mothers with accurate perceptions of their child's T1DM risk, high maternal anxiety was associated with study withdrawal [9]. This information was used to identify families at high risk for leaving the TEDDY study in the first year; these families were then provided with an intervention to promote retention [10]. While factors associated with withdrawal could be used to screen for families at risk of dropout, the effectiveness of interventions aimed at improving the retention of participants can also be influenced by the families' specific reasons for withdrawing. Thus, in this study we examined data from all families who left TEDDY (both GP and FDR) during the first three study years, including sociodemographic and psychosocial variables, and their reasons for opting out of the study.

2. Methods

2.1. TEDDY Study and Data. The TEDDY study has centers in four countries (Finland, Germany, Sweden, and the United States) and is supported by the National Institutes of Health (NIH). The study protocol includes study visits every three months from 3-4 months of age until the child is four years old and biannually thereafter. The study protocol includes blood draws, nasal swabs, height and weight measurements, and parental interviews where aspects of the child's health are recorded together with different types of life events. At regular intervals TEDDY parents fill out questionnaires with demographic questions, health histories, life events, and parents' worries and anxiety concerning the child's increased genetic risk for T1DM. Parents are also requested to complete food diaries and collect stool samples. Altogether, the TEDDY study protocol is very demanding in length and in terms of the frequency and nature of its components [1].

The collection of cord blood for screening and possible TEDDY enrollment started in September 1, 2004, and ended February 28, 2010. A total of 424,788 children were screened for increased HLA conferred genetic risk for T1DM and 21,589 were HLA eligible [11]. The enrollment rate of families with children at increased genetic risk was 38.4% from the general population (GP) and 64.8% from FDR families. The number and proportion of eligible children as well as the number of children enrolled differed both between countries and between GP and FDR families [8].

The earlier a family withdrew from the study, the fewer data points were available. For all children, demographic factors like country, gender, month of birth, FDR/GP status, and mother's age were obtained in connection with the collection of cord blood to determine eligibility for TEDDY. Data for all children enrolled in TEDDY were also available from the questionnaires that each parent completed in connection with the first TEDDY visit. These psychosocial measures contained questions on parents' views on the child's risk for developing diabetes, their worries about that possibility, and their thoughts on having the child tested for genetic T1DM risk. The mother also answered questions on lifestyle factors during pregnancy (smoking and alcohol consumption). For families withdrawing after the first study year, there were additional demographic data collected during the first year of TEDDY, including parents' education, child ethnic minority status, only child status, and household crowding. Psychosocial data were collected repeatedly starting at the 3 and 6 months' visits, at 15 months, at 27 months, and yearly. In the current study, the psychosocial data collected immediately before withdrawal were used. These data are worries (e.g., *How often do you worry that your child will get diabetes: never/very often*), anxiety (*short version of the State-Trait Anxiety Inventory* (*SAI*)) [12], depression (*Bradley's Wellbeing Scale*) [13], study satisfaction (*three correlated questions summed into a satisfaction score: Overall, how do you feel*

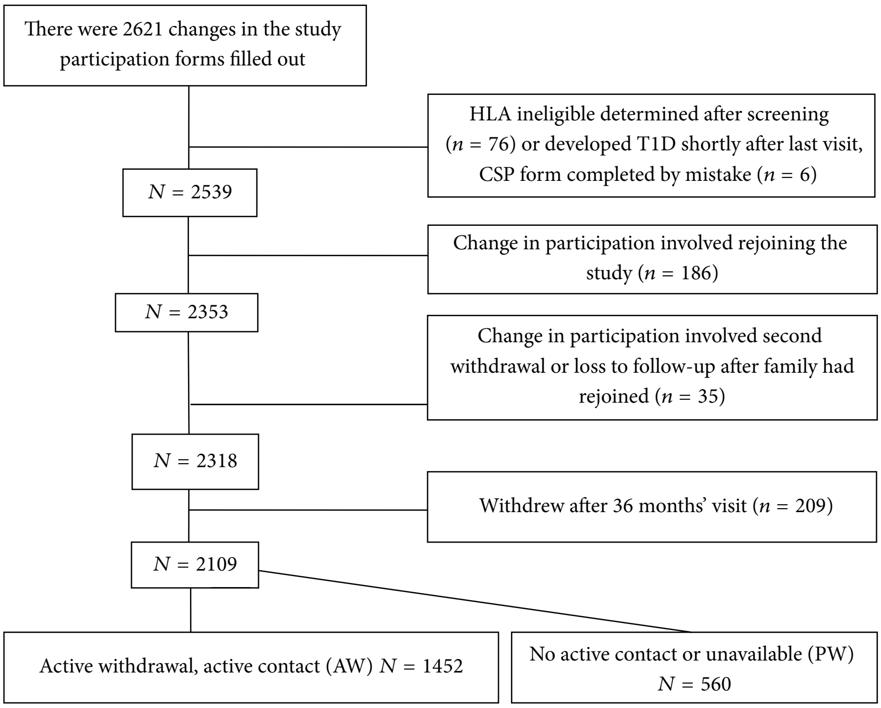

Figure 1: Study population.

about having your child participate in the TEDDY study? Do you think your child's participation in the TEDDY study was a good decision? Would you recommend the TEDDY study to a friend?), and risk perception (*Compared to other children do you think your child's risk to develop diabetes is much lower/much higher?*).

2.2. Data Collection. When a family withdrew from TEDDY, a Change in Study Participation Form (CSP Form) was filled out by TEDDY staff and any reason the parent gave for leaving the study was recorded. More than one reason could be recorded. If a family did not give a reason for leaving the study this was also noted. The last visit when any data were collected from the family was taken as the time of withdrawal even though the CSP form could be completed at a much later date. For some families, the decision to withdraw from TEDDY was difficult and could span over a long period of time with several cancelled visits and no collection of data before a final decision to leave the study. If a family did not come to the clinic for more than a year despite scheduled visits and did not contribute any data over the course of one year, the family was considered to be a Passive Withdrawal (PW) and a CSP Form was completed. Families that became unavailable and impossible to reach were also PW and were considered TEDDY withdrawals.

2.3. Statistical Analysis. Differences in frequencies between categorical groups were tested by chi-square tests. For continuous variables, differences in means were tested by independent two-sample t-tests. Multiple linear regression was used to examine the association of demographic and psychosocial variables with specific common reasons for withdrawing. Demographic variables available on all subjects were examined first and later psychosocial factors were added. Data from the last questionnaire prior to withdrawal were used to estimate maternal anxiety, risk perception, worry, and study satisfaction. If for any reason there were missing data, information was taken from the last questionnaire available. Univariate and multiple logistic regression models were used to test for significant factors associated with type of withdrawal (PW versus AW). Analyses were performed using SAS 9.2. p values less than 0.05 were considered statistically significant.

3. Results

A total of 8677 children were recruited into the TEDDY study. From September 1, 2004, until July 31, 2012, there were 2621 CSP forms filled out. CSP forms from all children who left the study on or before the 3-year visit were selected for analysis. Figure 1 gives an overview of how the study cohort was created. In all, 512 forms were excluded from the study for reasons outlined in the figure, resulting in 2109 CSP forms describing the first time withdrawal of the family from the study. Of these, 1549 forms came from families who told the staff they wanted to withdraw from TEDDY (AW); 90% gave at least one reason why they opted out. A total of 560 families (26.6%) did not respond to repeated scheduling attempts for more than a year or became impossible to contact and were withdrawn by the TEDDY staff without any further contact (PW). In Figure 2, the number of AW and PW for the different countries is shown by visit. Overall, study withdrawal was highest during the first year of the study and decreased thereafter and AW was far more common than PW. The United States had the highest frequency of PW ($n = 378$;

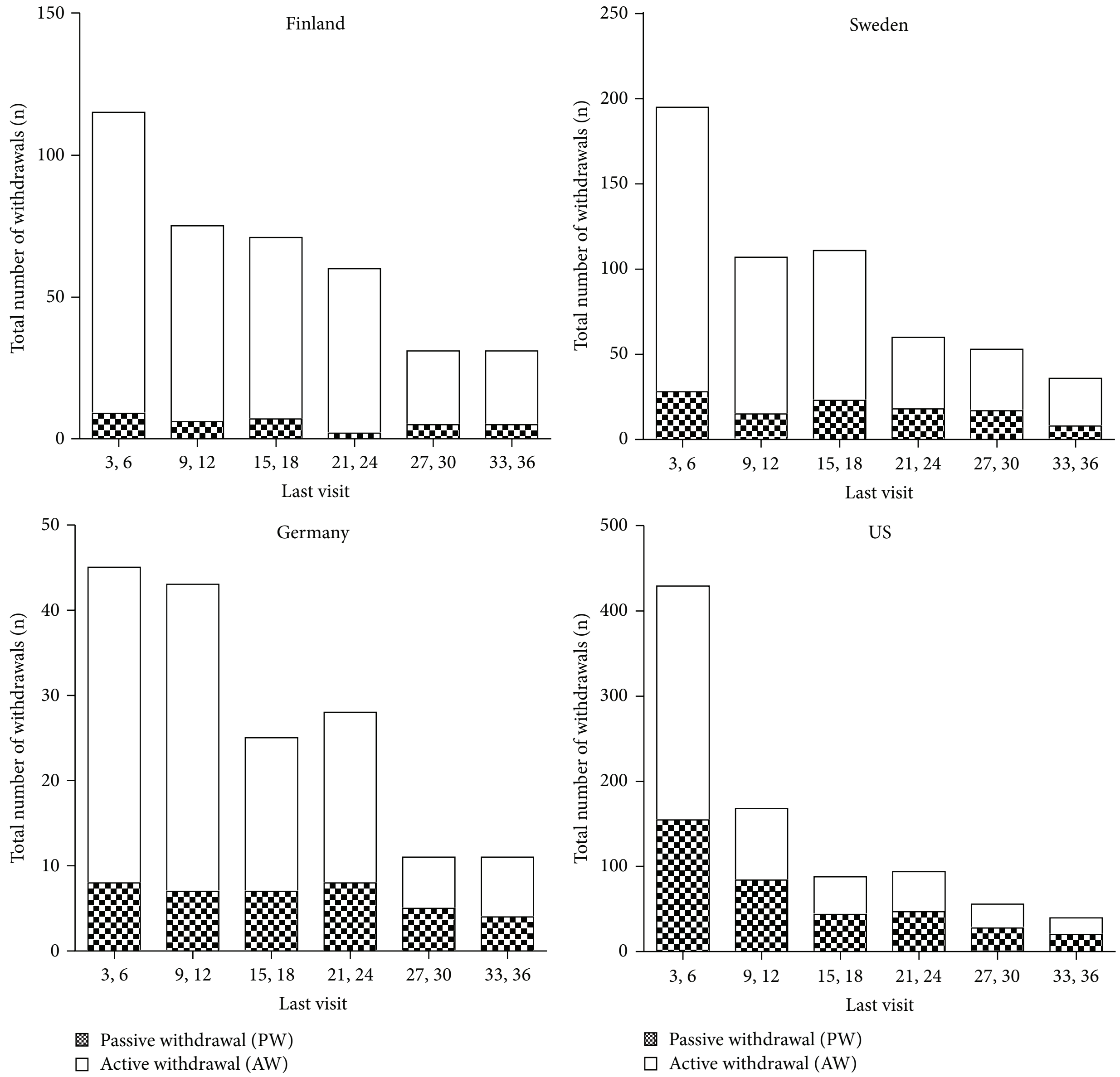

Figure 2: Number of withdrawals by age of last visit and by country divided into passive withdrawals (PW) (checked) and active withdrawals (AW) (white).

23.9%) and the relative proportion of PW increased over time. Finland had the lowest PW rate ($n = 34$; 8.9%) and it remained low across all study years. In Germany 39 children (23.9%) and in Sweden 109 children (19.0%) were classified as PW. There was a significantly increasing trend of PW proportion over the study period in Germany ($p = 0.024$) and Sweden during the three years ($p = 0.001$) even though the number of both PW and AW decreased.

Univariate and multiple regressions were used to identify factors that differentiated between AW and PW. PW were significantly more common in other countries compared to Finland, among young moms, and in older children. In the univariate models, high anxiety, maternal smoking during pregnancy, and lack of father participation in TEDDY were associated with PW. However, these factors did not remain significant in the multivariate model (Table 1).

Table 2 depicts characteristics of the AW by age of the child at the time of withdrawal. In the first half year after enrollment, 24.1% of the AW were young mothers (<25 years) which was significantly different compared to year 3 when 14.8% were young mothers. The early AW were also more anxious mothers (<0.001) and mothers more worried about their child developing diabetes ($p = 0.003$) compared to those remaining in the study. There were no significant associations between the accuracy of the mother's T1DM risk perception or study satisfaction and the child's age at withdrawal.

The frequencies of different reasons reported by the AW distributed over visits during the three study years are shown

Table 1: Factors associated with passive withdrawal (PW) versus active withdrawal (AW).

Factors[a]	Number mean (SD)	Univariate				Multivariate		
		% of PW	OR	95% CI	*p* value	OR	95% CI	*p* value
Country of residence								
Finland	383	8.9	1.00	Ref.		1.00	Ref.	
Sweden	562	19.4	2.47	1.64–3.72		2.86	1.85–4.44	
Germany	163	23.9	3.22	1.95–5.34		3.73	2.16–6.43	
US	1001	37.8	4.28	3.26–9.06	<0.001	6.57	4.35–9.93	<0.0011
Maternal age at child's birth (years)								
Years	28.9 (5.7)		0.94	0.93–0.96	<0.001	0.95	0.93–0.97	<0.001
<29 years	1016	32.0						
≥29 years	1093	21.5						
Child's age of withdrawal (years)								
Years	1.16 (0.80)		1.12	0.99–1.25	0.08	1.33	1.16–1.52	<0.001
<1.16 years	1231	25.8						
≥1.16 years	878	27.6						
Gender								
Female	1094	25.9	1.00	Ref.		1.00	Ref.	
Male	1015	27.3	1.08	0.88–1.31	0.46	1.10	0.88–1.36	0.40
FDR[a]								
No	1957	26.8	1.00	Ref.		1.00	Ref.	
Yes	152	23.7	0.85	0.57–1.25	0.41	0.95	0.62–1.47	0.81
Smoking during pregnancy								
No	1556	25.2	1.00	Ref.		1.00	Ref.	
Yes	415	30.4	1.30	1.02–1.64	0.03	1.31	1.00–1.72	0.05
Alcohol 3rd trimester								
No	1713	26.1	1.00	Ref.		1.00	Ref.	
Yes	289	27.3	1.07	0.81–1.41	0.66	1.16	0.85–1.60	0.35
Worked during pregnancy								
No or reduced hours	1184	26.6	1.00	Ref.		1.00	Ref.	
Yes or increased hours	819	25.8	0.96	0.78–1.17	0.67	0.92	0.74–1.15	0.45
High anxiety (SAI > 48)								
Score	40.9 (10.7)		1.02	1.01–1.03	<0.001	1.00	0.99–1.01	0.80
<40.9 score	1059	22.6						
≥40.9 score	921	29.4						
Risk perception								
Underestimate	901	27.3	1.00	Ref.		1.00	Ref.	
Accurate	1097	25.2	0.90	0.73–1.09	0.28	0.99	0.80–1.23	0.93
Father not active (3 mo)[b]								
No	1807	25.0	1.00	Ref.		1.00	Ref.	
Yes	302	36.1	1.70	1.31–2.20	<0.001	1.27	0.90–1.78	0.17

[a] FDR = first degree relative has type 1 diabetes. [b] Father did not answer 3-month questionnaires.

Table 2: Active withdrawals by child's age of withdrawal and demographic factors, maternal psychosocial factors, and maternal study satisfaction.

Factors	All 3–36 m (*N*)	Year 1 3–6 m *N* (row %) or mean (SD)	Year 1 9–12 m *N* (row %) or mean (SD)	Year 2 15–24 m *N* (row %) or mean (SD)	Year 3 27–36 m *N* (row %) or mean (SD)	p value
Number of active withdrawals	1549	584 (37.7)	324 (20.9)	431 (27.8)	210 (13.6)	
Country of residence						
Finland	349	106 (30.4)	69 (19.8)	122 (35.0)	52 (14.9)	
Sweden	453	167 (36.9)	92 (20.3)	130 (28.7)	64 (14.1)	
Germany	124	37 (29.8)	36 (29.0)	38 (30.6)	13 (10.5)	
US	623	274 (44.0)	127 (20.4)	141 (22.6)	81 (13.0)	<0.001
Gender						
Female	811	323 (39.8)	159 (19.6)	232 (28.6)	97 (12.0)	
Male	738	261 (35.4)	165 (22.4)	199 (27.0)	113 (15.3)	0.07
First degree relative with T1D						
No	1433	534 (37.3)	302 (21.1)	406 (28.3)	91 (13.3)	
Yes	116	50 (43.1)	22 (19.0)	25 (21.6)	19 (16.4)	0.30
Maternal age at child's birth						
years	29.4 (5.6)	28.9 (5.8)	29.0 (5.2)	29.6 (5.5)	30.9 (5.5)	<0.001
Highly anxious at last visit (SAI > 48)[a]						
No	1241	413 (33.3)	259 (20.9)	375 (30.5)	191 (15.4)	
Yes	229	116 (50.7)	55 (24.0)	45 (19.7)	13 (5.7)	<0.001
Worry about diabetes at last visit[a,b]						
Never or rarely	706	104 (14.7)	166 (23.5)	290 (41.4)	144 (20.4)	
Sometimes or very often	344	56 (16.3)	114 (33.1)	113 (33.4)	59 (17.2)	0.004
Risk perception at last visit[a]						
Underestimate	692	247 (35.7)	147 (21.2)	207 (30.1)	90 (13.0)	
Accurate	783	283 (36.1)	170 (21.7)	213 (27.5)	115 (14.7)	0.63
Study satisfaction at last visit[a,b]						
Very satisfied	276	38 (13.8)	77 (27.9)	108 (39.1)	53 (19.2)	
Satisfied	289	44 (15.2)	87 (30.1)	99 (34.3)	59 (20.4)	
Somewhat satisfied	274	39 (14.2)	71 (25.9)	115 (42.0)	49 (17.9)	
Neutral or dissatisfied	208	38 (18.3)	44 (21.2)	84 (40.4)	42 (20.2)	0.47

[a] If no measure last visit, the second to last visit is taken if available.

[b] Study satisfaction and worry about diabetes are not asked in the first questionnaires so there are fewer available answers at 3 and 6 months.

in Table 3. The different reasons are grouped into "protocol characteristics" or "family factors." The two reasons most frequently given for leaving TEDDY were concerns about the blood draw ($n = 359$; 55% of all protocol characteristics) and being too busy/not having enough time ($n = 587$; 66.6% of all family factors). Other frequently mentioned protocol characteristics included the following: the protocol is too demanding, transportation difficulties, and the frequency of visits. Among the family factors, feeling overwhelmed/being too stressed is the second most common reason given ($n = 206$, 23.4%). Having concerns about the blood draw was more often mentioned for older children ($p = 0.039$), not wanting to be reminded of the child's risk was significantly more often reported as a reason for withdrawal during the first visits ($p = 0.003$), and being too busy/not having enough time was more often reported in the later visits ($p = 0.037$). During the study period, 11% ($n = 97$) of the families cited moving out of the area as a reason for opting out. A total of 165 families (10.7%) did not want to give a reason for leaving or only wanted to wait and see what might happen.

The result of multiple regressions examining demographic factors in all AW subjects for the two most often mentioned reasons for withdrawal (concerns about blood draw and being too busy) is presented in Table 4. German and US mothers were more likely to report the blood draw as the reason for leaving TEDDY compared to Finland and Sweden. Also, the blood draw was mentioned more often as the child got older and if the child was a girl. Being too busy was given as the reason for leaving TEDDY most often among Swedish mothers and least often among German mothers. This reason was more common in families with an older TEDDY child and if the child was a boy.

Table 3: Frequency of common reasons for withdrawing from the TEDDY study during the first three study years. Percentages for reasons mentioned more frequently are shown.

Withdrawals	Last visit before withdrawal (month)					
	Year 1	Year 1	Year 2	Year 3	All	
	3–6 m	9–12 m	15–24 m	27–36 m	3–36 m	
	N (row %)	*N* (row %)	*N* (row %)	*N* (row %)	*N*	%
Active withdrawals (AW)	**584 (37.7)**	**324 (20.9)**	**431 (27.8)**	**210 (13.6)**	**1549**	**73.4**
Reasons for withdrawal						
Protocol characteristics	**244 (37.4)**	**128 (19.6)**	**195 (29.9)**	**86 (13.2)**	**653**	**100**
Concerns about blood draw	124 (34.5)	63 (17.5)	112 (31.2)	60 (16.7)	359	55.0[a]
Protocol too demanding	68 (40.0)	41 (24.1)	43 (25.3)	18 (10.6)	170	26.0[a]
Transportation difficulties	44 (41.1)	21 (19.6)	35 (32.7)	7 (6.5)	107	16.4
Concerns about frequency of visits	40 (39.2)	20 (19.6)	33 (32.4)	9 (8.8)	102	15.6
Concerns about stool samples	14	9	13	7	43	6.6
Concerns about questionnaires	15	8	10	4	37	5.7
Food diaries too troublesome	12	1	2	1	34	5.2
Do not want to be reminded of risk	19	6	5	1	31	4.7
Duration of study is too long	1	3	5	1	10	1.5
No treatment to prevent offered	3	1	2	1	7	1.1
Worried about privacy	1	1	0	0	2	—
Worried about loss of insurance	3	0	0	0	3	—
Other protocol characteristics	2	3	5	2	12	1.8
Family factors	**279 (35.6)**	**162 (20.7)**	**231 (29.5)**	**112 (14.3)**	**784**	**100**
Too busy/not enough time	187 (31.9)	134 (22.8)	185 (31.5)	81 (13.8)	587	66.6[a]
Feeling overwhelmed/stressed	82 (39.8)	40 (19.4)	58 (28.2)	26 (12.6)	206	23.4
Moving out of the study area	33 (30.4)	23 (23.7)	22 (22.7)	19 (19.6)	97	11.0
Child medical/behavioral problems	29 (40.3)	16 (22.2)	16 (22.7)	11 (19.6)	72	8.2
Family member emotional problems	15	9	18	10	52	5.9
Does not want to be in research	9	3	8	5	25	2.8
Family member does not agree to participate	8	0	5	4	17	1.9
Family member in another study	1	0	2	0	3	—
Subject already in another study	0	1	0	0	1	—
Fam. health care provider not recommended	1	0	0	0	1	—
Language barrier	1	0	0	0	1	—
Other family factors	4	2	4	3	13	1.5
Active contact made but no reason given or wants to wait and see	**70 (42.4)**	**28 (17.0)**	**42 (25.4)**	**25 (15.2)**	**165**	**10.7**

[a] Significant difference between age groups: concerns about blood draw ($p = 0.039$), do not want to be reminded of risk ($p = 0.003$), and too busy/not enough time ($p = 0.037$).

Maternal smoking during pregnancy, mother working during pregnancy, maternal alcohol consumption during pregnancy, father participation in TEDDY, and whether the TEDDY child was a FDR or from the GP were not associated with either reason for leaving TEDDY.

In Table 5, two logistic regressions explore maternal psychosocial factors in relation to the two most frequently mentioned factors for withdrawing, concerns about blood draw and being too busy. The regressions are adjusted for country of residence, maternal age, age of child at study withdrawal, and gender. The results show that concerns about blood draw were associated with the mother's study satisfaction both at 6 months and at the last visit before withdrawal. At both 6 months and the last visit, mothers

Table 4: Multiple logistic regression examining demographic factors in relation to (a) concerns about blood or (b) being too busy as a reason for withdrawing among those who actively withdrew.

Factors at enrollment	Demographic measures in relation to concerns about blood draw and being too busy (n = 1549)					
	(a) Concerns about blood draw			(b) Being too busy		
	OR	95% CI	p value	OR	95% CI	p value
Country of residence						
Finland	1.00	Ref.		1.00	Ref.	
Sweden	1.33	0.91–1.93		1.47	1.10–1.96	
US	1.72	1.21–2.43		0.83	0.63–1.09	
Germany	7.80	4.89–12.4	<0.001	0.48	0.30–0.77	<0.001
Maternal age at child's birth (yrs)						
Years	1.05	1.02–1.07	<0.001	1.00	0.98–1.01	0.62
Child's age of withdrawal (months)						
Months	1.20	1.03–1.40	0.02	1.15	1.01–1.31	0.04
Gender						
Male	1.00	Ref.		1.00	Ref.	
Female	1.44	1.12–1.85	0.004	0.78	0.63–0.96	0.02

Note: FDR/GP status, smoking during pregnancy, working during pregnancy, alcohol consumption during pregnancy, and dad's participation in TEDDY were not associated with either concerns about blood draw or being too busy.

who reported less satisfaction with TEDDY were more likely to report concerns about the blood draw as the reason for leaving TEDDY. The relationship between study satisfaction and mothers' report of being too busy as the reason to leave TEDDY was less clear. No other psychosocial factors (maternal anxiety or mother's risk perception) showed an association with the two most common reasons for leaving the TEDDY study.

4. Discussion

The TEDDY study, which seeks to identify factors associated with the development of T1DM, has a demanding protocol for both the children and their parents. The study is also longitudinal with four visits to a TEDDY clinic each year until the child is four years of age and biannually thereafter until the child is fifteen years of age. After 8 years, 72.2% of the recruited children are still participating in the study. The majority of families who left gave a reason for leaving. PW was more common among the US participants. Being a large country with a diverse population, it is more difficult to track people compared to the European countries. We previously reported that U.S. families often failed to respond to phone messages or letters inviting them to join TEDDY [8], constituting passive refusal, which is similar to PW.

Finland had the lowest number of PW and similar numbers over the years, while the proportion of PW in Germany and Sweden tended to increase during the three study years even though the total number of withdrawals decreased significantly. Some study sites may keep a TEDDY participant as "active" in TEDDY despite multiple missed visits. After getting to know TEDDY staff over many months some families may have difficulty directly telling staff that they are leaving the study and may instead just "no-show." Differences between study centers in how families are managed might develop over time and this is a weakness of the current results reported. However, it is difficult for a large study like TEDDY to systematically define how staff uniformly manage study families over many years.

Sociodemographic factors also related to study withdrawal. PW mothers were younger and more likely to smoke during pregnancy than those retained in the study. In the univariate analysis, lack of father participation in TEDDY was associated with PW but this effect was not statistically significant in the multivariate model. In previous work, we found that lack of father participation was an important predictor of study withdrawal in the first year of TEDDY [9]. Father involvement in a study may be a more important determinant of whether a family stays in a study or withdraws; it may not predict whether the withdrawal is active or passive.

Logistical aspects of the study were found to be common reasons for withdrawal. Even though TEDDY staff is very skilled, drawing blood from a small child can be very challenging and cause unpleasant experiences both for the child and the parent. Other studies have reported that blood draws can be an obstacle for study participation and a reason for opting out [7]. Reporting the blood draw as a reason for leaving TEDDY was more common later in the study than in the early phase. All blood draws are done after application of dermal anesthetics so a baby might react less than a slightly older child who might have learned to fear the blood draw. This observation has been verified by Swedish TEDDY nurses who conducted a parent survey of the child's reaction to the blood draw. In fact, parents tended to rate stronger reactions in older children (personal communication).

Being too busy and not having time to do the TEDDY tasks was the most frequently mentioned reason for leaving the study. Being stressed and feeling overwhelmed was

Table 5: Logistic regression examining maternal psychosocial factors in relation to (a) concerns about blood draw or (b) being too busy as a reason for withdrawing after adjusting for country of residence, maternal age, child's age at withdrawal, and gender (see Table 4).

Psychosocial factors	Psychosocial measures in relation to concerns about blood and being too busy after adjusting for demographic factors ($n \sim 1031$)					
	(a) Concerns about blood draw			(b) Being too busy		
	OR	95% CI	*p* value	OR	95% CI	*p* value
Maternal high anxiety (SAI > 48)						
Score	1.00	0.98–1.01	0.42	0.99	0.98–1.00	0.09
Mother's risk perception						
Underestimate	1.00	Ref.		1.00	Ref.	
Accurate	1.01	0.74–1.38	0.95	0.91	0.70–1.18	0.49
Study satisfaction (6 mo)						
Very satisfied	1.00	Ref.		1.00	Ref.	
Satisfied	1.38	0.89–2.15		1.24	0.88–1.74	
Somewhat satisfied	1.80	1.16–2.78		1.80	1.27–2.59	
Neutral or dissatisfied	2.73	1.68–4.42	<0.001	1.11	0.73–1.69	0.007
Study satisfaction (last visit)						
Very satisfied	1.00	Ref.		1.00	Ref.	
Satisfied	1.57	0.99–2.49		1.19	0.84–1.69	
Somewhat satisfied	2.54	1.61–4.03		1.43	1.00–2.05	
Neutral or dissatisfied	2.64	1.62–4.31	<0.001	1.33	0.89–1.97	0.252

another important reason for not participating anymore. Being busy was significantly more often mentioned as a reason for withdrawal at the later study visits. It may be that when a baby is born, the mother is often home caring for the baby and may not experience the TEDDY tasks as burdensome, compared to later when she may return to work. Also, some TEDDY tasks are easier to complete when the child is a baby like collecting stool samples or doing a 3-day food diary. Also, being in the beginning of a study may give participants a feeling of curiosity and enthusiasm, something that may disappear as the study seems less novel to families.

Psychological reasons also played a role in withdrawal for some families, particularly early in the study. Mothers in families who withdrew early, after the first or second TEDDY visit, appeared to be more anxious and worried about their child getting diabetes compared to mothers in families leaving the study at 9 months or later. This is underscored by the observation that mothers who reported that they did not want to be reminded of the child's risk of T1DM as a reason for withdrawal often left TEDDY after the first two visits.

The two most important factors mentioned as reasons for withdrawal (blood draw and being too busy) were each analyzed in separate regression models, first in relation to demographic factors and in a second model in relation to maternal psychological factors and study satisfaction. Reporting the blood draw as a reason for withdrawal was more common if the child was a girl while stating that the family was too busy to participate was more common if the child was a boy. A study on infant pain response following immunization injection demonstrated that parental behavior has a key role in influencing how infants respond to painful procedures with differences between female and male infants [14]. We can only speculate that parents may be more sensitive to the possible discomfort of the blood draw in girls than in boys; boys are often expected to be braver than girls. Another study found that girls' pain threshold is lower than that of boys, at least for slightly older children compared to the TEDDY children in our study [15]. This could indicate that the reaction of girls to the blood draw might be stronger than that of the boys and therefore the parents might be more prone to opt out when the child is a girl even when the child is younger.

Why being too busy was more often mentioned when the child was a boy is harder to explain. Sometimes boys are more physically active and this may create more problems for parents in collecting TEDDY samples and data in preparation for the visit. It may also mean that boys are more likely to openly protest going to the TEDDY clinic. All this taken together might give parents a feeling of not having time and being too busy. In the current study, parents who gave the blood draw as a reason for leaving often expressed lower satisfaction with the study both at 6 months, when this was first assessed in TEDDY, and in the survey completed before opting out. It is likely that difficulties with the blood draw were seen early in the study, sometimes continued, and resulted in lower satisfaction with the TEDDY experience and ultimately withdrawal from the study.

In a prior study exploring reasons of why parents stay in TEDDY, having someone watching the child for development of T1DM was the most often mentioned reason. Among the minority of parents who had considered leaving the study, the blood draw, being too busy/not having enough time, a demanding protocol, and food diaries were the most frequently reported reasons for considering leaving [16].

These results are in line with what was found in the present study.

In this study, reasons for withdrawal were obtained by the TEDDY staff via interview when the parents decided to leave TEDDY, while our prior published work collected this information by questionnaire [16]. Therefore, the method of obtaining this data does not seem to be important as the results were similar. What is lacking is a more in-depth explanation of why parents are too busy and do not have time to remain in TEDDY. Retention and compliance in a longitudinal study like TEDDY are critical for the success of the study so detailed information about why families leave is important for developing strategies for improving study retention.

5. Conclusion

Results from this study suggest some significant factors that should be taken into account to counteract opting out in longitudinal studies focusing on a population at genetic risk for T1DM like TEDDY. Psychological factors clearly play a role in early withdrawal and thus early in the study it is important to record and pay attention to parents' anxieties and worries and to implement procedures that may reduce or address these challenges. Also, young mothers, particularly if the father is not fully present, are at early risk for leaving the study and may need extra attention. Procedures that can be experienced as painful and frightening, like a venous blood draw, need to be used with great caution and all ways to facilitate obtaining the specimen need to be considered. It is important for researchers to carefully think through all components in the study that might increase the demands on the participants and it is important to avoid overburdening families, which may increase the risk of withdrawal. Regular investigations of the subjects' satisfaction with the study can give important information on how the study subjects are experiencing their participation and can predict withdrawal.

Appendix

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Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Research Article

Demographical, Clinical, and Psychological Characteristics of Users and Nonusers of an Online Platform for T2DM Patients (e-VitaDM-3/ZODIAC-44)

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Background. Online platforms offer opportunities for support in changing lifestyle and taking responsibility for one's health, but engaging patients with type 2 diabetes is challenging. Previous studies have shown that patients interested in platforms were more often male, younger, and higher educated. This study aims to investigate differences in clinical and psychological characteristics between users and nonusers of a newly developed platform. *Methods*. A prospective study started in the Drenthe region of Netherlands. Participants in the study concerning quality of care and quality of life were additionally invited to use the platform. *Results*. 633 patients were registered after they opted for platform use. Of these patients, 361 (57.0%) never logged on, 184 (29.1%) were labeled "curious" users, and 88 (13.9%) were identified as "active" users. Users had lower HbA1c levels and more often hypertension compared to nonusers, and reported higher quality of life, better well-being, lower diabetes-related distress, and better medication adherence. *Discussion*. Platform use was associated with more favorable clinical and psychological characteristics relative to nonuse. Those with greater severity of disease, lower mood, and progression of disease used the platform the least. Other approaches need to be developed to reach these patients. Furthermore, improving the platform could also help to reach them. This trial is registered with Clinicaltrials.gov NCT01570140.

1. Background

Type 2 diabetes mellitus (T2DM) in itself is associated with poorer health-related quality of life (HRQoL) [1]. People with T2DM are susceptible to develop long term complications, such as retinopathy, neuropathy, nephropathy, and chronic heart disease, which negatively influence HRQoL [2]. To prevent or delay development of these long term complications, adequate treatment modalities are necessary which mainly involve lifestyle changes and pharmacological treatment. Adherence to medication prescription and implementing life style changes are often better maintained and facilitated, when patients consider themselves more responsible for their treatment and have more knowledge regarding the causes and consequences of their disease. Improvements in knowledge about their disease can be described as promotion of health literacy. e-Health applications, such as web-portals, teleconsultation, and online care platforms, have the potential to support patients in changing lifestyle and taking more responsibility for their own health [3]. However, varying

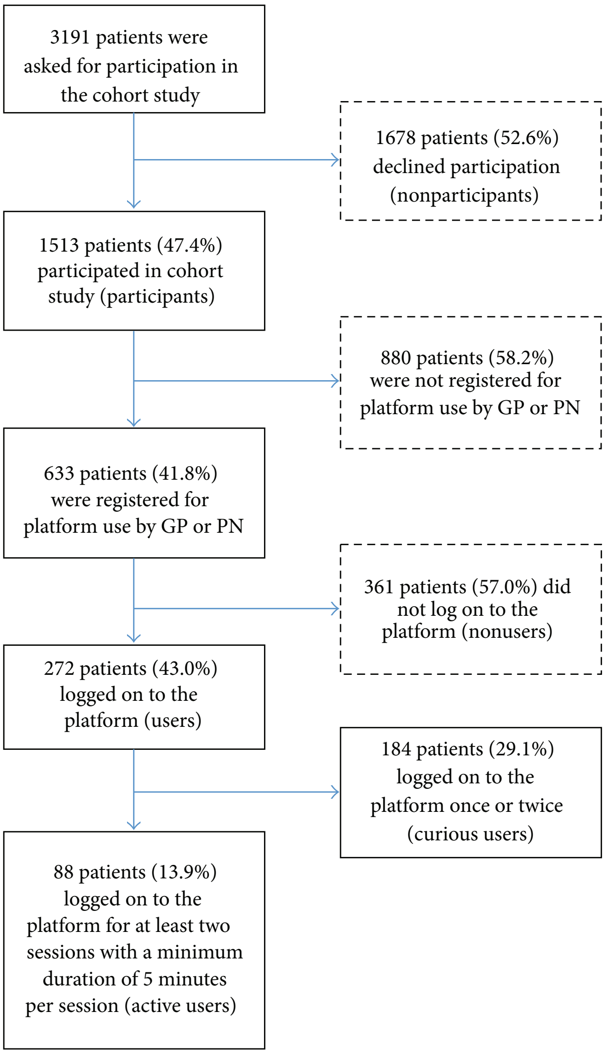

Figure 1: Flowchart of patients and definitions.

effects on clinical outcomes, quality of life, degree of self-care, perceived stress levels, patient satisfaction, and costs have been reported [4–10].

Previous studies showed that patients who were interested in using an online care platform were more often male, younger, and higher educated [11, 12]. However, within the subgroup of interested patients these differences were not found between actual users and nonusers [11]. In addition, other factors associated with higher portal enrollment and utilization are higher income, nonblack race, higher self-efficacy, and having better regulated diabetes [13]. Identifying the differences between platform users and nonusers could provide information to help target and support nonusers in becoming more active in their diabetes self-management.

The aim of the present, explorative study was to investigate possible differences in demographic, clinical, and psychological characteristics between users and nonusers of the platform e-Vita.

2. Methods

2.1. Study Design. We performed a cross-sectional analysis of baseline data of users and nonusers of the online patient platform e-Vita. Data was obtained from a prospective observational cohort study. Detailed information about the methods and design of the study as a whole can be found elsewhere [14].

2.2. Study Population and Setting. Forty-three out of 110 general practices in the Drenthe region of the Netherlands invited their T2DM patients for participation in a prospective observational cohort study concerning quality of care and HRQoL. Patients were also invited to use the online care platform e-Vita, in addition to their usual treatment. Patients interested in using the platform were registered by their practice nurse (PN) and received a user ID. In this ongoing study, participants were recruited from May 2012 onward.

Table 1: Differences and notable characteristics of nonusers, curious users, and active users.

n (%) or mean (SD) Demographic and clinical parameters	Nonusers (*n* = 361)	Missing	Curious users (*n* = 184)	Missing	Active users (*n* = 88)	Missing	Univariate *p* value
Men	214 (59.3)	0 (0)	113 (61.4)	0 (0)	50 (56.8)	0 (0)	0.760
Age in years	62.1 ± 9.5 63.0 (56.5–68.0)	0 (0)	61.8 ± 9.5 62.0 (56.3–68.0)	0 (0)	62.0 ± 9.4 63.0 (57.0–67.0)	0 (0)	0.935
Ethnicity							
Caucasian	292 (99.0)	66 (18.3)	143 (100)	41 (22.3)	65 (100)	23 (6.1)	0.706
Other	3 (1.0)		0 (0)		0 (0)		0.382
Employment							
Fulltime/part-time working	99 (34.3)	72 (19.9)	61 (39.6)	30 (16.3)	20 (23.8)	4 (4.5)	0.063
Retired	134 (46.4)		70 (45.5)		46 (54.8)		
Unemployed/housekeeper	38 (13.1)		20 (13.0)		9 (10.7)		
Incapacitated	18 (6.2)		3 (1.9)		9 (10.7)		
Educational level							
None	0 (0)	73 (20.2)	1 (0.7)	31 (16.8)	0 (0)	4 (4.5)	0.125
Primary school	24 (8.3)		9 (5.9)		4 (4.8)		
Low	127 (44.1)		52 (34.0)		27 (32.1)		
Intermediate	86 (29.9)		51 (33.3)		30 (35.7)		
High	51 (17.7)		40 (26.1)		23 (27.4)		
T2DM duration in years	6.2 ± 4.6 6.0 (2.0–9.0)	9 (2.5)	5.7 ± 4.4 5.0 (2.0–8.0)	1 (0.5)	5.4 ± 4.4 4.5 (2.0–8.0)	0 (0)	0.165
HbA1c in mmol/mol	50.6 ± 9.5 50.0 (45.0–54.0)	3 (0.8)	48.7 ± 7.4 48.0 (43.0–54.0)	0 (0)	47.0 ± 7.0 46.0 (43.0–50.8)	0 (0)	**0.001**
BMI	29.8 ± 4.9 29.0 (26.5–32.5)	3 (0.8)	30.0 ± 4.8 29.3 (26.9–32.3)	0 (0)	29.9 ± 8.0 28.0 (26.0–32.6)	2 (2.3)	0.921
Comorbidities/complications							
Hypertension	191 (84.1)	134 (37.1)	113 (93.4)	63 (34.2)	51 (92.7)	33 (37.5)	**0.025**
Items of Europep: patients who scored 4 (good) to 5 (excellent)							
What is your assessment of the general practitioner over the last 12 months with respect to the following?							
Making it easy for you to tell him or her about your problem	345 (93.5)	18 (4.7)	187 (97.9)	17 (8.2)	84 (93.3)	2 (2.2)	**0.047**
EQ-5D index-score	0.9 ± 0.2	72 (19.9)	0.9 ± 0.1	32 (17.4)	0.9 ± 0.2	4 (4.5)	**0.030**
EQ-VAS	74.7 ± 17.4 80.0 (60.0–90.0)	74 (20.5)	79.3 ± 13.8 80.0 (73.0–90.0)	35 (19.0)	76.9 ± 16.5 80.0 (0.0–90.0)	5 (5.7)	**0.032**
WHO-5 score indicates suboptimal well-being, screening depression advised	36 (12.6)	76 (21.1)	8 (5.3)	33 (17.9)	9 (10.8)	1 (1.1)	**0.018**
WHO-5 answers advise screening depression	43 (15.5)	76 (21.1)	6 (4.0)	33 (17.9)	11 (13.3)	1 (1.1)	**0.002**
PAID-5 total score	2.8 ± 3.1 2.0 (0.0–4.5)	76 (21.1)	1.8 ± 2.4 1.0 (0.0–3.0)	32 (17.4)	2.2 ± 2.5 1.0 (0.0–4.0)	1 (1.1)	**0.016**
SDSCA							
Medication in number of days	6.7 ± 1.0 7.0 (7.0–7.0)	73 (20.2)	7.0 ± 0.2 7.0 (7.0–7.0)	30 (16.3)	6.8 ± 0.8 7.0 (7.0–7.0)	4 (4.5)	**0.020**

Table 2: Cronbach's alpha for multi-item scales.

Multi-item scale	α
Europep	
Total	0.963
Subscale general practice	0.966
Subscale general practitioner	0.840
EQ-5D	0.652
WHO-5	0.872
PAID-5	0.867
SDSCA	
Total	0.517
Subscale general diet	0.875
Subscale specific diet	0[1]
Subscale total diet	0.446[2]
Subscale exercise	0.663
Subscale blood-glucose testing	0.912
Subscale foot-care	0.593

[1] Because of the negative intercorrelation between the two items Cronbach's alpha is reported to be 0.

[2] The alpha for the subscale total diet is lower than that for the subscale general diet due to the low reliability of the subscale specific diet.

The current analysis includes patients recruited from May 2012 till March 2014.

2.3. Measurements. Demographic and clinical data were obtained from the personal health record systems of the general practitioners (GP), based on a core dataset of T2DM related information as advised by the Dutch Diabetes Federation and the Dutch College of General Practitioners [14]. All T2DM patients participating in the study filled in a range of validated questionnaires concerning perceived quality of life measured by the EuroQol Five Dimension (EQ-5D) Scale [15–17], emotional well-being measured by the World Health Organization Wellbeing Index 5-Item (WHO-5) questionnaire [18, 19], diabetes-related distress measured by the Problem Areas in Diabetes 5-Item (PAID-5) questionnaire [20], diabetes self-care behavior measured by 7 Dimensions of the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire [21], and quality of received care measured by the Europep [22]. Suboptimal emotional well-being was defined by a raw score lower than 13 on the WHO-5 [23]. Additional questions about smoking habits, employment, and educational background were also included. To identify users and nonusers, registration data from the application software and log-files were used.

2.4. Description of e-Vita Platform. The e-Vita platform for T2DM patients (accessible through the login button on https://www.e-vita.nl/) [11, 14, 24] contains the following components: (1) an overview of health data concerning annual check-ups from 2009 onward, (2) educational modules meant to support care through self-management by setting person-specific goals and actions [25], (3) prompting patient self-monitoring of clinical values, (4) educational modules aimed at increasing diabetes knowledge, and (5) providing reliable information on T2DM in general.

2.5. Users and Nonusers. Information about login status and log-data were used to group patients into nonusers and users. All patients who logged in at least once were considered as users. Patients who had been online for at least two sessions with a minimum of five minutes per session were defined as "active" users; other patients were defined as "curious" users. A session included all logins to the platform within thirty minutes [24].

2.6. Statistical Analyses. Statistical analyses were performed using SPSS version 20 (IBM Corporation, Somers, NY, USA). Quantitative variables are described in means and standard deviations when normally distributed; otherwise medians and interquartile ranges are also described. Categorical variables are described in numbers and percentages. To identify differences in the domains of interest between the different groups of users, the Linear Mixed Models procedure was used, with groups of users being fixed factors (nonusers being the reference group), while adjusting for age and sex. Fisher's exact test was used for categorical data. Differences were considered to be significant at a p value of <0.05. In addition, results are adjusted for age and gender. Because of the explorative design of this study, no corrections for multiple testing were made [26]. Instead, the calculated p values are only used as an indication of to what extent a difference could be interesting for further research.

2.7. Ethics. This study was approved by the Medical Ethical Review Committee of Isala, Zwolle, the Netherlands, and registered in Clinicaltrials.gov under number NCT01570140.

3. Results

In the period from May 2012 to March 2014, 3191 patients were invited to participate in the cohort study and to use the e-Vita

Table 3: Results of multivariate analysis, adjusted for age and gender.

	b-coefficient	95% CI		*p* value
		Lower bound	Upper bound	
T2DM duration in years				
Intercept	0.018	−2.325	2.360	0.988
Platform use				0.186
Active users	−0.845	−1.876	0.186	0.108
Curious users	−0.511	−1.300	0.277	0.203
Nonusers	Ref. Cat.			
Male	−0.121	−0.832	0.589	0.738
Female	Ref. Cat.			
Age	0.101	0.064	0.138	<0.0005
HbA1c in mmol/mol				
Intercept	53.431	48.931	57.931	<0.0005
Platform use				<0.0005
Active users	−3.624	−5.627	−1.621	<**0.0005**
Curious users	−1.989	−3.516	−0.462	**0.011**
Nonusers	Ref. Cat.			
Male	1.103	−0.270	2.477	0.115
Female	Ref. Cat.			
Age	−0.055	−0.127	0.016	0.126
BMI				
Intercept	37.430	34.658	40.202	<0.0005
Platform use				0.924
Active users	0.079	−1.159	1.317	0.900
Curious users	0.189	−0.747	1.124	0.692
Nonusers	Ref. Cat.			
Male	−1.087	−1.931	−0.244	0.012
Female	Ref. Cat.			
Age	−0.113	−0.156	−0.069	<0.0005
EQ-5D				
Intercept	0.866	0.773	0.958	<0.0005
Platform use				0.022
Active users	0.008	−0.031	0.047	0.674
Curious users	0.044	0.013	0.076	**0.006**
Nonusers	Ref. Cat.			
Male	0.056	0.027	0.085	<0.0005
Female	Ref. Cat.			
Age	−0.001	−0.002	0.001	0.343
EQ-VAS				
Intercept	71.007	61.663	80.350	<0.0005
Platform use				0.019
Active users	2.291	−1.691	6.275	0.259
Curious users	4.611	1.384	7.838	**0.005**
Nonusers	Ref. Cat.			
Male	2.977	0.095	5.859	0.043
Female	Ref. Cat.			
Age	0.030	−0.118	0.178	0.690
WHO-5				
Intercept	58.138	48.911	67.365	<0.0005
Platform use				0.065
Active users	−0.089	−4.008	3.829	0.964
Curious users	3.609	0.446	6.773	**0.025**
Nonusers	Ref. Cat.			
Male	5.766	2.932	8.600	<0.0005
Female	Ref. Cat.			
Age	0.142	−0.004	0.289	0.057

Table 3: Continued.

	b-coefficient	95% CI		*p* value
		Lower bound	Upper bound	
PAID-5				
Intercept	5.129	3.520	6.737	<0.0005
Platform use				0.004
Active users	−0.511	−1.195	0.173	0.143
Curious users	−0.929	−1.480	−0.378	**0.001**
Nonusers	Ref. Cat.			
Male	−0.143	−0.639	0.353	0.571
Female	Ref. Cat.			
Age	−0.037	−0.062	−0.011	0.005
SDSCA-medication				
Intercept	6.087	5.575	6.600	<0.0005
Platform use				0.028
Active users	0.081	−0.132	0.296	0.458
Curious users	0.236	0.063	0.408	**0.008**
Nonusers	Ref. Cat.			
Male	0.096	−0.058	0.250	0.222
Female	Ref. Cat.			
Age	0.010	0.002	0.018	0.020

platform. 633 patients were registered for care platform use. See Figure 1 for the patient flow.

Table 1 shows all differences and other notable characteristics for the comparison between nonusers, curious users, and active users of the platform. No differences were found in demographical characteristics between nonusers, curious users, and active users. HbA1c level of nonusers was higher compared to curious users ($p = 0.038$) and to active users ($p = 0.001$). Curious and active users were more often known with hypertension compared to nonusers ($p = 0.025$). Curious users assessed the GP better on one question of the Europep compared to nonusers and active users ($p = 0.047$). Curious users scored higher on EQ-5D ($p = 0.030$) and EQ-VAS (0.032) compared to nonusers, with no significant differences between curious users and active users or nonusers and active users. In addition, curious users' WHO-5 score as well as their answers to the individual WHO-5 questions reported less depressive symptoms compared to nonusers and active users. Curious users scored lower on PAID-5 compared to nonusers ($p = 0.016$), with no significant differences between curious users versus active users and nonusers versus active users. Curious users performed better on one dimension of self-reported self-management activities (medication intake) compared to nonusers ($p = 0.020$), with no significant difference between curious users versus active users and nonusers versus active users. Table 2 shows the Cronbach's alpha for all the multi-item scales.

See Appendix A for tables with all characteristics as mentioned in the methods section for the comparison between nonusers and users. See Appendix B for tables with all characteristics for the comparison between nonusers, curious users, and active users.

The differences in characteristics between nonusers, curious users, and active users have also been adjusted for age and gender in a multivariate analysis. The results are shown in Table 3. p values below 0.05 were found for differences regarding HbA1c between active users and nonusers (−3.624 mmol/mol) as well as between curious users and nonusers (−1.989 mmol/mol) and for differences between curious users and nonusers regarding EQ-5D (0.044), EQ-VAS (4.611), WHO-5 (3.609), PAID-5 (−0.929), and medication intake (0.236).

4. Discussion

In this exploratory study we found that only a small amount of clinical and psychological characteristics were associated with platform use. Curious users as well as active users had lower HbA1c compared to nonusers, which is in agreement with other studies [27, 28]. The more frequent presence of hypertension in curious and active users, however, contradicts with these studies. Curious users scored higher on EQ-5D and EQ-VAS and lower on PAID-5. Curious users scored also better on medication intake, which may reflect higher self-efficacy, in agreement with the study by Sarkar et al. [29]. After adjustment for age and gender, the difference in WHO-5 score between curious users and nonusers was also significant.

We observed that most of the patients, who were registered for platform use, never logged on. This could be

TABLE 4: Demographic and clinical characteristics of users and nonusers.

Demographic and clinical parameters n (%)/mean ± SD/median (25–75 quartiles)	Nonusers ($n = 361$)	Missing	Users ($n = 272$)	Missing	Univariate p value
Men	214 (59.3)	0 (0)	163 (59.9)	0 (0)	0.95
Age in years	62.1 ± 9.5 63.0 (56.5–68.0)	0 (0)	61.8 ± 9.4 62.5 (57.0–68.0)	0 (0)	0.732
Ethnicity					
Caucasian	292 (99.0)	66 (18.3)	208 (100)	64 (2.5)	0.271
Other	3 (1.0)		0 (0)		
T2DM duration in years	6.2 ± 4.6 6.0 (2.0–9.0)	9 (2.5)	5.6 ± 4.4 5.0 (2.0–8.0)	1 (0.4)	0.068
HbA1c in mmol/mol	50.6 ± 9.5 50.0 (45.0–54.0)	3 (0.8)	48.2 ± 7.3 47.0 (43.0–53.0)	0 (0)	<**0.0005**
BMI	29.8 ± 4.9 29.0 (26.5–32.5)	3 (0.8)	30.0 ± 6.0 28.7 (26.3–32.4)	2 (0.7)	0.724
Systolic blood pressure in mmHG	135.6 ± 15.5	0 (0)	136.5 ± 16.0	4 (1.5)	0.463
Cholesterol in mmol/L	4.4 ± 1.0	4 (1.1)	4.4 ± 0.9	2 (0.7)	0.499
HDL in mmol/L	1.3 ± 0.4	4 (1.1)	1.3 ± 0.4	3 (1.1)	0.581
Cholesterol/HDL ratio	3.6 ± 1.1	160 (44.3)	3.6 ± 1.3	92 (33.8)	0.899
LDL in mmol/L	2.4 ± 0.9	12 (3.3)	2.3 ± 0.8	6 (2.2)	0.240
Triglycerides in mmol/L	1.7 ± 1.0 1.5 (1.0–2.1)	7 (1.9)	1.8 ± 1.2 1.5 (1.1–2.1)	2 (0.7)	0.482
Creatinine in μmol/L	78.6 ± 17.2 77.0 (67.0–88.0)	6 (1.7)	79.9 ± 17.5 79.0 (67.0–90.0)	1 (0.4)	0.359
Alb./creat. ratio in mg/mmol					
Men	2.0 ± 4.4 0.7 (0.3–1.5)	23 (10.7)	1.9 ± 5.8 0.5 (0.3–1.5)	25 (15.3)	0.853
Women	1.6 ± 3.5 0.7 (0.3–1.5)	31 (21.1)	0.9 ± 1.1 0.6 (0.4–1.2)	18 (16.5)	0.070
MDRD in mL/min/1.73 m^2	79.1 ± 49.0 75.0 (61.0–88.0)	5 (1.4)	76.0 ± 16.6 74.0 (61.0–87.0)	1 (0.4)	0.329
Smoking					
Yes	54 (15.1)	3 (0.8)	41 (15.1)	1 (0.4)	0.306
Before	158 (44.1)		104 (38.4)		
No	146 (40.8)		126 (46.5)		
Alcohol consumption in units/day					
0	166 (58.9)	79 (21.9)	139 (60.7)	43 (15.8)	0.870
1	61 (21.6)		52 (22.7)		
2	39 (13.8)		30 (13.1)		
3	11 (3.9)		7 (3.1)		
4	4 (1.4)		1 (0.4)		
5	0 (0)		0 (0)		
6	1 (0.4)		0 (0)		
Employment					
Fulltime/part-time working	99 (34.3)	72 (19.9)	81 (34.0)	34 (12.5)	0.909
Retired	134 (46.4)		116 (48.7)		
Unemployed/ housekeeper	38 (13.1)		29 (12.2)		
Incapacitated	18 (6.2)		12 (5.0)		
Educational level					
None	0 (0)	73 (20.2)	1 (0.4)	35 (12.9)	**0.017**
Primary school	24 (8.3)		13 (5.5)		
Low	127 (44.1)		79 (33.3)		
Intermediate	86 (29.9)		81 (29.8)		
High	51 (17.7)		63 (23.2)		

Table 5: Medication use of users and nonusers.

Medication prescription n (%)	Nonusers (n = 361)	Missing	Users (n = 272)	Missing	Univariate p value
Diabetes-related					
Oral treatment only	251 (71.3)	9 (2.5)	192 (71.9)	5 (1.8)	0.702
Insulin treatment only	4 (1.1)	9 (2.5)	1 (0.4)	5 (1.8)	0.931
Mix of oral and insulin treatment	40 (11.4)	9 (2.5)	23 (8.6)	5 (1.8)	0.248
No medication	57 (16.2)	9 (2.5)	51 (19.1)	5 (1.8)	0.417
Comorbidity or complication related					
Calcium channel blockers	50 (14.2)	9 (2.5)	47 (17.6)	5 (1.8)	0.236
Beta blockers	128 (36.4)	9 (2.5)	110 (41.2)	5 (1.8)	0.145
Diuretics	121 (34.4)	9 (2.5)	94 (35.2)	5 (1.8)	0.870
Ace and RAAS inhibitors	196 (55.7)	9 (2.5)	141 (52.8)	5 (1.8)	0.480
Other blood pressure lowering medications	3 (0.9)	9 (2.5)	1 (0.4)	5 (1.8)	0.637
Lipid lowering medication	280 (79.5)	9 (2.5)	213 (79.8)	5 (1.8)	0.847

Table 6: Complications and risk factors of users and nonusers.

Complications and risk factors n (%)	Nonusers (n = 361)	Missing	Users (n = 272)	Missing	Univariate p value
Cardiovascular, total	225 (96.2)	127 (35.2)	187 (98.4)	82 (30.1)	0.240
Cardiovascular, specific					
Angina pectoris	41 (21.7)	172 (47.6)	28 (19.7)	130 (47.8)	0.787
Myocardial infarct	29 (15.3)	172 (47.6)	23 (16.0)	128 (47.1)	0.880
Other/chronic ischemic heart diseases	34 (16.1)	150 (41.6)	24 (13.6)	96 (35.3)	0.569
Hypertension	191 (84.1)	134 (37.1)	164 (93.2)	96 (35.3)	**0.008**
TIA	12 (6.4)	174 (48.2)	7 (5.0)	133 (48.9)	0.642
CVA	13 (7.0)	176 (48.8)	10 (7.1)	132 (48.5)	1.000
Intermittent claudication	7 (3.3)	150 (41.6)	7 (4.0)	96 (35.3)	0.788
Aortic aneurysms	4 (1.9)	150 (41.6)	2 (1.1)	96 (35.3)	0.693
CABG	15 (5.1)	68 (18.8)	11 (5.4)	68 (25.0)	1.000
PTCA	28 (9.6)	68 (18.8)	14 (6.8)	67 (24.6)	0.327
Heart failure	14 (8.1)	189 (52.4)	10 (7.4)	136 (50.0)	0.834
Retinopathy	19 (9.3)	156 (43.2)	18 (10.2)	95 (34.9)	0.863
Renal impairment	35 (18.6)	173 (47.9)	26 (18.6)	132 (48.5)	1.000
Albuminuria					
Men	30 (14.5)	7 (3.3)	20 (12.6)	4 (2.5)	0.647
Women	8 (5.8)	8 (5.4)	1 (1.0)	5 (4.6)	0.082
Neuropathy	49 (22.2)	140 (38.8)	39 (22.4)	98 (36.0)	1.000
Foot complication					
SIMMs 0	228 (77.6)	67 (18.6)	161 (76.7)	62 (22.8)	0.783
SIMMs 1	57 (19.4)		40 (19.0)		
SIMMs 2 or 3	9 (3.1)		9 (4.3)		
Psychiatric disorders	19 (9.0)	150 (41.6)	9 (5.1)	96 (35.3)	0.124

SIMMS refers to risk factors in the diabetic foot, the number is the stage which ranges from 0–3.
0: no loss of protective sensibility (PS) & Peripheral arterial disease (PAV).
1: loss of PS or PAV, with no signs of increased local pressure.
2: loss of PS in combination with and/or PAV and/or signs of local elevated pressure.
3: ulcer or amputation in history.

Table 7: Scores on quality of care (Europep) of users and nonusers.

Items of Europep: patients who scored 4 (good) or 5 (excellent) *n* (%)	Nonusers ($n = 361$)	Missing	Users ($n = 272$)	Missing	Univariate *p* value
What is your assessment of the general practitioner over the last 12 months with respect to the following?					
Making you feel you have time during consultation	337 (97.4)	15 (4.2)	256 (98.1)	11 (4.0)	0.622
Showing interest in your personal situation	324 (94.5)	18 (5.0)	246 (94.6)	12 (4.4)	0.864
Making it easy for you to tell him or her about your problem	323 (93.4)	15 (4.2)	245 (96.5)	18 (6.6)	0.110
Involving you in decisions about your medical care	311 (92.3)	24 (6.6)	239 (94.1)	18 (6.6)	0.290
Listening to you	322 (92.3)	12 (3.3)	243 (94.6)	15 (5.5)	0.270
Keeping your records and data confidential	310 (95.7)	37 (10.2)	236 (95.9)	26 (9.6)	0.846
Providing quick relief of your symptoms	272 (87.5)	50 (13.9)	201 (85.9)	38 (14.0)	0.635
Helping you to feel well so that you can perform your normal daily activities	265 (89.8)	66 (18.3)	196 (91.2)	57 (21.0)	0.483
Thoroughness of the approach to your problems	308 (91.4)	24 (6.6)	227 (89.7)	19 (7.0)	0.786
Your physical examination	292 (90.1)	37 (10.2)	222 (92.1)	31 (11.4)	0.327
Offering services for preventing diseases (screening, health checks, and immunizations)	286 (91.4)	48 (13.3)	225 (92.6)	29 (10.7)	0.655
Explaining the purpose of examinations, tests, and treatments	307 (93.0)	31 (8.6)	240 (93.8)	16 (5.9)	0.518
Telling you enough about your symptoms and/or illness	306 (92.2)	29 (8.0)	238 (93.3)	17 (6.3)	0.448
Helping you deal with emotions related to your health status	198 (86.8)	133 (36.8)	133 (84.7)	115 (42.3)	0.888
Helping understand why it is important to follow the GP's advice	295 (89.7)	32 (8.9)	219 (89.4)	27 (9.9)	0.894
Knowing what has been done or told during previous contacts in the practice	270 (84.9)	43 (11.9)	219 (89.4)	27 (9.9)	0.071
Preparing you for what to expect from specialists, hospital care, and other care providers	199 (85.4)	128 (35.5)	156 (83.5)	85 (31.3)	0.513
What is your assessment of the general practice over the last 12 months with respect to the following?					
The helpfulness of the practice staff (other than the doctor) to you	313 (93.4)	26 (7.2)	235 (92.9)	19 (7.0)	0.878
Getting an appointment to suit you	301 (88.5)	21 (5.8)	224 (86.5)	13 (4.8)	0.639
Getting through to the practice on telephone	249 (73.0)	20 (5.5)	180 (69.5)	13 (4.8)	0.662
Being able to talk to the general practitioner on the telephone	167 (70.5)	124 (34.3)	106 (63.1)	104 (38.2)	0.150
Waiting time in the waiting room	246 (71.3)	16 (4.4)	170 (65.4)	12 (4.4)	0.175
Providing quick services for urgent health problems	241 (90.3)	94 (26.0)	171 (86.8)	75 (27.6)	0.398

influenced by (an insufficient) intrinsic motivation and (no) intention to change behaviours. Another explanation could be that patients do not see the platform as useful or as an added value to regular treatment. As an alternative explanation, login procedures might be too difficult and after trying for some time they might give up.

Previous research showed that web-portals and online care platforms are susceptible to implementation problems, low participation rates, and nonadherence, which, amongst others, can be caused by a mismatch in expectations between software developers, health care providers, and users [30–37]. Other reasons for limited use of care platforms or

Table 8: Scores on quality of life (EQ-5D), well-being (WHO-5), diabetes-related distress (PAID-5), and self-care behavior (SDSCA).

EQ-5D, WHO-5, PAID-5, and SDSCA *n* (%)/mean ± SD/median (25–75 quartiles)	Nonusers ($n = 361$)	Missing	Users ($n = 272$)	Missing	Univariate *p* value
EQ-5D index-score	0.9 ± 0.2	72 (19.9)	0.9 ± 0.1	36 (13.2)	**0.028**
EQ-VAS	74.7 ± 17.4 80.0 (60.0–90.0)	74 (20.5)	78.4 ± 14.9 80.0 (71.0–90.0)	40 (14.7)	**0.014**
WHO-5 index-score	70.4 ± 17.9 76.0 (60.0–80.0)	76 (21.1)	72.7 ± 14.2 76.0 (68.0–80.0)	38 (14.0)	0.096
WHO-5 score indicates suboptimal well-being, screening depression advised	36 (12.6)	76 (21.1)	17 (7.3)	38 (14.0)	**0.018**
WHO-5 answers advise screening depression	43 (15.5)	76 (21.1)	17 (7.3)	38 (14.0)	**0.004**
PAID-5 total score	2.8 ± 3.1 2.0 (0.0–4.5)	76 (21.1)	2.0 ± 2.5 1.0 (0.0–3.0)	38 (14.0)	**0.005**
PAID-5 score indicates distress	15 (5.3)	76 (21.1)	6 (2.6)	38 (14.0)	0.058
SDSCA					
General diet in number of days	5.4 ± 1.8 6.0 (5.0–7.0)	76 (21.1)	5.6 ± 1.8 6.0 (5.0–7.0)	37 (13.6)	0.269
Specific diet in number of days	5.6 ± 1.1 5.7 (4.7–6.3)	73 (20.2)	5.7 ± 1.0 6.0 (5.3–6.7)	34 (12.5)	0.056
Exercise in number of days	4.0 ± 2.0 4.0 (2.5–5.5)	72 (19.9)	4.0 ± 1.8 4.0 (2.5–5.5)	34 (12.5)	0.919
Blood-glucose in number of days	2.1 ± 2.2 1.0 (0.0–4.0)	74 (20.5)	2.0 ± 2.2 1.0 (0.5–3.5)	34 (12.5)	0.675
Foot-care in number of days	1.9 ± 2.0 1.5 (0.0–3.5)	72 (19.9)	1.9 ± 2.0 1.0 (0.0–3.5)	34 (12.5)	0.695
Medication in number of days	6.7 ± 1.0 7.0 (7.0–7.0)	73 (20.2)	6.9 ± 0.5 7.0 (7.0–7.0)	34 (12.5)	**0.013**
Smoking	54 (25.1)	146 (40.4)	38 (22.8)	105 (38.6)	**0.418**

nonadherence rates are as follows: abundance of functionalities on a platform, no connection with the needs of patients, implementation by management only without active involvement of care providers, no embedding in the regular care process, no space for habituation, underestimation of the complexity of lifestyle changes in general [38], and barriers to easy access to a portal (e.g., complicated login procedures). Despite the use of focus groups for designing and testing, these reasons might also be applicable to the e-Vita platform and improvements could be made.

The current study has some limitations. A preselection of participants could in part have influenced results. Only patients who expressed their interest received a user-ID [14]; see also Figure 1. Relevant and significant differences might be more difficult to find.

Data were not complete for all patients, especially with regard to complications and risk factors (complete for 50–60%; see Tables 6 and 11). This may have led to an underestimation of presence of complications and risk factors. In addition, not all patients were seen by their GP or PN for the regular yearly check-up in the year 2012, which contributed to missing values in clinical parameters. Some questions about the assessment of the general practice and the general practitioner were poorly answered in general. A reason for this could be social desirability; patients may not like to be negative about their GP and prefer not answering these questions.

Although the online care platform e-Vita was designed for being suitable for all T2DM patients, a general assumption is that those with greater severity of disease, lower mood, progression of the disease, and complications would probably benefit most from an online care platform. However, when assessing the presented results, these patients use the platform the least.

Possibly, the current users were already more in control of their life and health and could therefore be more open to other forms of support, including e-Health facilities. Challenges to reach other patients remain manifold. A patients' passive attitude may not be overcome by only providing e-facilities, since one's interest and the sense of disease burden are low or even absent in the majority of the T2DM population. Factors as knowledge, motivation, and intention could be considered in future research.

Table 9: Demographic and clinical characteristics of curious users, active users, and nonusers.

Demographic and clinical parameters *n* (%)/mean ± SD/median (25–75 quartiles)	Nonusers (*n* = 361)	Missing	Curious users (*n* = 184)	Missing	Active users (*n* = 88)	Missing	Univariate *p* value
Men	214 (59.3)	0 (0)	113 (61.4)	0 (0)	50 (56.8)	0 (0)	0.760
Age in years	62.1 ± 9.5 63.0 (56.5–68.0)	0 (0)	61.8 ± 9.5 62.0 (56.3–68.0)	0 (0)	62.0 ± 9.4 63.0 (57.0–67.0)	0 (0)	0.935
Ethnicity							
Caucasian	292 (99.0)	66 (18.3)	143 (100)	41 (22.3)	65 (100)	23 (6.1)	0.706
Other	3 (1.0)		0 (0)		0 (0)		0.382
T2DM duration in years	6.2 ± 4.6 6.0 (2.0–9.0)	9 (2.5)	5.7 ± 4.4 5.0 (2.0–8.0)	1 (0.5)	5.4 ± 4.4 4.5 (2.0–8.0)	0 (0)	0.165
HbA1c in mmol/mol	50.6 ± 9.5 50.0 (45.0–54.0)	3 (0.8)	48.7 ± 7.4 48.0 (43.0–54.0)	0 (0)	47.0 ± 7.0 46.0 (43.0–50.8)	0 (0)	**0.001**
BMI	29.8 ± 4.9 29.0 (26.5–32.5)	3 (0.8)	30.0 ± 4.8 29.3 (26.9–32.3)	0 (0)	29.9 ± 8.0 28.0 (26.0–32.6)	2 (2.3)	0.921
Systolic blood pressure in mmHG	135.6 ± 15.5	0 (0)	137.2 ± 16.3	2 (1.1)	135.1 ± 15.3	2 (2.3)	0.463
Cholesterol in mmol/L	4.4 ± 1.0	4 (1.1)	4.4 ± 0.8	0 (0)	4.4 ± 0.9	2 (2.3)	0.775
HDL in mmol/L	1.3 ± 0.4	4 (1.1)	1.2 ± 0.3	1 (0.5)	1.3 ± 0.4	2 (2.3)	0.071
Cholesterol/HDL ratio	3.6 ± 1.1	160 (44.3)	3.7 ± 1.4	57 (31.0)	3.4 ± 1.0	35 (39.8)	0.185
LDL in mmol/L	2.4 ± 0.9	12 (3.3)	2.4 ± 0.8	3 (1.6)	2.3 ± 0.8	3 (3.4)	0.473
Triglycerides in mmol/L	1.7 ± 1.0 1.5 (1.0–2.1)	7 (1.9)	1.8 ± 1.3 1.5 (1.1–2.1)	0 (0)	1.7 ± 1.0 1.4 (1.0–2.0)	2 (2.3)	0.531
Creatinine in μmol/L	78.6 ± 17.2 77.0 (67.0–88.0)	6 (1.7)	80.9 ± 17.4 79.0 (68.0–92.0)	1 (0.5)	77.8 ± 17.8 75.5 (66.0–85.8)	0 (0)	0.259
Alb./creat. ratio in mg/mmol							
Men	2.0 ± 4.4 0.7 (0.3–1.5)	23 (10.7)	2.2 ± 6.9 0.5 (0.3–1.5)	18 (15.9)	1.3 ± 1.7 0.7 (0.3–1.5)	7 (14.0)	0.636
Women	1.6 ± 3.5 0.7 (0.3–1.5)	31 (21.1)	1.1 ± 1.3 0.7 (0.4–1.5)	8 (11.3)	0.6 ± 0.5 0.6 (0.3–0.9)	10 (26.4)	0.155
MDRD in mL/min/1.73 m^2	79.1 ± 49.0 75.0 (61.0–88.0)	5 (1.4)	75.7 ± 16.2 73.0 (61.0–87.0)	1 (0.5)	76.7 ± 17.4 75.5 (61.0–89.0)	0 (0)	0.610
Smoking							
Yes	54 (15.1)	3 (0.8)	30 (16.4)	1 (0.5)	11 (12.5)	0 (0)	0.382
Before	158 (44.1)		73 (39.7)		31 (35.2)		
No	146 (40.8)		80 (43.7)		46 (52.3)		
Alcohol consumption in units/day							
0	166 (58.9)	79 (21.9)	98 (60.9)	23 (12.5)	41 (60.3)	20 (22.7)	0.646
1	61 (21.6)		8 (23.6)		14 (20.6)		
2	39 (13.8)		17 (10.6)		13 (19.1)		
3	11 (3.9)		7 (4.3)		0 (0)		
4	4 (1.4)		1 (0.5)		0 (0)		
5	0 (0)		0 (0)		0 (0)		
6	1 (0.4)		0 (0)		0 (0)		
Employment							
Fulltime/part-time working	99 (34.3)	72 (19.9)	61 (39.6)	30 (16.3)	20 (23.8)	4 (4.5)	0.063
Retired	134 (46.4)		70 (45.5)		46 (54.8)		
Unemployed/housekeeper	38 (13.1)		20 (13.0)		9 (10.7)		
Incapacitated	18 (6.2)		3 (1.9)		9 (10.7)		
Educational level							
None	0 (0)	73 (20.2)	1 (0.7)	31 (16.8)	0 (0)	4 (4.5)	0.125
Primary school	24 (8.3)		9 (5.9)		4 (4.8)		
Low	127 (44.1)		52 (34.0)		27 (32.1)		
Intermediate	86 (29.9)		51 (33.3)		30 (35.7)		
High	51 (17.7)		40 (26.1)		23 (27.4)		

Table 10: Medication prescription of curious users, active users, and nonusers.

Medication prescription *n* (%)	Nonusers (*n* = 361)	Missing	Curious users (*n* = 184)	Missing	Active users (*n* = 88)	Missing	Univariate *p* value
Diabetes-related							
Oral treatment only	251 (71.3)	9 (2.5)	128 (71.5)	5 (2.7)	64 (72.7)	0 (0)	1.000
Insulin treatment only	4 (1.1)	9 (2.5)	1 (0.5)	5 (2.7)	0 (0)	0 (0)	0.899
Mix of oral and insulin treatment	40 (11.4)	9 (2.5)	18 (10.1)	5 (2.7)	5 (5.7)	0 (0)	0.242
No medication	57 (16.2)	9 (2.5)	32 (17.9)	5 (2.7)	19 (21.6)	0 (0)	0.521
Comorbidity or complication related							
Calcium channel blockers	50 (14.2)	9 (2.5)	31 (17.3)	5 (2.7)	16 (18.2)	0 (0)	0.415
Beta blockers	128 (36.4)	9 (2.5)	74 (41.3)	5 (2.7)	36 (40.9)	0 (0)	0.324
Diuretics	121 (34.4)	9 (2.5)	63 (35.2)	5 (2.7)	31 (35.2)	0 (0)	0.979
Ace and RAAS inhibitors	196 (55.7)	9 (2.5)	94 (52.5)	5 (2.7)	47 (53.4)	0 (0)	0.738
Other blood pressure lowering medications	3 (0.9)	9 (2.5)	0 (0)	5 (2.7)	1 (1.1)	0 (0)	0.357
Lipid lowering medication	280 (79.5)	9 (2.5)	141 (78.8)	5 (2.7)	72 (81.8)	0 (0)	0.868

Table 11: Complications and risk factors of curious users, active users, and nonusers.

Complications and risk factors *n* (%)	Nonusers (*n* = 361)	Missing	Curious users (*n* = 184)	Missing	Active users (*n* = 88)	Missing	Univariate *p* value
Cardiovascular, total	225 (96.2)	127 (35.2)	128 (98.5)	54 (29.3)	59 (98.3)	28 (31.8)	0.506
Cardiovascular, specific							
Angina pectoris	41 (21.7)	172 (47.6)	21 (21.4)	86 (46.7)	7 (15.9)	44 (50.0)	0.698
Myocardial infarct	29 (15.3)	172 (47.6)	15 (15.3)	86 (46.7)	8 (17.4)	42 (47.7)	0.932
Other/chronic ischemic heart diseases	34 (16.1)	150 (41.6)	18 (14.9)	63 (34.2)	6 (10.9)	33 (37.5)	0.750
Hypertension	191 (84.1)	134 (37.1)	113 (93.4)	63 (34.2)	51 (92.7)	33 (37.5)	**0.025**
TIA	12 (6.4)	174 (48.2)	4 (4.2)	88 (47.8)	3 (7.0)	45 (51.1)	0.747
CVA	13 (7.0)	176 (48.8)	6 (6.1)	86 (46.7)	4 (9.5)	46 (52.3)	0.745
Intermittent claudication	7 (3.3)	150 (41.6)	4 (3.3)	63 (34.2)	3 (5.5)	33 (37.5)	0.689
Aortic aneurysms	4 (1.9)	150 (41.6)	1 (0.8)	63 (34.2)	1 (1.8)	33 (37.5)	0.731
CABG	15 (5.1)	68 (18.8)	7 (5.0)	43 (23.4)	4 (6.3)	25 (28.4)	0.916
PTCA	28 (9.6)	68 (18.8)	9 (6.4)	43 (23.4)	5 (7.8)	24 (27.3)	0.588
Heart failure	14 (8.1)	189 (52.4)	9 (9.4)	88 (47.8)	1 (2.5)	48 (54.5)	0.409
Retinopathy	19 (9.3)	156 (43.2)	14 (11.7)	64 (34.8)	4 (7.0)	31 (35.2)	0.640
Renal impairment	35 (18.6)	173 (47.9)	15 (15.5)	87 (47.3)	11 (25.6)	45 (51.1)	0.350
Albuminuria							
Men	30 (14.5)	7 (3.3)	14 (12.6)	2 (1.8)	6 (12.5)	2 (4.0)	0.908
Women	8 (5.8)	8 (5.4)	1 (1.4)	1 (1.4)	0 (0)	4 (10.5)	0.226
Neuropathy	49 (22.2)	140 (38.8)	30 (24.6)	62 (33.7)	9 (17.3)	36 (40.9)	0.594
Foot complication							
SIMMs 0	228 (77.6)	67 (18.6)	105 (73.4)	41 (22.3)	56 (83.6)	21 (23.9)	0.524
SIMMs 1	57 (19.4)		31 (21.7)		9 (13.4)		
SIMMs 2 or 3	9 (3.1)		7 (4.9)		2 (3.0)		
Psychiatric disorders	19 (9.0)	150 (41.6)	7 (5.8)	63 (34.2)	2 (3.6)	33 (37.5)	0.317

Table 12: Scores on quality of care (Europep) of curious users, active users, and nonusers.

Items of Europep: patients who scored 4 (good) to 5 (excellent) *n* (%)	Nonusers ($n = 361$)	Missing	Curious users ($n = 184$)	Missing	Active users ($n = 88$)	Missing	Univariate *p* value
What is your assessment of the general practitioner over the last 12 months with respect to the following?							
Making you feel that you have time during consultation	737 (95.1)	105 (11.9)	174 (99.4)	9 (4.9)	82 (95.3)	2 (2.3)	0.159
Showing interest in your personal situation	707 (91.6)	108 (12.3)	165 (94.8)	10 (5.4)	81 (94.2)	2 (2.3)	0.970
Making it easy for you to tell him or her about your problem	694 (92.2)	127 (14.4)	165 (98.2)	16 (8.7)	80 (93.0)	2 (2.3)	**0.047**
Involving you in decisions about your medical care	680 (90.7)	130 (14.8)	159 (93.5)	14 (7.6)	80 (95.2)	4 (4.5)	0.489
Listening to you	709 (92.0)	109 (12.4)	163 (94.8)	12 (6.5)	80 (94.1)	3 (3.4)	0.579
Keeping your records and data confidential	661 (93.8)	175 (19.9)	161 (97.0)	18 (9.8)	75 (93.8)	8 (9.1)	0.764
Providing quick relief of your symptoms	588 (83.9)	179 (20.3)	137 (86.2)	25 (13.6)	64 (85.3)	13 (14.8)	0.863
Helping you to feel well so that you can perform your normal daily activities	599 (89.7)	212 (24.1)	135 (91.8)	37 (20.1)	61 (89.7)	20 (22.7)	0.780
Thoroughness of the approach to your problems	675 (90.7)	136 (15.5)	153 (90.5)	15 (8.2)	74 (88.1)	4 (4.5)	0.769
Your physical examination	639 (90.8)	176 (20.0)	153 (92.7)	19 (10.3)	69 (90.8)	12 (13.6)	0.577
Offering services for preventing diseases (screening, health checks, and immunizations)	653 (92.5)	174 (19.8)	151 (91.5)	19 (10.3)	74 (94.9)	10 (11.4)	0.539
Explaining the purpose of examinations, tests, and treatments	677 (92.4)	147 (16.7)	163 (94.8)	12 (6.5)	77 (91.7)	4 (4.5)	0.402
Telling you enough about your symptoms and/or illness	662 (90.2)	146 (16.6)	158 (92.4)	13 (7.1)	80 (95.2)	4 (4.5)	0.579
Helping you deal with emotions related to your health status	424 (84.8)	380 (43.2)	89 (86.4)	81 (44.0)	44 (81.5)	34 (38.6)	0.659
Helping understand why it is important to follow the GP's advice	631 (89.1)	172 (19.5)	146 (89.6)	21 (11.4)	73 (89.0)	6 (6.8)	0.965
Knowing what has been done or told during previous contacts in the practice	601 (86.8)	188 (21.4)	148 (90.2)	20 (10.9)	71 (87.7)	7 (8.0)	0.158
Preparing you for what to expect from specialists, hospital care, and other care providers	424 (82.8)	368 (41.8)	107 (8.3)	54 (29.3)	49 (86.0)	31 (35.2)	0.577
What is your assessment of the general practice over the last 12 months with respect to the following?							
The helpfulness of the practice staff (other than the doctor) to you	313 (93.4)	26 (7.2)	158 (92.9)	14 (7.6)	77 (92.8)	5 (5.7)	0.953
Getting an appointment to suit you	301 (88.5)	21 (5.8)	152 (86.9)	9 (4.9)	72 (85.7)	4 (4.5)	0.867
Getting through to the practice on telephone	249 (73.0)	20 (5.5)	120 (68.6)	9 (4.9)	60 (71.4)	4 (4.5)	0.777
Being able to talk to the general practitioner on the telephone	167 (70.5)	124 (34.3)	71 (62.8)	71 (38.6)	35 (63.6)	33 (37.5)	0.306
Waiting time in the waiting room	246 (71.3)	16 (4.4)	119 (68.4)	10 (5.4)	51 (59.3)	2 (2.3)	0.148
Providing quick services for urgent health problems	241 (90.3)	94 (26.0)	118 (86.8)	48 (26.1)	53 (86.9)	27 (30.7)	0.658

Table 13: Scores on quality of life (EQ-5D), well-being (WHO-5), diabetes-related distress (PAID-5), and self-care behavior (SDSCA) of curious users, active users, and nonusers.

EQ-5D, WHO-5, PAID-5, and SDSCA *n* (%)/mean ± SD/median (25–75 quartiles)	Nonusers (*n* = 361)	Missing	Curious users (*n* = 184)	Missing	Active users (*n* = 88)	Missing	Univariate *p* value
EQ-5D index-score	0.9 ± 0.2	72 (19.9)	0.9 ± 0.1	32 (17.4)	0.9 ± 0.2	4 (4.5)	**0.030**
EQ-VAS	74.7 ± 17.4 80.0 (60.0–90.0)	74 (20.5)	79.3 ± 13.8 80.0 (73.0–90.0)	35 (19.0)	76.9 ± 16.5 80.0 (0.0–90.0)	5 (5.7)	**0.032**
WHO-5 index-score	70.4 ± 17.9 76.0 (60.0–80.0)	76 (21.1)	74.1 ± 12.7 76.0 (68.0–80.0)	33 (17.9)	70.2 ± 16.5 76.0 (60.0–80.0)	1 (1.1)	0.080
WHO-5 score indicates suboptimal well-being, screening depression advised	36 (12.6)	76 (21.1)	8 (5.3)	33 (17.9)	9 (10.8)	1 (1.1)	**0.018**
WHO-5 answers advise screening depression	43 (15.5)	76 (21.1)	6 (4.0)	33 (17.9)	11 (13.3)	1 (1.1)	**0.002**
PAID-5 total score	2.8 ± 3.1 2.0 (0.0–4.5)	76 (21.1)	1.8 ± 2.4 1.0 (0.0–3.0)	32 (17.4)	2.2 ± 2.5 1.0 (0.0–4.0)	1 (1.1)	**0.016**
PAID-5 score indicates distress	15 (5.3)	76 (21.1)	4 (2.6)	32 (17.4)	2 (2.4)	1 (1.1)	0.183
SDSCA							
General diet in number of days	5.4 ± 1.8 6.0 (5.0–7.0)	76 (21.1)	5.5 ± 1.9 6.0 (5.0–7.0)	32 (17.4)	5.8 ± 1.7 6.0 (5.5–7.0)	5 (5.7)	0.258
Specific diet in number of days	5.6 ± 1.1 5.7 (4.7–6.3)	73 (20.2)	5.7 ± 1.0 6.0 (5.0–6.7)	30 (16.3)	5.7 ± 1.0 6.0 (5.3–6.6)	4 (4.5)	0.160
Exercise in number of days	4.0 ± 2.0 4.0 (2.5–5.5)	72 (19.9)	4.1 ± 1.8 4.0 (2.9–5.6)	30 (16.3)	3.8 ± 1.8 3.8 (2.5–5.0)	4 (4.5)	0.612
Blood-glucose in number of days	2.1 ± 2.2 1.0 (0.0–4.0)	74 (20.5)	2.1 ± 2.4 1.0 (0.0–4.0)	30 (16.3)	1.8 ± 1.8 1.0 (0.5–2.3)	4 (4.5)	0.241
Foot-care in number of days	1.9 ± 2.0 1.5 (0.0–3.5)	72 (19.9)	1.9 ± 2.0 1.0 (0.0–3.5)	30 (16.3)	1.8 ± 2.0 1.0 (0.0–3.5)	4 (4.5)	0.924
Medication in number of days	6.7 ± 1.0 7.0 (7.0–7.0)	73 (20.2)	7.0 ± 0.2 7.0 (7.0–7.0)	30 (16.3)	6.8 ± 0.8 7.0 (7.0–7.0)	4 (4.5)	**0.020**
Smoking	54 (25.1)	146 (40.4)	24 (21.8)	74 (40.2)	14 (24.6)	31 (35.2)	0.704

Appendices

A. Results of Users and Nonusers of the Online Care Platform e-Vita

See Tables 4, 5, 6, 7, and 8.

B. Results of Curious Users, Active Users, and Nonusers of the Online Care Platform e-Vita

See Tables 9, 10, 11, 12, and 13.

Abbreviations

EQ-5D:	EuroQol-5 Dimensions
EQ-VAS:	EuroQol Visual Analogue Scale
GFR:	Glomerular filtration rate
GP:	General practitioner
HRQoL:	Health-related quality of life
MDRD:	Modification of Diet in Renal Disease
PAID-5:	Problem Areas in Diabetes-5 questions
PN:	Practice nurse
SDSCA:	Summary of Diabetes Self-Care Activities
T2DM:	Type 2 diabetes mellitus
WHO-5:	WHO-Five Item Measure of Well-Being.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Research Article

Health Related Quality of Life among Omani Men and Women with Type 2 Diabetes

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The aim of this study was to explore predictors of health related quality of life (HRQoL) among men and women with type 2 diabetes. This cross-sectional descriptive study consisted of a random sample of 300 adults with type 2 diabetes in a selected public hospital. Euro-QoL and Revised Summary of Diabetes Self-Care Activities scales were used to collect data between January and June 2010. Schooling and ability to manage positively were highly significant predictors of quality of life (QoL) among women as compared to men. Age, prevention of activities of daily living and knowledge/management of diabetes were significant predictors of Health state among women as compared to men. Findings demonstrate that 30.6% (versus 35.7%) of the variance in the total QoL and 14% (versus 23%) of the variance in health state could be explained by personal and clinical characteristics among women and men, respectively. The study underlines the importance for nurse educators to assess HRQoL among men and women and to develop effective self-care management strategies based on personal and clinical characteristics.

1. Introduction

Diabetes mellitus (DM) is a chronic progressive metabolic disorder due to absolute (type 1) or relative (type 2) deficiency of insulin hormone [1]. Worldwide, 366 million people were estimated to have diabetes mellitus in the year 2011, and numbers are predicted to double by 2030 [2–4]. DM has caused approximately 4.6 million deaths in the age group of 20–79 years in a ten-year period from 2001 to 2011, accounting for approximately 8.2% of mortality [5, 6]. Almost 80% of deaths related to diabetes occur in low- and middle-income developing countries [7]. The incidence of type 2 diabetes (T2D) with an early onset associated with complications has risen in recent years in Oman compared to other Middle East countries [8–10]. The impact of T2D may limit function and quality of life among men and women. Individuals with T2D need a disciplined balance between the demands of self-care and preferred lifestyles.

Type 2 diabetes is developing into an international public health problem, with a significant increase in the Middle East region [6, 11]. In Oman, the prevalence of T2D escalated from 11.6% (2000) to 15% (2005) and rose to 16.1% (2010), with rising prevalence among all age groups [12, 13]. These figures are expected to double by 2030 [11] due to the life threatening long term complications [14, 15] and substantial impact on health and well-being [16–18]. A significant number of Omani men and women lack knowledge, skills, and information on self-care management while coping with T2D [8]. Hence, an exploration of personal and clinical factors to improve self-care behaviors among Omani men and women with T2D is important in assisting them in managing their health.

2. Review of Literature

Health related quality of life (HRQoL) is a multidimensional construct with bearing on a person's physical, cognitive,

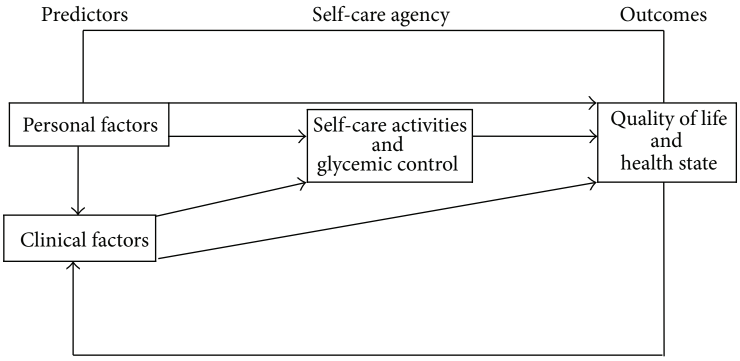

Figure 1: Health related quality of life among adults with type 2 diabetes (adapted from Sousa et al. [33]).

social, emotional, psychological, role, and spiritual status [19, 20]. HRQOL is an acceptable outcome or efficacy of self-care among adults with T2D (Figure 1). The literature on perceptions of living with T2D is extensive and has been shown to correlate with quality of life (QoL) [21, 22]. Several studies show that adults with T2D rate their QoL lower than the general population [23–26] as compared to those with type 1 diabetes (T1D) [27, 28]. Women with T2D have been found to have a lower quality of life than men [29–31], and those with a longer duration of T2D had poor QoL [32]. A self-care management model [33] leads to better glycemic control [34] and QoL [35], while those with poor glycemic control were found to have low QoL [36, 37]. No studies focusing on the predictors of QoL and health status among Omani men and women have been reported. Hence, the purpose of this study was to examine the predictors of QoL and health state and to examine comparisons among Omani men and women.

3. Material and Methods

3.1. Design. A cross-sectional descriptive study was conducted among adults with T2D in the outpatient diabetes clinic in a selected public hospital.

3.2. Sample/Participants. A sampling framework list of the accessible population with known type 2 diabetes ($N = 2000$) was obtained from the diabetes clinic in a selected public tertiary hospital in Oman. A simple random sampling using random number tables was used to recruit Omani adults who were screened in this diabetes clinic. The inclusion criteria were adults above 18 years diagnosed with T2D for two years who were able to understand, communicate, and converse in Arabic or English language and were not currently pregnant. The exclusion criteria were adults with known diagnosis of T1D, unknown T2D, cognitive/neurological impairment, mental/physical disability, or critical or advanced complications.

Sample size was estimated with the G^*Power software at a power of 0.95 with an effect size of 0.15 using 10 predictors (independent variables), an alpha of 0.05, and standard deviation of 1% on two-tailed testing [38, 39]. To obtain a power of 0.95 and assuming a 30% incompletion rate, a total sample size of 330 was required for these input parameters. Subsequently, a random sample of 330 adults with T2D was recruited.

3.3. Measurement. A review of the literature was conducted to select standardized instruments to measure the identified concepts of HRQoL and health/self-care activities. Two instruments were reviewed and selected. Physiological indicators were used to assess diabetes control and body weight. The sociodemographic and clinical-related information was primarily gathered by a demographic and clinical baseline tool which included age, gender, schooling (educational level), duration of diabetes, diabetes education, knowledge and management, ability to manage, activities of daily living, and medication.

Health related quality of life was evaluated with the Euro-Qol (EQ-5D) [40, 41]. The EQ-5D-5L consists of five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Each dimension had five levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The EQ visual analog scale (VAS) then recorded the respondent's self-rated health on a 20 centimeter (10-point interval) vertical VAS with endpoints categorized as "the best health you can imagine" and "the worst health you can imagine." Worst imaginable health state was recorded as 0 at the bottom of the scale, and best imaginable health state was achieved as 100 at the top. Both the 5-item index score and the VAS score were then converted into a value score between 0 ("worst health state") and 1 ("best health state") [24, 40].

Self-care activities (SCA) were evaluated with the Revised Summary of Diabetes Self-Care Activities Scale (SDSCA) to assess aspects of the diabetes regimen and evaluate the dietary management skills of the participants. The SDSCA scale is a self-reporting measure of the frequency of performing 13 diabetes self-care tasks and consisted of six subscales of the diabetes self-management (DSM) behaviors: diet, exercise, blood glucose testing, medication taking, foot care, and smoking behavior over the prior seven days [42]. Interitem correlations had a range of $r = 0.20$–0.76 (mean = 0.47) for four SDSCA subscales and 6-month test-retest reliability had a range of $r = 0.00$–0.58 (mean = 0.40) [42].

The glycosylated or glycated hemoglobin (HbA1c) value was classified into good glycemic control if the HbA1c values are less than or equal to (≤) 7% and poor glycemic control if HbA1c values are greater than (>) 7%. Glycemic control of ≤7.0% is endorsed as a treatment goal [17, 43]. Body mass index (BMI) in weight in kilograms/square of height in meters (Kg/m^2) was categorized as underweight if ≤18.5 Kg/m^2, normal if 18.5–24.9 Kg/m^2, overweight if 25–29.9 Kg/m^2, and obese if ≥30 Kg/m^2 [44]. Weight and height were measured by a portable digital scale and a portable stadiometer.

3.4. Validity and Reliability. The EQ-5D, SDSCA, and demographic and clinical characteristics instruments were translated to Arabic and back-translated and checked with monolingual testing. No discrepancies were found between the original and linguistic translated versions of the instruments. The linguistic validation of the Arabic version of the tools was found to be adequate. The final instruments used in this study were administered to 30 Omani adults with T2D twice in a 2-week interval. Intraclass correlation coefficient was intended to evaluate the test-retest reliability for the subdimensions of the EQ-5D (0.75 and 0.91). Interitem correlations had a range of $r = 0.75$–0.86 for four SDSCA subscales and item-to-total correlations had a range of 0.77–0.91 for the SDSCA. Good evidence for internal consistency was shown using Cronbach's alpha for the SDSCA which demonstrated $\alpha = 0.87$, which was considered acceptable.

3.5. Data Collection. Data were collected using EQ-5D and SDSCA standardized questionnaires after the pilot study between January and June 2010 among 330 adults with T2D in the diabetes clinic. Study participants were provided with an explanation of the study, and informed consent was obtained. Ethical approval was provided by the Ethics and Research Committee, College of Nursing at Sultan Qaboos University. Informed written and verbal consent was acquired from each participant who met the inclusion criteria through a written letter. Confidentiality was retained between the investigator and the participant. Informed consent and the completed questionnaires were stored and kept in locked cabinets. During the study, 30 selected adults dropped from the study. A 91% ($N = 300$) completion response rate was obtained.

4. Data Analysis and Results

Study surveys and biological samples were labeled with a unique study identifier. Coded data files were kept separately from the code list to maintain anonymity. The Statistical Packages for Social Sciences (SPSS) was used for analysis. A probability of <0.05 was considered statistically significant. Descriptive and inferential statistics were calculated using the SPSS statistical package version 21.0 (SPSS Inc., Chicago, IL, USA). A normality test and multicollinearity checks were performed. The determinants of QoL were assessed with ANOVA and multivariate generalized linear model (GLM)/MANOVA [45–48]. Predictors were determined for MANOVA using important determinants from ANOVA [47].

4.1. Demographic and Clinical Characteristics (Table 1). The highest percent of Omani men was between 50–59 years (40.6%) as compared to 21.7% among the women (Table 1). The highest frequency of adherence to self-care activities was an average of three days/week among men (61.5%) and women (60.5%). A higher percentage of the men (62.2%) had poor HbA1c values as compared to women (46.5%).

For men, 30.1% reported that T2D mostly prevented their activities of daily living as compared to 26.8% reported among the women. Nearly half percentage of the women (53.5%) and men (50.3%) had moderate ability to manage diabetes positively. More women (79.6%) were on prescribed oral hypoglycemic agents as compared to men (70.6%); while the remaining participants were on insulin.

4.2. Predictors of QoL and Health State among Men and Women (Tables 2–5). Women had slightly higher mean QoL scores ($p < 0.05$) for age, schooling, prevention of activities of daily living, ability to manage positively, and knowledge of diabetes and its management as compared to men (Table 2). Women had higher mean health state scores for age and prevention of activities of daily living and knowledge of diabetes and its management as compared to men. Schooling and ability to manage positively were highly significant predictors of QoL among women ($p < 0.05$) as compared to men. Age, prevention of activities of daily living and knowledge/management of diabetes were significant predictors of Health state among women as compared to men. Ability to manage diabetes positively was a significant predictor of health state among men as compared to women.

Schooling and ability to manage diabetes positively were significant with QoL among women; while age, prevention of activities of daily living, and knowledge of diabetes and management were significant with health state among women as compared to men (Table 2). Ability to manage diabetes positively was significant with health state among men compared to women.

Women had higher mean QoL scores for duration of diabetes, diabetes education, and medication as compared to men (Table 3). Positively higher perception on health state scores was found with duration of diabetes, SCA, diabetes education, medication, BMI, and HbA1c among women. SCA and medication were highly significant predictors of health state among women; while BMI was highly significant among men. SCA and medication were significant with health state among women; while BMI was significant with health state among men (Table 3). In this study, quality of life and health state were interdependent variables. MANOVA models were used with all determinants emerging from the ANOVA tests as predictors of QoL and health state (Tables 2–5). These personal and clinical characteristics interact with the specific domains valued as important in life, which explains the significant differences in QoL and health state among Omani men and women.

A further GLM technique was useful to explore the relationship between QoL and health state, interdependent variables with the predictors (like age and duration of diabetes) as seen in Tables 4 and 5. The combined effect of predictors on QoL and health state using Wilks's lambda multivariate

Table 1: Personal and clinical characteristics among Omani men and women ($N = 300$).

Number	Variables	Categories	Men $N = 143$		Women $N = 157$	
			Frequency	Percent	Frequency	Percent
1	Age (years)	30–39	18	12.6	29	18.5
		40–49	39	27.3	64	40.8
		50–59	58	40.6	34	21.7
		60 & above	28	19.6	30	19.1
2	Schooling	Until 8th grade	35	24.5	59	37.6
		High school	59	41.3	58	36.9
		Diploma	48	33.6	38	24.2
		Technical	1	0.7	2	1.3
3	Knowledge of diabetes and its management	Poor	14	9.8	2	1.3
		Fair	11	7.7	14	8.9
		Satisfactory	26	18.2	25	15.9
		Above average	22	15.4	43	27.4
		Good	55	38.5	51	32.5
		Very good	14	9.8	16	10.2
		Excellent	1	0.7	6	3.8
4	Duration of diabetes	0–9	57	39.9	55	35.0
		10–19	67	46.9	77	49.0
		20 & above	19	13.3	25	15.9
5	Self-care activities (SDSCA)	0–3 days/week	88	61.5	95	60.5
		4–7 days/week	55	38.5	62	39.5
6	Diabetes education	No	50	35.0	65	41.4
		Yes	93	65.0	92	58.6
7	Body mass index (kg/m^2)	<18.5/Underweight	4	2.8	4	2.5
		18.5–24.9/Healthy weight	96	67.1	106	67.5
		25.0–29.9/Overweight	43	30.1	47	29.9
8	HbA1c (%)	<7.0%	54	37.8	84	53.5
		>7.0%	89	62.2	73	46.5

tests (Table 4) shows duration of diabetes, prevention of activities of daily living, and ability to manage positively were significant predictors of QoL and health state among men as compared to women.

The test of overall model significance (Table 5) showed the model is important for each dependent variable (QoL and health state). MANOVA models were used with all independent variables in the ANOVA tests as predictors of QoL and health state (Table 5). MANOVA results are explained with the test of overall model significance and the test of overall individual effects of predictors. Among women with T2D, 30.6% of the variance in the total QoL and 14% of the variance in health state could be explained by personal and clinical characteristics (Table 5), while 35.7% of the variance in the total QoL and 23% of the variance in health state was explained by personal and clinical characteristics among men. These R^2 values indicated a supportive relationship among the predictors of QoL and health state. QoL and health state scores were strongly correlated with the age, diabetes duration, and prior diabetes education. Hence, personal and clinical characteristics had a significant positive effect on QoL and health state supporting the self-care diabetes management model.

"Tests of between-subjects effects" (Table 5) apply an F test of significance to the relation of each covariate (age, diabetes duration, SCA, diabetes education, ability to manage positively, and BMI) in relation to each of the dependent variables (QoL and health state). Age and diabetes education were significant predictors of QoL, and SCA was a significant predictor of health state among women as compared to men. Duration of diabetes, diabetes education, ability to manage diabetes positively, and BMI were significant predictors of health state among men as compared to women.

5. Discussion

Higher schooling, increased ability to manage diabetes, higher age, moderate level of prevention of activities of daily living, higher knowledge of diabetes and management, higher SCA, and use of medication among women influenced their QoL and health state as compared to men. This state contributed to an increased QoL and health among women as

Table 2: Personal characteristics and total QoL and health state among men and women.

Determinants	Categories	Men's QoL		Women's QoL		Men's health state		Women's health state	
		Mean	Sig/p	Mean	Sig/p	Mean	Sig/p	Mean	Sig/p
Age	30–39	12.22	0.000*	12.38	0.000*	69.44	0.523	76.38	0.000*
	40–49	10.05		10.45		69.36		67.34	
	50–59	8.93		8.50		70.09		73.09	
	60 & above	9.29		8.73		66.61		66.33	
Schooling	Until 8th grade	9.89	0.482	9.85	0.002*	67.86	0.425	70.76	0.895
	High school	9.90		11.07		70.68		69.66	
	Diploma	9.35		8.84		68.02		69.47	
	Technical	11.00		10.00		75.00		72.50	
DM prevents activities of daily living	Never	12.17	0.000*	10.24	0.000*	74.17	0.291	73.33	0.036*
	Rarely	11.12		11.60		66.52		65.83	
	Sometimes	10.29		12.29		66.43		71.79	
	Moderately	8.68		9.00		70.36		69.32	
	Mostly	9.00		8.38		68.95		71.07	
	Always	8.75		9.25		70.00		75.00	
	Everyday	0		11.00		0		70.00	
Ability to manage positively	Poor ability	9.22	0.590	10.46	0.058*	65.00	0.006*	65.77	0.346
	Moderate ability	9.88		9.80		67.01		70.36	
	Good ability	9.61		10.57		72.18		70.89	
	Excellent ability	0		7.00		0		66.25	
Knowledge of DM and its management	Poor	10.86	0.001*	8.00	0.003*	72.50	0.296	82.50	0.050*
	Fair	11.45		11.64		64.09		71.43	
	Satisfactory	9.58		11.16		68.27		65.20	
	Above average	9.73		9.00		68.18		70.47	
	Good	8.96		9.69		69.45		71.47	
	Very good	10.43		10.38		70.36		68.13	
	Excellent	10.00		12.33		85.00		73.33	
	Total	9.72		10.06		69.13		70.06	

$^*p < 0.05$ is the level of significance (sig).

they overcome challenges in coping with T2D. Results of the study were congruent with previous studies [49, 50] that show better self-care leads to improved QoL. In this study, men with T2D had low QoL which was consistent with a previous study [51].

In middle aged women, perceived diabetes did not prevent their activities of living, and they showed above average knowledge and management of diabetes. A strong effect was found for interactions between females and QoL due to higher schooling and ability to manage diabetes positively; while higher age, prevention of ADL, and knowledge/management of diabetes were significant with health state among women. SCA, diabetes education, and medication significantly predicted health state among women. Better physical activity among women contributes to higher QoL and had better understanding of their diabetes. These findings were consistent with other studies [52] that show younger age [53], education [54], longer duration of DM, fasting glucose levels [55], strong knowledge [56], and positive attitude [57–59] had significantly explained higher QoL scores.

Men had consistently lower QoL for all domains compared to women. Poor QoL can prevent men with T2D from achieving improved glucose control. Specific elements like ability to manage positively and BMI influenced QoL and health state among men as compared to women. In turn, low QoL affects HbA1c. Hence, better HbA1c and SCA are major predictors of QoL and health state. Independent predictors can have a contradictory effect on different aspects of QoL. Some studies show that men can experience more restrictions in daily life than women due to unexplained physical and emotional problems [57, 60].

An important finding is an impact of higher ability to manage diabetes positively and prevention of prevents activities of daily living that significantly predicted QoL; while BMI significantly predicted health state among men. The effects were stronger for those with high school and diploma level education and longer duration of diabetes, prevention

Table 3: Clinical characteristics and total QOL and health state among men and women.

Variables	Categories	Men QoL		Women QoL		Men health state		Women health state	
		Mean	Sig/p	Mean	Sig/p	Mean	Sig/p	Mean	Sig/p
Duration	0–9	8.81	0.000*	8.98	0.002*	70.70	0.013*	70.00	0.001*
	10–19	10.15		10.73		69.55		72.14	
	20 & above	10.95		10.36		62.89		63.80	
Self-care activities	0–3 days/week	9.80	0.589	10.02	0.848	69.94	0.226	68.68	0.035*
	4–7 days/week	9.60		10.11		67.82		72.18	
Prior diabetes education	No	10.46	0.002*	10.58	0.056*	66.70	0.036*	67.15	0.002*
	Yes	9.32		9.68		70.43		72.12	
Medication	OH	10.09	0.002*	10.40	0.003*	69.55	0.686	70.04	0.003*
	Insulin	9.03		8.72		68.44		70.16	
	OH and insulin	8.20		0		67.00		0	
Body mass index (kg/m^2)	<18.5/Underweight	9.75	0.875	10.00	0.885	66.25	0.007*	76.25	0.390
	18.5–24.9/Healthy weight	9.78		9.98		67.45		70.24	
	25.0–29.9/Overweight	9.58		10.23		73.14		69.15	
HbA1c	<7%	9.52	0.371	9.76	0.174	69.54	0.708	70.95	0.241
	>7%	9.84		10.40		68.88		69.04	

* $p < 0.05$ is the level of significance (sig).

Table 4: Combined effect of predictors on QoL and health state: multivariate tests/GLM.

Wilks's lambda		Men			Women	
Effect	Value	F	Sig./p	Value	F	Sig./p
Intercept	0.586	45.957	0.000*	0.607	46.602	0.000*
Age	0.965	2.391	0.050*	0.804	17.581	0.000*
Schooling	0.995	0.307	0.736	0.996	0.300	0.741
Years of diabetes	0.927	5.155	0.007*	0.977	1.706	0.185
Self-care activities	0.996	0.252	0.778	0.974	1.950	0.146
Diabetes education program	0.937	4.340	0.015*	0.961	2.892	0.050*
DM prevents activities of daily living	0.898	7.365	0.001*	0.983	1.235	0.294
Ability to manage positively	0.953	3.210	0.044*	0.998	0.112	0.894
Knowledge of diabetes/management	0.995	0.306	0.737	1.000	0.034	0.966
Medications	0.981	1.249	0.290	0.993	0.528	0.591
Body mass index	0.926	5.176	0.007*	0.968	2.377	0.050*
HbA1c	0.993	0.428	0.653	0.988	0.877	0.418

* $p < 0.05$ is the level of significance (sig).
Design: intercept + age + schooling + duration of diabetes + self-care activities + diabetes education program + perceiving DM prevents activities of daily living + ability to manage positively + knowledge of diabetes and its management + medications + BMI + HbA1c.

of activities of daily living, ability to manage positively, and body mass index which were significant determinants among men. Some men have more self-confidence in their ability to manage diabetes and are less likely to be depressed or anxious. Hence, good knowledge and a positive attitude are predictors of adherence to self-care and promote QoL. Men with higher educational levels, strong knowledge, and positive attitude had a higher probability of attaining greater QoL scores [56]. Age [61], psychological perception, SCA, HbA1c, and lower levels of physical activity [62] were significantly associated with higher QoL among men.

The most striking difference was that women had higher QoL scores and health state for higher age and low BMI and adhered better to oral medications and SCA. This finding reflects the inclination of women with higher education to participate in their own self-care. Age, duration of diabetes, diabetes education, and ability to manage diabetes had higher QoL and health state among men. Hence, chronicity of T2D has a differential impact on QoL and health state among women and men. Patients of both genders with lower HbA1c values were shown to have better QoL [63]. Similar studies show high BMI is a strong predictor of decreased QoL [57, 64] and lower BMI was associated with higher QoL [65]. Insulin and higher BMI were associated with lower QoL [33, 61, 63]. QoL and health state scores were lower in women compared with men and lower with longer duration of T2D [54]. HbA1c

Table 5: Overall model significance and tests of between-subjects effects.

Source	Dependent variable	Men			Women		
	Outcomes	Mean Square	*F*	Sig./*p*	Mean Square	*F*	Sig./*p*
Corrected model	QoL	20.219	6.615	0.000	36.888	5.822	0.000
	Health state	307.235	3.550	0.000	204.893	2.146	0.021
Intercept	QoL	152.364	49.849	0.000	184.703	29.152	0.000
	Health state	3067.884	35.452	0.000	5790.067	60.638	0.000
Age	QoL	0.798	0.261	0.610	181.721	28.681	0.000*
	Health state	376.955	4.356	0.039*	524.830	5.496	0.020*
Schooling	QoL	0.509	0.166	0.684	0.012	0.002	0.966
	Health state	42.830	0.495	0.483	57.694	0.604	0.438
Years of diabetes	QoL	16.577	5.424	0.021*	20.945	3.306	0.050*
	Health state	501.693	5.798	0.017*	18.774	0.197	0.658
Self-care activities	QoL	0.750	0.245	0.621	4.686	0.740	0.391
	Health state	19.141	0.221	0.639	290.368	3.041	0.05*
Diabetes education	QoL	5.044	1.650	0.201	18.808	2.968	0.05*
	Health state	658.313	7.607	0.007*	298.142	3.122	0.050*
DM prevents activities of daily living	QoL	43.917	14.369	0.000*	9.693	1.530	0.218
	Health state	12.687	0.147	0.702	102.130	1.070	0.303
Ability to manage positively	QoL	1.641	0.537	0.465	0.253	0.040	0.842
	Health state	485.729	5.613	0.019*	18.416	0.193	0.661
Knowledge of diabetes and its management	QoL	1.706	0.558	0.456	0.045	0.007	0.933
	Health state	2.853	0.033	0.856	5.747	0.060	0.807
Medications	QoL	7.523	2.461	0.119	0.206	0.033	0.857
	Health state	1.027	0.012	0.913	99.743	1.045	0.308
Body mass index	QoL	0.014	0.005	0.946	15.544	2.453	0.119
	Health state	893.502	10.325	0.002*	243.893	2.554	0.112
HbA1c	QoL	2.173	0.711	0.401	10.261	1.620	0.205
	Health state	17.990	0.208	0.649	18.486	0.194	0.661

Generalized linear model: * $p < 0.05$ is the level of significance (sig). Computed using alpha = 0.05.
Men: QoL $R^2 = 0.357$ (adjusted $R^2 = 0.303$); health state $R^2 = 0.230$ (adjusted $R^2 = 0.165$).
Women: QoL $R^2 = 0.306$ (adjusted $R^2 = 0.254$); health state $R^2 = 0.140$ (adjusted $R^2 = 0.075$).

and QoL have a significant association in previous studies [66, 67]. Higher age, income, and education had better QoL among women [56, 61, 67, 68]. Men and women who have good health have significant health states with T2D [52, 69].

The study limitations are interactive effects of psychological and clinical predictors that may be relevant for comprehensive understanding of the impact on the domains of health-related QoL among men and women.

6. Conclusions

The amount of variance influenced by the personal and clinical factors and explained in the GLM is useful in understanding how HRQoL influences Omani men and women. Poor glycemic control increases the risk of developing long term complications of T2D, which causes poor health state and QoL. Maintaining HbA1c within a desirable range is an indicator of good glycemic control and was a contributor to better QoL.

The assessment of QoL and health state is a key component of the self-care management model (Figure 1). This assessment is culturally specific and may assist in early identification to allow for appropriate self-care among individuals with T2D who are at risk for decreased QoL. This study gives useful information to help design appropriate culturally specific interventions related to various aspects of QoL [70]. The SCM model approach indicates that adults need to use their self-care behaviors for goal attainment and to take control of T2D, thus enhancing HRQoL.

This study provides important QoL evidence that may help the diabetes nurse educator (DNE) to identify adults who are at risk of low QoL and develop interventions for healthy lifestyle behaviors based on personal needs, clinical characteristics, and health state. The DNE can educate assist in motivating the patient with T2D to control blood glucose levels, have an annual screening examination, report any changes in health immediately, and engage in rigorous SCM. An effective SCM model empowers men and women in proactively managing T2D and finding ways to overcome the problems with mobility, usual care, self-care, anxiety, and pain. SCM interventions by the DNE should be tailored to the individual taking into account personal needs and motivation to change as well as clinical factors that influence better QoL (Figure 1). The nurse as an educator has an opportunity to positively influence outcomes (QoL and health state) by using effective behavioral skills and a collaborative health care approach.

Summary Box

(1) What does this paper contribute to the community? Women had higher mean QoL scores for age, schooling, prevention of activities of daily living, ability to manage positively, and knowledge of diabetes and its management.

(2) Women had higher mean health state scores for age and perceiving DM prevents activities of daily living and knowledge of diabetes and its management.

(3) Age, duration of diabetes, diabetes education, self-care activities, ability to manage diabetes positively, and BMI were significant predictors of QoL and health state among women and men.

Conflict of Interests

There are no organizations or communities with conflict of interests or coveting interests related to the study. The co-authors declare that they have no competing interests.

Authors' Contribution

Melba Sheila D'Souza, Ramesh Venkatesaperumal, and Subrahmanya Nairy Karkada provided substantial contributions to conception and design, acquisition of data, and analysis and interpretation of data. Ramesh Venkatesaperumal, Melba Sheila D'Souza, Susan D. Ruppert, and Devakirubai Jacob participated in drafting the article and revising it critically for important intellectual inquiry. All the authors agreed on the final version of the paper to be published.

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Review Article

Working Together to Promote Diabetes Control: A Practical Guide for Diabetes Health Care Providers in Establishing a Working Alliance to Achieve Self-Management Support

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The quality of the "patient-carer" relationship is the foundation of self-management support and has been shown to influence treatment outcome in relation to psychological and somatic illness, including diabetes. It has long been accepted within applied psychology that the quality of the client-therapist relationship—termed the *working alliance*—is of central importance to treatment outcome and may account for a significant degree of the overall treatment effect. Diabetes healthcare providers have recently expressed a need for further training in communication techniques and in the psychological aspects of diabetes. Could we take a page from the psychological treatment manual on *working alliance* in therapy to guide the diabetes healthcare provider in their role of supporting the person with diabetes achieve and maintain better metabolic control? This paper examines the role of the working alliance in diabetes care and offers a practical guide to the diabetes healthcare provider in establishing a working alliance with the person with diabetes in managing diabetes.

1. Introduction

Diabetes mellitus is a widespread chronic disease that has reached epidemic proportions globally [1]. The successful management of diabetes is contingent upon the person with diabetes' ability to achieve glycaemic control through adhering to a demanding daily treatment regimen consisting of taking medication, blood glucose testing, dietary and exercise behaviour, and so forth. Many people with diabetes find it difficult to adhere to the lifestyle- and behavioural- changes necessary to promote effective management of diabetes and are at an increased risk for burdensome complications such as nephropathy, neuropathy, retinopathy, amputation, cardiovascular disease, and other serious conditions.

Many of the behaviours that are required to improve health outcomes are identified by the healthcare provider who recommends and provides education regarding these behaviours to the person in their care. The person receiving care is then faced with the challenge of following-through on the recommendations. In terms of relational dynamics, making recommendations and providing education involve the healthcare provider adopting an expert role, with the person with diabetes typically adopting an uninformed help-seeker role. This relational dynamic is paternalistic in that the healthcare provider is the authority on the person's care and controls the care process, and the role of the person in care is to receive, understand, and follow the direction given. There is evidence to suggest that the quality of the communication between the person with diabetes and the healthcare provider has a strong impact on self-management and clinical outcomes such as A1c. For example, a cross-sectional analysis of almost 10.000 people with diabetes found significant and clinically meaningful relationships between poor communication with healthcare providers and difficulties taking medication, especially oral hypoglycemic medications [2]. Moreover, recent findings from the second Diabetes Attitudes Wishes and Needs (DAWN2) study revealed that only 24% of the people with diabetes surveyed (out of a total of 8596 participants) recalled being asked how diabetes affected their life [3]. The importance of the relationship dynamic between the healthcare provider and the person with diabetes can be appreciated when one considers the issue of motivation and barriers to change. For individuals who present with high motivation to change along with few barriers to change, recommendations and education might be sufficient to result in high adherence to diabetes management behaviours. In cases for which the motivation to change is limited and significant barriers to change are present, why would knowing what to do and how to do it overcome these challenges?

While recommendation- and education-based strategies can be effective in promoting self-management behaviours, the degree of efficacy is often contingent upon third factor variables. For instance, a person's ambivalence to following rigorous treatment recommendations (perhaps due to the burden of maintaining self-care behaviours) as well as the emotional reaction from the appraisal of the meaning and consequences of the recommendations (for example: I do not have the resources to cope with or manage such a change and I am feeling very stressed) can impact on decision-making and self-management [4, 5]. Moreover, there is consistent evidence demonstrating that knowledge alone is insufficient in achieving behaviour change in relation to diabetes self-management [6, 7]. It has also been shown that the interpersonal aspects of communication in diabetes care, such as involvement in decision-making (e.g., the tasks to be performed) and goal setting (e.g., the agreed outcomes), are valued more highly by the person with diabetes than passive acquisition of information [8]. This way of thinking shifts the dynamic of the relationship between the healthcare provider and the person with diabetes from one of paternalism, to one of collaboration, through empowering the person with diabetes to retain their autonomy (sense of control) throughout the care process [5]. Moreover, such participatory approaches have been shown to improve treatment outcomes, such as greater change in personal responsibility for diabetes [9] and improvements in A1c levels and end-organ complications [10]. Communication, therefore, is more than just the transfer of information or skills from one person to another, but a relationship that can impact on how the person with diabetes relates to and engages in their diabetes care.

A person with diabetes' commitment to follow treatment recommendations is partly affected by appraisals regarding the health-care provider's perceived characteristics, such as trustworthiness, integrity, and supportiveness [11]. As such, poor communication may not only produce deficits in knowledge acquisition and consequently the person with diabetes' ability to make informed choices regarding diabetes care, but may also lead the person receiving care to attribute negative characteristics (e.g., unsympathetic) to the caregiver that may obstruct or corrode the "person with diabetes-healthcare provider (PWD-HCP) relationship." It has long been understood that common factors in psychotherapy (factors not specific to any mode of treatment) such as the client-therapist relationship are of central importance to treatment outcome [12–14]. Common factors may account for up to 45% of the treatment effect across many different psychological conditions [15]. In other words, the specific technique(s) of any psychological intervention only accounts for a portion of the overall treatment effect. Common factors are a ubiquitous part of any interpersonal communication and a component of the professional relationship, whether one is aware of it or not. Psychologists use their understanding of common factors in working with clients to increase the likelihood of helping the client achieve their treatment goals. Focus on common factors, especially the *working alliance*, has become standard practice in applied psychology.

Healthcare providers have recently expressed a need for further training in communication techniques and in the psychological aspects of diabetes [16]. Could we take a page from the psychological treatment manual on common factors in therapy to guide the diabetes healthcare provider in their role of supporting the person with diabetes achieve and maintain better metabolic control? The aim of this paper is to examine the potential role of the working alliance in diabetes care and to offer a practical guide to the diabetes care provider in establishing a PWD-HCP working alliance in managing diabetes.

1.1. Working Alliance in Diabetes Care. Common factors in treatment include the person with diabetes' expectations in regard to treatment outcome, beliefs regarding the efficacy of the interventions applied (whether pharmacological, psychological, or other), and the quality of the PWD-HCP relationship, termed the working alliance [15, 17]. When adopting a common factors approach, how the healthcare provider interacts with the person with diabetes is as important as any specific behavioural or biomedical intervention used; that is, the focus is not just on *what* we do but also on *how* we do it. Working alliance is perhaps the best empirically supported common factor in relation to treatment outcome [14, 17–19]. In the context of diabetes management, working alliance can be understood as the collaborative effort between the person with diabetes and the healthcare provider to manage diabetes and prevent further complications, while also trying to reduce the psychological burden that the sustained and arduous management of diabetes can induce. The working alliance between the person with diabetes and the healthcare provider can be divided into three components (based on the working alliance model by Bordin, [20]).

(1) Tasks. The cooperative component of the professional relationship encompasses the agreed upon treatment based activities such as measuring blood glucose levels, adjusting insulin doses, taking oral medications, eating more healthily, and maintaining an active lifestyle. Lack of motivation to change often reflects a lack of task alliance between the person with diabetes and the healthcare provider.

(2) Goals. The cooperative component of the professional relationship encompasses the agreed upon aims or outcomes

of the treatment such as good glycaemic control, lower blood pressure, and low LDL cholesterol, achieving or maintaining a healthier weight. Lack of a goal alliance might be reflected in a case where the person with diabetes wants to live a lifestyle as close to their prediabetes lifestyle as possible (what the person with diabetes describes as being "normal"), while in contrast the healthcare provider wants the person with diabetes to actively engage in diabetes tasks to improve A1c levels. Moreover, lack of goal alliance often results from the healthcare provider focusing near-exclusively on A1c as the main outcome, while the person with diabetes may struggle to understand and make A1c personally relevant, instead focusing on quality of life issues.

(3) Bond. The emotional and value-based component of the professional relationship encompass affective appraisals such as trust, warmth, empathy, and acceptance. If the bond alliance is lacking, the person with diabetes might perceive the healthcare provider as judgemental and/or lacking in understanding.

Although there is strong empirical support for the beneficial effects of the working alliance in the psychological research literature [21], very little is known about the role of working alliance in the context of chronic physical illness, including diabetes care. Working alliance has been found to be significantly associated with more optimal treatment adherence to and greater satisfaction with treatment in a sample of 118 patients diagnosed with a chronic medical illness including diabetes [22] and significantly associated with treatment adherence in people with diabetes [23, 24]. In studies by Attale et al. [25] and Viinamäki et al. [26] working alliance was also found to have a significant positive association with metabolic control in people with type 1 diabetes. Thus, when a good level of collaboration (shared tasks and goals) and a strong bond are established, the active ingredient of the intervention (pharmacological, psychological, or educational) may increase in efficacy through an increase in treatment self-management or through other treatment related factors. In other words, a good working alliance can be understood as a "conditio sine qua non" to effective treatment outcome. Strains or breaks in the working alliance could lead to less optimal self-care behaviours and suboptimal glycaemic control (see Figure 1 for a conceptual model of working alliance in diabetes care). As such, the potential contribution of the working alliance merits serious attention in diabetes care. How then does the healthcare provider establish a good working alliance with the person with diabetes?

1.2. Building a Working Alliance. The example below describes how a dialogue between a healthcare provider and a person diagnosed with type 2 diabetes displaying ambivalence in regard to treatment related behaviour change could develop in building a working alliance.

HCP: Perhaps today, in addition to reviewing your glucose levels, we could also focus on other things important to you in regards living with and managing your diabetes. (The HCP modifies the usual treatment agenda to negotiate a collaborative relationship. Note: prioritising the rigid application of the technique or treatment protocol over the PWD's unique needs is an incomplete care approach, which can result in a strained alliance and poor treatment outcome [12].)

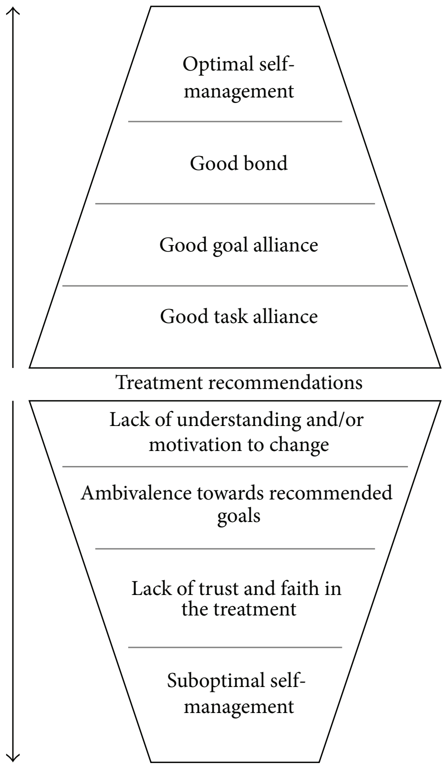

Figure 1: Conceptual model of the role of working alliance in diabetes care.

PWD: That would be great. I know I'm not the best patient. . . I cannot seem to stick to the recommended diet.

HCP: Would you consider being less hard on yourself? It's not easy to change habits, and I am here to help (here the HCP is communicating an understanding of the patient's situation and signalling that "we" (see Frishman [27]) are working together towards achieving the treatment goals [Bond]).

PWD: I just cannot seem to stay away from junk-food, even though I know it's bad for me. . .and if I continue down this path I know things are only going to get worse.

HCP: You are worried about things getting worse. Are there things we could change to avoid things from getting worse? (The *task* is to regulate diet, the *goal* is to stop "things getting worse").

Working alliance in the medical setting can be measured using a reworded short client version (to reflect the medical relationship—see Fuertes et al. [22]) of the Working Alliance Inventory (WAI-12: [28, 29]). The WAI contains 12 items, measured on a 7-point scale, and includes three subscales: *tasks*, items that measure the degree to which patient and provider agree on the actions to be carried out in the treatment process; *goals*, items that measure the degree to which patient and provider agree on what is to be achieved through following the treatment regimen; and *bond*, items that measure the degree of trust, acceptance, and belief in the healthcare provider's recommendations. The WAI-12 has been found to have acceptable psychometric properties when used as an overall (single factor) measure of the patient-provider working alliance [22].

Empathy towards the person with diabetes is arguably one of the most important evidence-based factors in the PWD-HCP relationship [30–32]. Empathy is similar in many respects to other interpersonal constructs such as warmth and acceptance and has a supportive function. However, empathy also involves the ability and the willingness of the healthcare provider to understand the person with diabetes' unique situation, to identify (*Ask*) and understand (*Listen*) how the person with diabetes sees and feels things [5] and to communicate this understanding when interacting with the person with diabetes (*Summarise*) [30–33]. The ability of the healthcare provider to communicate empathy is not only linked to the onset and maintenance of the PWD-HCP bond (the affective component of the relationship) but also contributes to establishing consensus on the tasks and goals to be included in the treatment process through a communicated understanding of the person with diabetes' unique situation [30, 31]. Empathy, as expressed using the *Ask*, *Listen*, and *Summarise* approach, then empowers the healthcare provider to *Invite* the person with diabetes to consider new information, such as specific diabetes management strategies. *Ask*, *Listen*, *Summarise*, and *Invite* is a relational dynamic that takes advantage of the principle of relational complementarity [34, 35], referring to the circumplex model of relationship functioning, in which affiliative behaviours are likely to be reciprocated. In other words, the best way to encourage someone to listen to you is to first listen to them.

Reach [5] describes empathy in this context as helping the person with diabetes to elucidate their preferences in relation to the treatment process. Although there are numerous studies showing a positive association between therapist-empathy and good treatment outcome in the psychotherapy literature [30, 31], studies examining this association in relation to diabetes care are scarce. However, a study by Hojat et al. [36] found that healthcare providers measuring high on levels of empathy had a significantly higher proportion of individuals in their care displaying good control of A1c (16%) and low-density lipoprotein cholesterol (15%) compared to healthcare providers with low empathy scores. Similar findings were also reported in a study by del Canale et al. [37], with significantly lower rates of metabolic complications (hyperosmolar state, diabetic ketoacidosis, and diabetic coma) found in patients of physicians measuring high in empathy compared to patients of physicians with moderate and low empathy. Communicating empathy is therefore an important component in diabetes care. The example below describes how a dialogue between a healthcare provider and a person with type 1 diabetes who has a fear of hypoglycaemia could develop in communicating empathy.

1.3. Expressing Empathy through Verbal Communication

PWD: I'm really worried that if I stay within the range you recommend that I may go low. . . and then I do not know what might happen.

HCP: Sounds like you are feeling anxious about taking your insulin as recommended, as this may lead to a severe hypo.

PWD: Yes. . . or worse. I have children and a husband. I've called in sick to work twice already this year. I'm worried about getting fired, and my family depend on me.

HCP: You are afraid something negative might happen to you, and that your family will be left to fend for themselves. I can see how that makes you reluctant to increase your dose of insulin.

PWD: Yes (tearfully).

Elliott et al. [31] have come up with recommendations on how to build a client-therapist relationship based on empathy. Based on these recommendations the following points of guidance in building a working alliance with the person with diabetes are offered. (1) Try to step into the person with diabetes' shoes and to understand the *how* and the *why* of the person's experiences, as well as communicating this understanding back to the person with diabetes (see the above example). (2) Showing an understanding of events from the person with diabetes' viewpoint does not mean simply repeating or reframing what the person says but trying genuinely to understand the individuals' perspective, motivations, and concerns in the moment. (3) Communication is both verbal and nonverbal, and coldness or warmth can be easily communicated both verbally and nonverbally. A genuine interest in the person with diabetes' psychological wellbeing and in understanding their experiences can be perceived by the person, even if not yet expressed verbally. (4) Do not easily assume that you correctly understand the person with diabetes' views or that they share your views. Communicating with a certain degree of uncertainty allows the person with diabetes to provide corrective feedback (e.g., well. . .not really. . .it's more like. . .). Also, do not assume that the person with diabetes understands you, even if they appear to understand. Finally, do not assume that because you understand the person with diabetes that the person feels understood.

Empathy in the medical setting can be measured using the Jefferson Scale of Empathy—Health Professional (JSE-HP [38]). The JSE-HP contains 20 items, measured on a 7-point Likert scale, with higher scores indicating the ability of the healthcare provider to communicate in an empathic way when interacting with the person in their care. For example, "*Health care providers should try to stand in their patients' shoes when providing care to them.*" The JSE has been found to have acceptable psychometric properties in measuring empathy in healthcare providers [38–41].

Potential barriers to healthcare providers focusing on developing *bond*, *task*, and *goal* alliance are that it is time-consuming and might elicit distress in the healthcare provider when they begin to understand the intensity of the burden that diabetes might convey on a person. While these barriers are understandable in a busy biomedically oriented practice, our experience in training healthcare providers in these methods is that these barriers resolve themselves over time. That is, after the 10th or 20th person with diabetes in which these methods are used, most healthcare providers start to value the time spent on forming a working alliance and see it as time well invested. Once a person's story is understood, that story tends to carry itself forward in time (i.e., the story only has to be told once) and the agreed upon tasks and goals based on this understanding tend to be more realistic for the person with diabetes.

2. Summary

The aim of this paper is to empower the diabetes healthcare provider to better support individuals with diabetes in managing their blood glucose levels through understanding the importance of the working alliance in diabetes care. There are always limitations to any treatment approach and some people with diabetes will continue to experience difficulty in managing their diabetes irrespective of the strength of the working alliance or the therapeutic approach used. By adopting a common factors approach, the healthcare provider will be better equipped to support the person with diabetes in living with and managing their diabetes. Communication based on empathy is likely to act as a catalyst for improved treatment self-management and the adoption of behaviors that facilitate change and lead to increased wellbeing in the person with diabetes. Corrosion in the working alliance and/or low empathy in the communication between the healthcare provider and the person in their care may lead to increased risk of disengagement from treatment and poorer metabolic control for the person with diabetes.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Research Article

The Impact of an Internet-Based Self-Management Intervention (HeLP-Diabetes) on the Psychological Well-Being of Adults with Type 2 Diabetes: A Mixed-Method Cohort Study

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This mixed-method study assessed the impact of an internet-based, self-management intervention ("HeLP-Diabetes") on the psychological well-being of adults with type 2 diabetes. Nineteen participants were recruited from 3 general practices. Data were collected at baseline and at 6 weeks follow-up. Access to HeLP-Diabetes was associated with a significant decrease in participants' diabetes-related distress ($Z = 2.04$, $p = 0.04$, and $d = 0.28$). No significant differences were found in emotional distress or self-efficacy. The qualitative data found that participants reported improvements including increased self-efficacy and support, better management of low mood, greater diabetes awareness, and taking the condition more seriously. Participants also reported making improvements to their eating habits, exercise routine, and medical management. Some negative experiences associated with using the intervention were mentioned including feelings of guilt for not using the intervention as suggested or not making any behavioral changes, as well as technical and navigational frustrations with the intervention. Internet-based self-management interventions may have the potential to decrease diabetes-related distress in people with type 2 diabetes. The qualitative data also suggests internet interventions can positively impact both psychological and behavioural outcomes of adults with type 2 diabetes.

1. Introduction

Type 2 diabetes is a complex and challenging condition affecting around 2.5 million people in the UK [1]. People with diabetes are more likely to develop heart disease, kidney failure, and blindness and to die prematurely than people without diabetes [2]. The risk of developing many of these problems can be reduced if people with type 2 diabetes are given the knowledge and skills to self-manage their condition. This involves making substantial behavioural and lifestyle changes [3]. However the psychological burden of living with diabetes can create significant barriers to managing these demands and achieving treatment goals [4, 5]. If a person is overwhelmed by the changes that need to be made, one response may be to deny the condition, which may lead to a reduction in knowledge, awareness, and skills needed to manage their diabetes [6]. Numerous studies have found that the prevalence of psychological difficulties such as anxiety and eating disorders is higher in people with diabetes than the general population [7, 8]. The prevalence of depression is approximately twice as high [9]. Poor psychological well-being in people with diabetes is associated with suboptimal glycaemic control and increased risk of complications [8, 10]. It is also associated with lower medication adherence, greater difficulties managing medical care, and lost productivity [11]. These findings highlight the importance of improving psychological wellbeing in people with type 2 diabetes in order to facilitate diabetes self-management [12, 13].

Structured education is known to promote self-management and reduce the incidence of diabetes complications [14] as well as improving emotional well-being, quality of life, and diabetes self-efficacy and clinical outcomes such as glycaemic control [15–17]. Examples of existing group-based self-management programmes for people with type 2 diabetes in the UK include DESMOND, X-PERT, and Co-Creating Health. Although these programmes have shown initial benefits [18, 19], there are concerns that benefits may not be sustained in the long term [20]. There are additional concerns that group-based programmes such as these may not suit all patients who need self-management training. People who work, have caring responsibilities at home, who have mobility problems, or who find group interactions difficult may all have difficulty attending. Thus there is an urgent needed to find cost-effective and acceptable methods of delivering sustainable self-management education for people with type 2 diabetes in the UK. In addition, although in 2008 the National Institute of Health and Clinical Excellence (NICE) advised that a key priority for implementation was the offer of structured education to every patient and/or their carer at the time of diagnosis with diabetes with annual reinforcement [21], only a minority of patients report being offered (less than 9%) or receiving (less than 4%) such education [22]. This suggests that health care providers are encountering difficulties implementing and resourcing quality education programmes.

One possible solution to this problem and a potentially alternative and acceptable means of delivering cost effective self-management education is the use of internet-based self-management interventions. Advantages to such interventions 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 [23]. Online support groups 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 [24]. Computerised Cognitive Behavioural Therapy (CCBT) has also been found to reduce anxiety and depression [25]. Also, several studies have shown that diabetes specific internet-based self-management interventions can improve health behaviours, clinical outcomes, and psychological well-being [26–28].

The aim of the current study was to use a mixed-methods approach to explore the impact of using a newly developed internet-based self-management intervention called Healthy Living for People with type 2 Diabetes (HeLP-Diabetes) on the psychological well-being of adults with type 2 diabetes. The intervention was developed to target cognitions (e.g., self-efficacy, intentions, and goals); psycho-social factors (e.g., emotions such as anxiety, denial, and anger; changes in relationships); and behaviours (e.g., diet, physical activity, smoking, alcohol consumption, and taking medicines) thought to mediate clinical outcomes and health related quality of life outcomes. It was expected that using HeLP-Diabetes would therefore reduce participants' diabetes-related distress and anxiety and help participants to gain a greater sense of control and self-efficacy over their diabetes.

2. Methods

2.1. Study Design. This was a longitudinal cohort study using qualitative and quantitative methods. The quantitative aspect involved a pretest, posttest, and uncontrolled design, with data collected at baseline and 6-week follow-up via online questionnaires. The primary outcome was diabetes-related distress. Secondary outcomes were emotional distress and self-efficacy. Semistructured interviews were conducted at the same two data collection points.

2.2. Participant Recruitment and Procedure. Adults with type 2 diabetes were recruited from three general practices in London. Two practices were identified by the North Central London Research Consortium (NoCLor) and one through MH's previous professional relationship with them. The eligibility inclusion criteria for participants were (1) aged 18 or over, (2) diagnosis of type 2 diabetes, and (3) ability to access the internet. 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; (5) were concurrently participating in a trial of a different self-management programme; (6) were actively suicidal or severely depressed (score above 11 on HAD-D scale); and (7) were receiving psychological therapy or counselling at the same time as the study. Ethical approval was obtained from the National Research Ethics Committee North West, Greater Manchester North, UK.

Eligible participants were identified by a GP at each practice and with the participants' permission either referred to the researcher or sent a postal invitation to take part in the study where participants contacted the researcher if they would like to take part. From this 19 participants (6 women and 13 men) were recruited (6 from referral, 13 from postal invitations). They were invited to a baseline facilitation appointment with the researcher at the practice. At this appointment participants were taken through the participant information sheet and had the opportunity to ask any questions before signing a consent form. Participants who consented were 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. This was followed by a 30-minute semistructured interview to find out the participants' current difficulties with their diabetes and what they would like to get out of the HeLP-Diabetes website. At the end of the interview participants were emailed a link to a number of online questionnaires assessing the outcome measures. They were provided with a unique identification number to enter into the questionnaires and asked to complete this as soon as possible when they got home. Four of the participants asked to complete the questionnaire within the facilitation appointment. Participants were invited to attend a follow-up appointment after using the HeLP-Diabetes website for 6 weeks where they were given a 30-minute semistructured interview which explored whether the website had made any difference to the participants' psychological well-being and which parts of the website they found helpful or unhelpful. Afterwards they were emailed a link to complete the same set of online questionnaires as completed at baseline. The majority of participants completed these at their general practice rather than at home. During this time the researcher sat on the other side of the room, unable to see the computer screen in order to avoid experimenter bias.

The majority of patients (86%) were well-educated, having continued in education beyond A-levels, males (68%) and had been diagnosed with diabetes for more than 5 years (74%). Less than half identified as White British (42%). The ages of the participants ranged from 41 to 83 years, with a mean of 63.5 (SD = 10.7) years of age. Group and individual demographic, clinical, and self-rated previous computer experience can be found in Tables 1 and 2.

2.3. Intervention. HeLP-Diabetes is an internet-based self-management intervention that was developed over the course of 2 years (2011 to 2013) as part of a National Institute Health Research (NIHR) programme grant held by EM at University College London. The design of this complex intervention has been informed by theory and the needs and preferences of patients and health professionals [29]. It has been developed using a process of participatory design with users (people with T2DM and health professionals) heavily involved in the conception and creation. HeLP-Diabetes takes a holistic view of self-management and addresses a wide range of patient needs including education, lifestyle changes, medicine management, emotional management, social support with forums, and personal stories and also addresses how patients interact and work with health professionals. The components of the intervention are described in more detail in Table 3. The information provided on HeLP-Diabetes is based on NICE guidelines. Participants were asked to use the intervention at least once or twice a week for six weeks.

Participants all attended a facilitation appointment (see above for details) and were given a printed guide to using HeLP-Diabetes at home. Both were designed to improve user engagement with the intervention. They were also given the option of receiving weekly phone calls, texts, or e-mails from MH 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 intervention.

2.4. Data Collection. Participants were asked to complete quantitative outcome measures (diabetes-related distress, emotional distress, and self-efficacy) online through a system called Opinio [30] at baseline and at a six week follow-up. Qualitative outcome data was collected using semistructured

Table 1: Demographic and clinical characteristics of participants.

Variable	Mean (SD) or frequency (%)
Demographics	
Age (years)	63.5 (10.7), range 41–83
Gender	32% female 68% male
Ethnicity	
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%)
Highest level qualification	
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%)
Marital status	
Married	9 (47%)
Single	5 (26%)
Divorced	4 (21%)
Preferred not to state	1 (5%)
First language	
English	15 (79%)
Spanish	1 (5%)
French	1 (5%)
Swahili	1 (5%)
Mandarin	1 (5%)
Clinical	
Duration of diabetes	
0–6 months	1 (5%)
1-2 years	1 (5%)
2–5 years	3 (16%)
5–10 years	6 (32%)
10+ years	8 (42%)
Current or previous diabetes-related complications	
Yes	8 (42%)
No	11 (58%)
*Self-rated computer experience**	
Advanced	7 (37%)
Intermediate	7 (37%)
Basic	5 (26%)

* Advanced (e.g., work is to do with the Internet); intermediate (e.g., used or currently use the Internet regularly); basic (e.g., used the Internet a few times but not often).

Table 2: Individual demographic information for each participant.

Participant	Gender	Age	Ethnicity	Duration of diabetes	Previous or current complications	Self-rated previous computer experience*
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

*Advanced (e.g., work is to do with the Internet); intermediate (e.g., used or currently use the Internet regularly); basic (e.g., used the Internet a few times but not often).

interviews at baseline and 6-week follow-up. The interviews were audio recorded with participant's permission and transcribed verbatim.

2.5. Outcome Measures

2.5.1. Diabetes-Related Distress. The primary outcome was diabetes-related distress measured by the Problem Areas in Diabetes Scale (PAID [10]). 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 and 100, with higher levels indicating elevated emotional distress. A cut-off of 40 has been recommended to indicate significant levels of distress [31, 32]. The PAID has been widely used to evaluate alternate self-management interventions for people with type 2 diabetes [33], including internet-based self-management programmes [15]. It is an easy-to-administer instrument with high internal consistency [10], good validity, and responsiveness to change [34].

2.5.2. Emotional Distress and Self-Efficacy. Secondary outcomes included emotional distress evaluated by a 14-item Hospital Anxiety and Depression Scale (HADS [35]) where a lower score indicates less emotional distress and self-efficacy measured by the 15-item Diabetes Management Self-Efficacy Scale UK (DMSES UK [36]) where a higher score indicates higher self-efficacy.

2.5.3. Qualitative Thematic Analysis of Semistructured before and after Interviews. We developed interview guides to reflect the aims of the study. The interview at baseline asked questions about the participant's current difficulties with their diabetes and what they would like to get from the HeLP-Diabetes intervention. The interview at 6-week follow-up asked questions about whether the intervention had made a difference to participant's wellbeing and which parts of the intervention they found helpful or unhelpful.

2.5.4. Usage. Use of the intervention was defined as the number of logins to the site per participant, measured by google analytics. Participants were also asked to estimate how often they had logged in over the 6 weeks at the follow-up appointment.

2.6. Data Analysis

2.6.1. Sample Size Calculation. 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 [37, 38], it was calculated that a sample of 16, with an alpha

Table 3: HeLP-Diabetes module names and descriptions.

Module names	Descriptions
Understanding Diabetes Treating Diabetes Living and Working with Diabetes	Three modules aimed at improving role and behavioural management. Information about what diabetes is (including possible complications), how to treat it (information about different medicines and alternative treatments), and living and working with diabetes (focusing on the impact it may have on relationships).
Staying Healthy	Focused on improving behavioural management and helping people to make lifestyle changes with regards to diet, physical activity, taking medicine, reducing smoking and alcohol consumption, and working with a diabetes care team.
Forum & Help	Focused on improving emotional and role management. Includes an interactive forum and personal stories of real people with type 2 diabetes.
My Health Record	Focused on improving behavioural management. A module that can interact with the user's health professional and contains the user's personal information, care plan, a list of medicines, appointments, and self-monitoring data.
Managing my Feelings	Focused on improving emotional management. Contains a computerised cognitive behavioural therapy course called "Living life to the full," which was adapted for people with diabetes by Williams [49]. 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.

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, which is approximately the minimum effect size needed to be clinically useful.

2.6.2. Quantitative. Descriptive analyses were performed to describe the baseline characteristics of participant's psychological well-being. The data were screened to check whether normality assumptions were met. Both PAID and HADS scores showed a deviation from normality (Shapiro-Wilk Test < 0.05); therefore the differences between pre- and postoutcome measures were analysed using nonparametric Wilcoxon signed rank tests.

2.6.3. Qualitative. Data were analysed thematically. Text from the transcribed interviews with participants was coded (by key terms and phrases) and sorted by theme (domains themes and subthemes). Two experienced researchers examined the initial coding from randomly selected data independently, comparing the codes to preliminary themes, and also audited the structure of the themes [39, 40]. NVivo version 10 software [41] was used to facilitate the coding and sorting process. A summary of the results was emailed to participants for respondent validation. Four participants responded and expressed that they felt the results were an accurate reflection of their experience.

2.6.4. Researchers' Background. Making the researcher values and beliefs clear is necessary to establish a basis for validity in qualitative research [39, 40]. MH has type 1 diabetes and decided not to disclose this 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. CD and EM were developers of the intervention, and MH and CB were not.

3. Results

3.1. Quantitative Results

3.1.1. Baseline Characteristics. The baseline PAID scores indicated that the sample had low levels of diabetes-related distress on entering the study (see Table 4). The scores on the HADS and DMSES indicated that overall the sample did not have clinical levels of depression or anxiety and they had a reasonable level of self-efficacy regarding their diabetes management.

3.1.2. Before and after Comparisons. Table 4 displays the results from the pre- and postintervention data comparisons. Wilcoxon signed-rank tests showed a significant difference between participants scores on the PAID at baseline and 6-week follow-up ($Z = 2.04$, $p = 0.04$, $d = 0.28$). There was a decrease of approximately 6 points on the PAID scale, with a small to moderate effect size, indicating a reduction in diabetes-related distress. There was no significant difference between before and after scores of the HADS ($Z = 0.89$, $p = 0.38$, and $d = 0.04$) or the DMSES ($Z = 1.87$, $p = 0.06$, and $d = 0.51$) suggesting no significant changes in emotional distress or diabetes-related self-efficacy.

3.1.3. Usage Data. The number of logins to the intervention recorded by google analytics over the 6 weeks ranged from 1 to 20 logins with a mean of 5.41 (S.D = 4.69). These data were somewhat supported by the self-report data. Eleven participants reported using the website more than once a week; seven reported using it less than once a week.

3.2. Qualitative Results

3.2.1. Baseline Interviews. The qualitative data from the baseline interviews were organised into two domains: "(1) Difficulties of living with diabetes" and "(2) Hopes for HeLP-Diabetes." The participants provided a large amount of detail on their experiences of living with diabetes and the daily

Table 4: Outcome measures at baseline and 6-week follow-up.

Measure	Before M (SD)	After M (SD)	Z score	Wilcoxon Signed Ranks Sig	Cohen's d
PAID	26.32 (20.88)	20.97 (16.53)	2.04	0.04*	0.28
HADS	12.33 (10.15)	12.78 (11.20)	0.89	0.38	0.04
DMSES	90.67 (20.17)	102.78 (26.66)	1.87	0.06	0.51

Notes. PAID = Problem Areas in Diabetes scale. HADS = Hospital Anxiety and Depression scale. DMSES = Diabetes Management Self-Efficacy scale UK. Please refer to Section 2 for an explanation of direction and range of each scale. Level of significance = 0.05*.

difficulties that they faced. These difficulties are summarised in Table 5, as they are described in more depth in other literatures [42]. The "Hopes for HeLP-Diabetes" domain was divided into four main themes: "Changing diet and losing weight," "Help with moods," "Learning from other people with diabetes," and "Wanting to learn more about diabetes." The participants are described by their identification number and further details can be found in Table 2. Additional quotes illustrative of each theme are provided in Table 5.

3.2.2. Hopes for HeLP-Diabetes

Theme 2.1: Changing Diet and Losing Weight. The majority of 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*" (P5). Others felt they needed help with "*willpower*" (P9) and to "*be more aware of losing weight*" (P16). 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.

Theme 2.2: Help with Moods. 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.

Theme 2.3: Learning from Other People. One participant expressed that they would like "*practical tips from people who have been there, done that*" (P5). 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.

Theme 2.4: Learning More about Diabetes. 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.

3.3. Postintervention Interview Data. Following approximately six weeks of using the HeLP-Diabetes website, eighteen (of the nineteen) participants attended a follow-up interview. The postintervention interview data was organised into three domains (positive outcomes: psychological; positive outcomes: behavioural; negative experiences of the website), each containing several themes as follows. The participants are described by their identification number and further details can be found in Table 2.

3.3.1. Positive Outcomes: Psychological

Theme 1.1: Feeling Better Informed and More Aware. 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. For some it helped them gain a better understanding of their symptoms such as fatigue: "*. . .I really did not know that being constantly exhausted was part of diabetes. . .*" (P4). Others felt that the new information 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. (P12)*

Participants talked about the benefit of being able to refer back to the information on the website in times of need. This provided 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*

Table 5: Domains, themes, su-themes, and illustrative quotes for the preintervention data.

Domains, themes, and subthemes	Illustrative quotes
(1) Difficulties of Living with Diabetes	
(1.1) Impact on psychological well-being	
(1.11) Worries about long term complications	"I ask God, you want to take something, take a leg but let me have my eyes." (P4)
(1.12) 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." (P1)
(1.13) 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." (P5)
(1.14) 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." (P14)
(1.15) 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." (P6)
(1.16) Feeling depressed and apathetic	". . . I'm not a depressing type of person, but it can make you feel down sometimes." (P17)
(1.2) Difficulties with self-management	
(1.21) 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" (P11)
(1.22) 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." (P3)
(1.23) Lack of control or predictability	"There are mysteries and disconnect between the prescribed treatment and the result." (P14)
(1.24) 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." (P5)
(1.3) Social pressures and impact on social roles	
(1.31) 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" (P8)
(1.32) 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." (P7)
(1.33) 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." (P4)
(1.34) 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." (P9)
(2) Hopes for HeLP-Diabetes	
(2.1) Changing diet and losing weight	"Hints on how I can lose weight and control my diabetes more." (P3)
(2.2) Help with moods	"That, Managing my Feelings – that looked quite interesting. That was something that has made me feel quite happy, actually." (P19)
(2.3) 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." (P13)
(2.4) 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 want to be ignorant or that, I want to know about this thing and know as much as I can about it." (P2)

> *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. (P5)*

No participants reported using any other self-management interventions during the course of the study.

Theme 1.2: Taking Diabetes More Seriously. Participants reported feeling more aware of the "*dangers*" (P2) of diabetes and consequently felt more motivated to improve their self-management. Participants did not report negative emotions resulting from the information about potential complications, possibly because it was presented along with information about how to avoid these complications.

> *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? (P7)*

Participants spoke about experiencing a shift in perception with regards to their diabetes. They talked about having previously viewed diabetes "*a bit casually*" (P4) but in reading more about diabetes complications they felt they were taking their condition more seriously. For several participants, taking their condition more seriously came with an increased sense of responsibility and ownership over managing their condition.

Theme 1.3: Increased Self-Efficacy and Support. Participants reported feeling an increased sense of self-efficacy in managing their diabetes following using the website.

> *I'm more aware of what is going on. I feel, like, I'm in control in a way. (P1)*

In particular participants reported an increase in motivation and self-efficacy through seeing other people on the website who were managing their diabetes.

> *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. (P7)*

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. (P9)*

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*" (P7).

Additionally, participants described feeling that it was beneficial to have advice from medical professionals available when needed. 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. (P5)*

Theme 1.4: 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*" (P1) despite diabetes. They 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 accept day to day worries and only act on them when necessary for managing their condition.

> *I've just accepted I'm a diabetic, and I've just got to live with it, so I do not, 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. (P8)*

3.3.2. 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.

Theme 2.1: Changes to Eating Habits. 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. (P19)*

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

> *I am much more conscious also of not snacking in between. (P15)*

Theme 2.2: Changes to Exercise. Participants reported that the website had highlighted to them "*that exercise is as* *important as anything*" (P3), 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. For some 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. (P2)*

Theme 2.3: 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.

> *Because the more I thought about it the more I could, for example, take my readings and control my blood sugar. (P3)*

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. (P15)*

3.3.3. Negative Experiences of the Website

Theme 3.1: Information 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. (P3)*

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 has't [sic] happened to me. (P12)*

Theme 3.2: 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 coping styles of people on the website, for example, being emotionally expressive, may have opposed the strategies that certain participants had adopted to help them cope with their diabetes, for example, 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. (P4)*

Theme 3.3: 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. (P5)*

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 unmotivated 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. (P6)*

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. (P10)*

Theme 3.4: 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. (P14)*

Theme 3.5: 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

Table 6: Outline of domains and themes for postintervention interviews.

Domains and themes	Prevalence
(1) Positive outcomes: psychological	
(1.1) Feeling better informed and more aware	General
(1.2) Taking diabetes more seriously	Common
(1.3) Increased self-efficacy and support	Common
(1.4) Improved management of worries and low mood	Common
(2) Positive outcomes: behavioural	
(2.1) Changes to eating habits	Common
(2.2) Changes to exercise	Variant
(2.3) Other changes to self-management	Variant
(3) Negative experiences of the website	
(3.1) Information not new or helpful	Common
(3.2) Not feeling able to relate to the experiences of others	Variant
(3.3) No changes to certain aspects of diabetes-related behaviour	Common
(3.4) Technical frustrations	Common
(3.5) 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.

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. (P11)*

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, C****t, you know, I can't even remember the passwords – that sort of thing. (P17)*

3.4. Comparison of before and after Themes. Comparison of the themes from the preintervention and the postintervention interviews shows that participants' expectations for the site were generally satisfied. Their main preintervention hopes were to improve their management of diet and moods; these improvements were reflected in the postintervention themes. They also wished to learn from others' experience of diabetes. There is a suggestion that this did not always work well, as one of the negative outcomes was that some participants did not feel able to relate to the experiences of other patients (Table 6).

4. Discussion

The aim of the study was to use a mixed-methods approach to examine the impact of an internet-based self-management intervention (HeLP-Diabetes) on the psychological well-being of people with type 2 diabetes over a 6-week period. The quantitative results showed a significant decrease in diabetes-related distress following access to the intervention with no significant change in levels of anxiety or depression. There was no significant change in diabetes-related self-efficacy despite this measure showing an average increase of 12 points.

The qualitative data expanded and explained the quantitative findings: participants reported that having access to practical information made them more aware of why and how they could self-manage. They stated they felt more supported and more able to manage low mood, as well as making improvements to their eating habits, exercise routine, and medical management. Negative impacts associated with using the intervention were also found, in the form of guilt (about not using the website, or about not making the desired behavioural changes), and frustration with navigating the website.

The above quantitative findings confirm a recent Cochrane review of computer-based diabetes self-management interventions for adults with type 2 diabetes [43] which showed overall no impact on clinical depression scores. They contrast with previous research [18] that has shown a diabetes education and self-management programme to have no effect on diabetes-related distress as measured by the PAID. This may possibly reflect the strong focus that HeLP-Diabetes has on emotional management and role management by including a cCBT module, forums, and personal stories. The qualitative findings support data showing that internet-based diabetes self-management interventions can lead to small significant increases in self-efficacy [27, 44] and changes to eating habits and exercise.

Negative experiences associated with using the intervention included feelings of guilt for not using the website as suggested or making any behavioral changes. This emotional reaction may link with the "Anger and self-criticism" that was described in the preintervention interviews. Within this latter subtheme, 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, for example, 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 [45]. It is possible that these feelings of self-blame and self-criticism around their self-management extended 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.

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 particular, the sample overall was well educated, mostly computer literate and with low levels of distress. These characteristics may reduce the transferability of the findings.

A particular strength of this study was the use of a mixed methodology. 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. 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 precisely and potentially more subtle changes in emotional and cognitive constructs.

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 [46]. 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 [47].

5. Conclusions

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 patients address it. These preliminary findings demonstrated that the use of HeLP-Diabetes was associated with a reduction in diabetes-related distress. 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 in managing it; and learn from others with type 2 diabetes so that they feel better able to manage their anxieties and low moods. The findings need to be replicated with a larger sample size and more robust design. This research is currently underway [48]. If confirmed, this would support the use of internet-based self-management support such as HeLP-Diabetes, particularly as high levels of distress appear to be causally related to poor glycaemic control [8, 10], and reducing distress may help improve control and reduce the risk of diabetes-related complications [12–15].

Disclaimer

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR, or the Department of Health.

Conflict of Interests

Elizabeth Murray is in the process of establishing a not-for-profit Community Interest Company (HeLP-Digital CIC) which will disseminate and promote implementation of HeLP-Diabetes in NHS England. All other authors declare that there is no conflict of interests regarding the publication of this paper.

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Research Article

Psychosocial Predictors of Weight Loss among American Indian and Alaska Native Participants in a Diabetes Prevention Translational Project

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The association of psychosocial factors (psychological distress, coping skills, family support, trauma exposure, and spirituality) with initial weight and weight loss among American Indians and Alaska Natives (AI/ANs) in a diabetes prevention translational project was investigated. Participants ($n = 3{,}135$) were confirmed as prediabetic and subsequently enrolled in the Special Diabetes Program for Indians Diabetes Prevention (SDPI-DP) demonstration project implemented at 36 Indian health care programs. Measures were obtained at baseline and after completing a 16-session educational curriculum focusing on weight loss through behavioral changes. At baseline, psychological distress and negative family support were linked to greater weight, whereas cultural spirituality was correlated with lower weight. Furthermore, psychological distress and negative family support predicted less weight loss, and positive family support predicted greater weight loss, over the course of the intervention. These bivariate relationships between psychosocial factors and weight remained statistically significant within a multivariate model, after controlling for sociodemographic characteristics. Conversely, coping skills and trauma exposure were not significantly associated with baseline weight or change in weight. These findings demonstrate the influence of psychosocial factors on weight loss in AI/AN communities and have substantial implications for incorporating adjunctive intervention components.

1. Introduction

Although diabetes is highly prevalent worldwide, its presence among American Indians and Alaska Natives (AI/ANs) is particularly alarming [1]. Adjusting for age, AI/ANs suffer from type 2 diabetes mellitus at rates greater than two times those of non-Hispanic whites and exhibit the highest prevalence of this disease of any racial group in the United States [1, 2]. Given the sharp increase in incident diabetes among AI/ANs over the last 20 years, these circumstances seem unlikely to change without substantial intervention [3–5].

The Special Diabetes Program for Indians Diabetes Prevention (SDPI-DP) demonstration project has been implemented over the past decade to address this problem using a well-established, evidence-based preventive intervention. The SDPI-DP initiative was developed based upon the National Institute of Diabetes, Digestive and Kidney Disease's (NIDDK) Diabetes Prevention Program (DPP), which was a large-scale clinical trial that demonstrated that lifestyle interventions (e.g., changing diet and exercise habits) can be effective in delaying or preventing the onset of diabetes in individuals who are at increased risk for developing this disease [6].

The DPP outcomes did not differ significantly for various ethnic groups, including American Indians [6]; however, the DPP was conducted as a highly controlled clinical trial, which did not allow for evaluating the effectiveness of lifestyle interventions in preventing the onset of diabetes in community-based settings with underserved populations. AI/AN communities often face a lack of health care resources and a highly mobile population, thereby making it particularly difficult to implement large-scale prevention programs. Therefore, the SDPI-DP worked with experts in a variety of AI/AN communities to implement cultural adaptations to the original DPP lifestyle curriculum (e.g., the use of indigenous foods, drumming during class sessions), in order to make the program more relevant to AI/AN individuals and more transferrable to a geographically, culturally, and organizationally diverse array of settings in tribal communities [7].

The SDPI-DP demonstration program resulted in reduced diabetes incidence among high risk AI/ANs at a rate comparable to the results for AI/ANs in the original DPP study [7]. In addition, improvements in weight, blood pressure, and lipid levels were detected following the intervention [7]. However, despite the overall effectiveness with which the intervention was delivered to SDPI-DP participants, several participant characteristics were related to retention in the program; participants who were younger, were male, had less education, and had lower income were more likely not to complete the core intervention [8]. These initial findings regarding the relationship between sociodemographic factors and retention led program staff to question the potential additional impact of individual-level psychosocial factors on participant engagement, ability to grasp the knowledge conveyed, and mastery of skills related to the behavioral changes associated with the desired outcomes. Therefore, it was determined that further analyses were warranted in order to evaluate the extent to which program outcomes were related to individual-level psychosocial characteristics.

The observation of a potential impact of psychosocial factors on self-management of medical illnesses is not unique. For example, the influence of depression and anxiety on intervention outcomes for individuals with prediabetes was examined in at least one previous study, and more positive baseline mood was correlated with increased physical activity [9]. In addition, a bidirectional relationship between depression and diabetes has been previously supported. Specifically, there is evidence that diabetes may increase the likelihood of depressive episodes and that depression may increase the risk of developing diabetes [10–13]. Furthermore, psychological distress in general has also been shown to be associated with many chronic health conditions, including obesity [14, 15], which is a significant risk factor for the development of type 2 diabetes. Other studies have identified increased odds of diabetes among AI/ANs with a history of trauma and significant life stressors [16, 17].

Conversely, strong coping skills and other positive emotional attributes have been found to enhance metabolic control among those with diabetes [18]. In addition, increased spirituality has been associated with improved self-management among African Americans who suffer from diabetes [19], lower stress and higher quality of life in persons afflicted by chronic illness [20], and decreased likelihood of developing depression [21]. Although the relationship between spirituality and diabetes has not been studied specifically in AI/AN populations, previous research has highlighted the importance of religious and spiritual practices for AI/AN individuals struggling to overcome other health issues, such as the problematic use of alcohol [22]. Additionally, family support has been correlated with increased weight loss in the prevention of diabetes among Arab Americans [23]. Similarly, positive family support was correlated with improved diet in a study of older Hispanic adults with diabetes [24]. Furthermore, active family nutritional support was linked to improved control of diabetes-related factors (i.e., triglycerides, cholesterol, and HbA1c) among Navajo tribal members [25]. Finally, several psychological and behavioral factors, including increased self-efficacy, were associated with improved weight loss for DPP participants [26].

Given this prior body of evidence supporting significant relationships between a variety of psychosocial characteristics and multiple health outcomes, the correlation of psychosocial factors (psychological distress, trauma exposure, coping skills, spirituality, and family support) with a key clinical indicator of diabetes risk (weight) among AI/ANs participating in the SDPI-DP demonstration project was assessed in the present study. Resulting insights could suggest enhancements targeting such factors in the core components of SDPI-DP that hold promise for increasing its effectiveness.

2. Materials and Methods

2.1. Participants. Eligibility criteria for participating in the SDPI-DP demonstration projects were being AI/AN (based on eligibility to receive IHS services), being at least 18 years of age, and having either impaired fasting glucose (IFG) (i.e., a fasting blood glucose (FBG) level of 100–125 mg/dL and an oral glucose tolerance test (OGTT) result <200 mg/dL) or impaired glucose tolerance (IGT) (i.e., an OGTT result of 140–199 mg/dL two hours after a 75 g oral glucose load and an FBG level <126 mg/dL). Exclusion criteria included a previous diagnosis of diabetes (not including those who only have had gestational diabetes), pregnancy, end-stage renal disease on dialysis, and any condition that would affect successful participation based on provider judgment (e.g., cardiac concerns given the physical activity element of the program, severe substance use, and undergoing treatment for cancer) [7]. Participants attended a 16-session educational curriculum, a series of lifestyle coaching sessions, and community-based exercise programs focused on reducing the risk of developing type 2 diabetes through moderate weight loss, increased physical activity, and healthy eating habits.

Clinical measurements and participant surveys were obtained at baseline, within 30 days of completing the 16-session curriculum, and annually thereafter. Participants were enrolled at one of 36 tribal, Indian Health Service (IHS) or urban Indian health care programs serving 80 tribes between 2006 and 2010. Seventy-eight percent of participants were from a rural geographic setting, and 22% were from an urban area. To be included in the current study, participants minimally completed a baseline clinical assessment and

Table 1: Characteristics of SDPI-DP participants.

Variable	M (SD) or *n* (%)
Gender	
Female	2330 (74.3%)
Male	805 (25.7%)
Age (years)	46.7 (12.6)
Education status[a]	
<High school	449 (15.2%)
High school graduate	641 (21.7%)
Some college	1330 (45.0%)
≥College graduate	538 (18.2%)
Annual household income[a]	
<\$15,000	539 (21.4%)
\$15,000 to <\$30,000	551 (21.9%)
\$30,000 to <\$50,000	721 (28.6%)
≥\$50,000	706 (28.0%)

Note. $N = 3{,}135$. Percentages for categorical variables do not always sum to 100% due to rounding error.

[a] Education status and annual household income were not available for all participants; therefore, *n*'s for these variables do not sum to 3,135.

a baseline survey ($n = 3{,}135$). The 193 individuals who completed a baseline clinical assessment but did not complete any participant surveys were excluded from these analyses. These individuals did not differ significantly from those included in the study with regard to age, gender, and baseline weight. The SDPI-DP protocol was approved by the Institutional Review Board of the University of Colorado Denver and the National IHS Institutional Review Board. When required, grantees obtained approval from other entities overseeing research in their programs (e.g., tribal review boards). All participants provided written informed consent and Health Insurance Portability and Accountability Act authorization.

A summary of participant sociodemographic characteristics is provided in Table 1. The study sample was 74% female and had a mean age at baseline of 46.7 years. Sixty-three percent of participants attended at least some college courses; 72% of participants reported annual household incomes of less than \$50,000.

2.2. Measures. Sociodemographic variables including participant gender, age, educational status, and annual household income were collected through a survey at baseline. Participant weight was obtained at each clinical assessment using standardized procedures.

Several psychosocial variables were assessed by participant surveys at baseline and follow-up. The 6-item Kessler Distress Scale [27] included items related to general psychological distress. Frequency of participants' experience of various symptoms of depression and anxiety during the previous 30 days was assessed using this scale. Item scores ranged from 1 (none of the time) to 5 (all the time). Participants' ability to cope with life stressors was measured using the Brief Resilient Coping Scale [28]. This 4-item scale asked participants to rate descriptions of coping reactions (e.g., approaching difficult situations in creative ways, focusing on the positive growth that can come from dealing with adversity), using a scale ranging from 1 (does not describe me at all) to 5 (describes me exactly). A modified 6-item version of the Diabetes Family Behavior Checklist [29] was used to measure participants' perceptions of positive and negative family support in regard to their efforts to prevent the onset of diabetes. SDPI-DP research staff modified the original checklist slightly by removing items that referred to specific activities for individuals with diabetes (e.g., family providing suggestions about taking insulin on time) that would not have been relevant to a program focusing on diabetes *prevention*. Participants rated how often their family members provided positive support on 4 items (e.g., exercising with them) and negative support on 2 items (e.g., criticizing them for not exercising regularly). Item scores on the six items ranged from 1 (less than once a month) to 5 (at least once a day). No items were reverse-scored, as items were phrased in either a positive or negative manner, consistent with the two scored dimensions.

Two additional psychosocial variables (trauma experience and spirituality) were assessed by participant surveys only at baseline. These two particular variables were not collected at follow-up due to the expectation of their high stability across a relatively short period of time. A single dichotomous variable from a Posttraumatic Stress Disorder (PTSD) screener [30] captured whether participants had ever experienced a significant traumatic event (e.g., being the victim of a violent crime or domestic violence, being in a disaster like a flood or fire, being in combat, being seriously injured in an accident, being sexually assaulted, and witnessing someone else being seriously injured or killed). This variable was coded either 0 (no trauma) or 1 (history of trauma). Spirituality was assessed via a 7-item scale designed specifically to capture the culturally relevant components of spirituality for AI/ANs [31]; item scores ranged from 1 (strongly disagree) to 5 (strongly agree). The items on this scale were developed through consultation with tribal leaders to reflect American Indian cultural views of the connectedness of humans to all other physical and transcendental entities. The seven items were as follows: (1) I am in harmony with all living things, (2) I feel connected with other people in life, (3) I follow my tribal path, (4) when I need to return to balance, I know what to do, (5) I feel like I am living the right way, (6) I give to others and receive from them in turn, and (7) I am a person of integrity.

2.3. Statistical Procedures. Confirmatory factor analyses were conducted at the item level for each psychosocial scale in order to establish measurement invariance across the two time points [32, 33]. Descriptive statistics then were calculated for all psychosocial variables. Scale scores were computed as the mean of the respective items. Subsequently, latent difference scores were created to measure change over time in the outcome variable (weight) and applicable psychosocial variables [33, 34]. Latent difference scores are not subject to the restrictive assumptions of traditional ANOVA approaches and permit the measurement of change without error by including multiple indicators of each construct at each of two time points [35]. This modeling approach decomposes the data from the second time point into two components: (1) variance associated with Time 1 and (2) variance associated with the difference from Time 1. Therefore, latent difference scores allow for the estimation of baseline variance as well as variance regarding change in a construct over time.

Following these initial steps, a series of bivariate analyses were conducted within a structural equation modeling framework, which separately evaluated the relationships between each psychosocial variable and weight. For psychosocial variables that were measured at both baseline and follow-up, three parameters of primary interest were estimated: (1) the correlation between the psychosocial characteristic and weight at baseline, (2) the predictive relationship of the baseline psychosocial characteristics on change in weight, and (3) the association of change in the psychosocial characteristic with change in weight. For psychosocial variables that were measured only at baseline (i.e., trauma and spirituality), only the first two parameters were estimated.

After evaluating the bivariate relationships, a multivariate model estimated the three parameters described above simultaneously for all psychosocial variables. This model also controlled for baseline sociodemographic characteristics, including gender, age, education, and income. Psychosocial variables were eliminated from the multivariate model in a stepwise manner if they reached a p value greater than 0.2 for all three primary parameters, in order to arrive at a final model. Biostatisticians have suggested that a p value greater than 0.2 is a reasonable cutoff to eliminate variables that are clearly nonsignificant in regression models [36]. An effect size measure for the final model (R^2) was computed as the proportion of variance of change in weight that was explained by the predictor variables.

Confirmatory factor analysis and structural equation models were tested using mean and covariance structures (MACS) modeling techniques [33]. MACS analyses allow for the inclusion of mean-level information in addition to the covariance structures information of standard structural equation modeling techniques, which is necessary for the interpretation of latent difference scores. MACS analyses also provide a particular advantage over ordinary least-squares regression approaches, namely, the fact that the unreliability of instruments/scales is taken into account and that corrections are made for measurement error. When employing structural equation modeling techniques, it is important to assess the degree to which the specified model "fits" the actual data in order to determine the appropriateness of a particular model. In the present study, the Root Mean Square Error of Approximation ($\text{RMSEA}_{(90\%\text{ confidence interval})}$; less than .08 is adequate fit and less than .05 is good fit), the Comparative Fit Index (CFI; greater than .90 is adequate fit and greater than .95 is good fit), and the Tucker-Lewis Index (TLI; greater than .90 is adequate fit and greater than .95 is good fit) were used as indices of model fit [32]. In all models, a p value of <.05 was considered statistically significant.

Full information maximum likelihood (FIML) was implemented in all analyses in order to address potential bias and decreased power due to missing data [37, 38]. Furthermore, although there was very little variation across programs in class attendance for the participants included in the current study (95% of participants who completed a follow-up assessment had completed at least 14 of the 16 recommended curriculum classes), other elements of the program may have varied slightly across sites. Therefore, in order to control for the clustering of participants into 36 separate health care programs, standard errors that are robust to nonnormality and nonindependence of observations were computed using a sandwich estimator. All analyses were conducted using Mplus Version 7.11 [39].

3. Results

Descriptive statistics for all clinical and psychosocial variables are presented in Table 2. Between baseline and follow-up, a significant decrease of 8.58 lbs was found with regard to average weight ($\Delta = -8.58$, $p < .001$). With regard to the change in psychosocial factors, general psychological distress decreased over time ($\Delta = -0.14$, $p < .001$), while coping abilities increased ($\Delta = 0.07$, $p < .001$). Furthermore, positive family support, as perceived by participants, was higher at follow-up ($\Delta = 0.27$, $p < .001$), whereas negative family support remained stable ($\Delta = 0.03$, $p = .28$). At baseline, 48% of SDPI-DP participants reported a lifetime history of at least one significant trauma, and the average level of reported cultural spirituality at baseline was 3.81 (on a scale from 1 to 5).

Confirmatory factor analyses of the Kessler distress, coping, and family support measures supported invariance of factor loadings and intercepts across the two measurement time points, which indicates that the measures exhibited similar structures and measured the same constructs across time. Strong factorial invariance was established for both the Kessler distress and coping measures, with all factor loadings and intercepts constrained to be equal across time. Partial measurement invariance was established for the family support measure, as one of the intercepts for the positive family support scale was not invariant across time. It is generally acceptable to use measures with partial invariance in further structural models, if at least two indicators (scale items) have an invariant factor loading and intercept [32, 33]. In the case of the family support measure, all six items exhibited loading invariance, and all but one item exhibited intercept invariance. It was important to establish that these psychosocial measures had identical or near identical structures at both time points in order to calculate reliable and valid difference scores.

Bivariate analyses were performed prior to running the multivariate model in order to evaluate the strengths of individual predictor/outcome relationships (see Table 3). All estimates (ψ = covariance; β = regression coefficient) are provided in an unstandardized metric in order to allow meaningful interpretation based upon the original scale ranges. All bivariate models exhibited good model fit (RMSEA < .05; CFI > .95; TLI > .95), and several significant correlations were found between psychosocial characteristics and weight at baseline. Greater psychological distress at baseline was related to higher baseline weight ($\psi = 2.44$, $p < .001$). In addition, greater negative family support was significantly correlated with higher baseline weight ($\psi = 4.55$, $p < .001$), whereas greater identification with culturally relevant spirituality was

Table 2: Correlations, means, and standard deviations at baseline and follow-up.

Variable	Weight T1 $n = 3{,}135$	Weight T2 $n = 2{,}259$	Kessler T1 $n = 3{,}053$	Kessler T2 $n = 2{,}008$	Coping T1 $n = 3{,}045$	Coping T2 $n = 1{,}997$	Pos FS T1 $n = 2{,}835$	Pos FS T2 $n = 1{,}974$	Neg FS T1 $n = 2{,}742$	Neg FS T2 $n = 1{,}874$	Trauma T1 $n = 2{,}896$	CultSpir T1 $n = 2{,}905$
Weight T1	—											
Weight T2	.98***	—										
Kessler T1	.07***	.08***	—									
Kessler T2	.08***	.10***	.67***	—								
Coping T1	−.03	−.02	−.20***	−.17***	—							
Coping T2	−.04	−.04	−.17***	−.25***	.54***	—						
Pos FS T1	.02	.04	−.03	−.05	.16***	.11**	—					
Pos FS T2	.05	.03	−.06	−.16***	.10**	.17***	.49***	—				
Neg FS T1	.10***	.11***	.17***	.11**	−.07*	−.04	.58***	.19***	—			
Neg FS T2	.08*	.12**	.15***	.19***	−.06	−.08**	.28***	.37***	.45***	—		
Trauma T1	.02	.02	.23***	.16***	.09***	.08**	−.02	−.04	−.00	.04	—	
CultSpir T1	−.11***	−.11***	−.25***	−.17***	.37***	.31***	.17***	.13***	−.07**	−.05	−.01	—
M	217.80	209.22***	1.72	1.58***	3.34	3.41***	2.32	2.59***	1.66	1.69	0.48	3.81
SD	52.35	50.88	0.66	0.55	0.65	0.64	0.70	0.77	0.89	0.86	0.50	0.55

Note. T1 = baseline; T2 = follow-up; Pos FS = positive family support; Neg FS = negative family support; CultSpir = cultural spirituality. Weight was measured in pounds. Asterisks beside a follow-up mean indicate a significant difference from the corresponding baseline mean.

$^{*}p < .05$. $^{**}p < .01$. $^{***}p < .001$.

Table 3: Correlates of baseline weight (ψ) and predictors of change in weight from baseline to follow-up (β) (unstandardized bivariate model results).

Psychosocial variable	Correlation of weight and psychosocial variable at baseline			Prediction of change in weight by psychosocial variable at baseline			Association of change in weight with change in psychosocial variable		
	ψ	SE	p	β	SE	p	β	SE	p
Kessler distress	2.44	0.63	<.001	1.85	0.43	<.001	3.23	0.50	<.001
Coping	−0.84	0.90	.347	0.11	0.41	.796	−0.59	0.55	.285
Positive family support	0.92	0.87	.290	−0.36	0.61	.559	−3.56	0.59	<.001
Negative family support	4.55	1.12	<.001	1.38	0.46	.003	3.13	0.55	<.001
Trauma	0.41	0.67	.540	0.73	0.57	.199			
Cultural spirituality	−3.13	0.67	<.001	0.36	0.37	.326			

Note. Positive family support and negative family support were tested within the same model, because they are two factors of one measure. Trauma and cultural spirituality were measured only at baseline.

associated with lower baseline weight ($\psi = -3.13$, $p < .001$). Baseline levels of coping, positive family support, and trauma experience were not significantly related to baseline weight.

In addition to investigating the relationships between psychosocial characteristics and weight at baseline, regression analyses were conducted in order to elucidate the predictive relationships between psychosocial variables (independent variables) and change in weight from baseline to follow-up (dependent variable). The results of these analyses underscore the importance of psychological distress and family support in predicting weight loss in AI/ANs with prediabetes. Greater psychological distress at baseline predicted less successful weight loss between baseline and follow-up ($\beta = 1.85$, $p < .001$), and an increase in psychological distress between baseline and follow-up was also significantly related to less successful weight loss ($\beta = 3.23$, $p < .001$). Participants who reported an increase in *positive* family support after the intervention were more successful in losing weight ($\beta = -3.56$, $p < .001$). Conversely, higher *negative* family support at baseline as well as an increase in *negative* family support after the intervention was significantly associated with less weight loss ($\beta = 1.38$, $p = .003$ and $\beta = 3.13$, $p < .001$, resp.). Coping, trauma experience, and cultural spirituality were not significantly related to weight change.

After conducting the bivariate analyses, all of the psychosocial variables were included in a single multivariate model. Sociodemographic variables (gender, age, education status, and annual household income) that have previously been shown to be related to participant engagement and retention in the SDPI-DP program [8] were entered as covariates in the model, in order to determine the effect of the psychosocial factors on weight change above and beyond any potential effect of sociodemographic characteristics. Using the stepwise procedure described above, coping and trauma experience were dropped from the final model, as they were neither correlated with baseline weight nor predictive of weight change. Results of the final multivariate model are presented in Figure 1, which mirror the results of the bivariate models, with one exception. After controlling for sociodemographic factors and other psychosocial variables, baseline psychological distress was no longer predictive of weight loss from baseline to follow-up. However, the correlations between psychological distress, negative family support, and cultural spirituality with weight at baseline remained significant. In addition, change in psychological distress, positive family support, and negative family support over the course of the intervention, as well as levels of negative family support at baseline, remained significantly associated with change in weight. Overall, the final multivariate model exhibited good model fit (RMSEA = $.026_{(.025-.028)}$; CFI = .966; TLI = .958) and accounted for 11% of the variability in weight change. This proportion of variance explained is not large, but it does represent a medium effect size [40].

4. Discussion

The importance of psychosocial characteristics as sources of diabetes risk and resilience has been demonstrated previously among AI/ANs [16, 17, 25, 41]. The present study is a critical first step in moving from research focused primarily on individuals *with diabetes* to examining factors related to successfully *preventing incident diabetes* among Native people at high risk of the disease. Although the influence of depression and anxiety on intervention outcomes for prediabetic individuals was examined in at least one previous study [9], the present study is the first to focus on determining which psychosocial factors successfully predict a specific outcome of a large-scale initiative aimed at preventing the onset of diabetes in the AI/AN population. Moreover, the statistical approach employed in the current study made it possible to simultaneously examine the relative contributions of the various psychosocial factors to successful health changes in a single model, unlike previous studies that have analyzed psychosocial factors in isolation of one another.

Specifically, structural equation modeling provides the ability to simultaneously examine the relationships of the psychosocial variables to a key clinical outcome with regard to baseline levels and change over time. As expected, when analyzing such relationships in a bivariate manner, several psychosocial factors were related to baseline levels of weight. Higher levels of psychological distress and negative family support were associated with higher weight, whereas greater

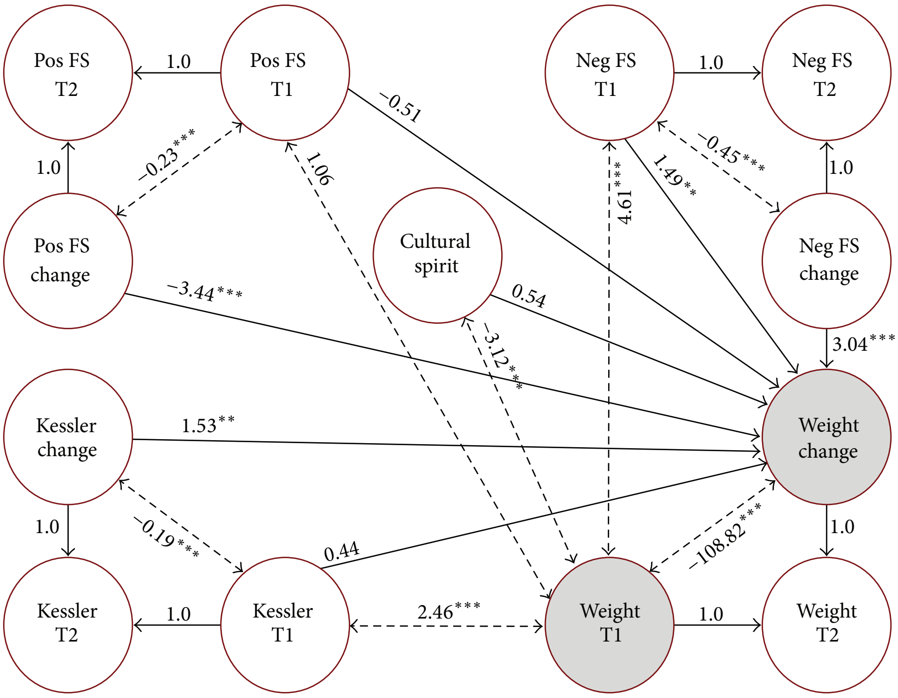

Figure 1: Final multivariate model results (unstandardized). Gender, age, education, and income were included in the model as covariates. Coping and trauma were dropped from the final model, because they were neither significant correlates of baseline weight nor significant predictors of change in weight. Double-headed arrows (dashed lines) represent correlations. Single-headed arrows (solid lines) represent regression paths. T1 = baseline; T2 = follow-up; Pos FS = positive family support; Neg FS = negative family support; cultural spirit = cultural spirituality. $^{**}p < .01$. $^{***}p < .001$.

spirituality was correlated with lower weight. The same pattern of correlations of these three psychosocial variables with weight at baseline also was supported in the multivariate model when controlling for sociodemographic factors.

Psychosocial factors were also related to the degree of weight change following participants' completion of the SDPI-DP intervention. Greater psychological distress at baseline and increased psychological distress over the course of the intervention both contributed to less weight loss. Similarly, greater negative family support at baseline and increased negative family support over the course of the intervention were associated with a smaller reduction in weight. Increased positive family support, on the other hand, predicted greater weight loss. Controlling for sociodemographic factors within a multivariate model, change in psychological distress, negative family support, and positive family support, as well as baseline levels of negative family support, continued to significantly affect weight reduction. The results of the present study are consistent with prior research on psychological distress as a risk factor with regard to chronic illness [14, 15, 18] and with previous findings regarding the role of positive family support in both reducing the risk of and successfully managing diabetes [23–25].

The results underscore the importance of regularly assessing the psychosocial status and functioning of AI/ANs at high risk of diabetes. Prevention programs will be well served by developing the capacity to evaluate and monitor participants' mental health status, including the presence of depression and anxiety, the nature and extent of their spirituality, and the adequacy of their family support. These personalized assessments, combined with the knowledge of the general effects of psychosocial factors uncovered in the present study, will allow program staff to know which adjunctive interventions may maximize participant benefit with respect to the desired outcomes (e.g., weight loss). For example, by increasing the focus on mental health components within the core curriculum, one could strengthen participants' strategies for decreasing depressive and stress-related symptoms, which then may make it more likely that the participants will be more engaged in the intervention and experience more successful weight loss. Offering self-management techniques, simple cognitive-behavioral skills, and referral to local support groups or treatment options is a logical extension of the goals, process, and structure of an intensive lifestyle balance intervention. Additionally, knowing that a participant has a strong preexisting spiritual focus may be helpful information for program staff who then may be able to use a participant's connectedness to the natural world as a pathway to increase motivation to engage in a healthier lifestyle. Likewise, given the strong relationship between family support and program outcomes, a greater effort should be made to incorporate close family members into various aspects of the prevention program. SDPI-DP demonstration projects have begun to do so, guided by their initial impressions of the potential gains.

For example, some programs encourage participants to identify a support person to attend curriculum classes and other program-related activities with the participant.

The present study has several limitations, which suggest directions for future research. Data specific to the psychosocial characteristics were collected solely by self-report, thereby possibly increasing shared method variance and artificially strengthening the relationships among these variables. Future studies may benefit from using a variety of methods to operationalize and assess similar constructs. For example, family support could be measured through multiple informants, including close family members, and levels of depression and anxiety could be assessed through interview-based rating scales. Nevertheless, the primary relationships of interest were between self-reported psychosocial characteristics and an objective clinical measure (weight), which were not subject to problems of shared method variance. It also bears noting that trends over only two time points were analyzed. The relationships between psychosocial factors and program outcomes may wax and wane over a longer follow-up period, or certain interactions may occur over time that are not evident within a relatively short follow-up period.

In addition, SDPI-DP participants were more likely to be female, be older, have a higher level of education, and have a higher household income than the general AI/AN adult population [42]. Though previous research has shown similar trends when comparing clinical populations to the general population [43, 44], the generalizability of the present findings to individuals with widely differing sociodemographic backgrounds may be limited. For example, it is possible that weight change for males may not be as strongly related to psychological distress or family support as it was for this largely female sample. In addition, individuals with less education and lower household income than the participants in the current study may be more likely to have suffered a greater number of significant traumas. Future studies should attempt to enroll individuals with broader sociodemographic characteristics and should include a measure of the number of traumas experienced, which would provide the opportunity to analyze a possible additive effect of repeated trauma upon successful weight loss that was not possible with the dichotomous trauma item used in the present investigation. Similarly, although both rural and urban participants were included in the study, the majority of participants lived in rural settings, which may further limit the generalizability of the results. Although it would be difficult to extend these results to the mainstream American population without further research, the current findings may also be applicable to other populations that share similar structures and values with AI/AN communities (e.g., a greater emphasis on extended family support as opposed to individualism; a spiritual emphasis on connectedness to others and nature).

Furthermore, although a medium effect size for the prediction of weight change within the multivariate model was observed (11% of outcome variability explained), additional factors are likely at work and will need to be addressed to more comprehensively improve the effectiveness of such prevention programs. Some additional factors may include lack of access to healthy food selections, high levels of family and caregiver stress that make it difficult to follow through with healthy eating and exercise routines, and lack of transportation to attend program classes. Moreover, characteristics of the treatment team and health care program in general previously have been shown to be related to participant retention, which in turn predicts program outcomes [7, 8]. Therefore, it likely will be critical to incorporate a multifaceted approach to crafting additional components that promise to enhance the intervention. For example, rather than just adding a standalone mental health screening module, a program might consider addressing barriers to participation (e.g., lack of transportation) in concert with increasing positive family support and thereby decrease the isolation that can lead to psychological distress. Finally, a more precise and comprehensive assessment of mental health status would enable a program to determine the most appropriate approach for decreasing symptoms likely to interfere with participation in the preventive intervention. In light of the relationship between depression and diabetes [10–13, 45, 46], referral to a mental health professional is a logical option to be pursued, although other possibilities, such as a group treatment model, should also be considered given the limited numbers of mental health providers within tribal, IHS, and urban Indian health care programs.

5. Conclusions

The present study demonstrates the importance of psychosocial factors for maximizing the potential benefits to participants in preventive interventions such as the SDPI-DP demonstration project. The challenge now becomes how to incorporate the lessons learned into the fabric of these programs. Augmentation of the current intervention may be achieved either directly by incorporating adjunctive components or indirectly through referral to relevant local resources. The overall goal of these program additions would be to maximize participants' engagement, their ability to grasp the knowledge conveyed, and their mastery of the skills related to the behavioral changes associated with the desired outcomes.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Research Article

New Methods in Exploring Old Topics: Case Studying Brittle Diabetes in the Family Context

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Background. In questing for a more refined quantitative research approach, we revisited vector autoregressive (VAR) modeling for the analysis of time series data in the context of the so far poorly explored concept of family dynamics surrounding instable diabetes type 1 (or brittle diabetes). *Method*. We adopted a new approach to VAR analysis from econometrics referred to as the optimized multivariate lag selection process and applied it to a set of raw data previously analyzed through standard approaches. *Results*. We illustrated recurring psychosomatic circles of cause and effect relationships between emotional and somatic parameters surrounding glycemic control of the child's diabetes and the affective states of all family members. *Conclusion*. The optimized multivariate lag selection process allowed for more specific, dynamic, and statistically reliable results (increasing R^2 tenfold in explaining glycemic variability), which were derived from a larger window of past explanatory variables (lags). Such highly quantitative versus historic more qualitative approaches to case study analysis of psychosomatics surrounding diabetes in adolescents were reflected critically.

1. Introduction

Sigmund Freud is rarely mentioned in scientific discourse without also belittling the lack of quantitative statistical evidence for his elaborate models. At the same time, his qualitative case reports and the conclusions he drew from them by far belong to the most well-known research in psychosomatic medicine. Despite all valid critique, one reason, we argue, may very well be the superiority of the single case study in first observing, describing, capturing, evaluating, and creatively reflecting on an infinite set of parameters surrounding any chosen topic. Out of this primary assessment, novel hypotheses and further (more costly) research may emerge.

It is our objective to reapply such primary assessment to the case of adolescent brittle diabetes (or more generally speaking, the psychosomatic underpinnings of diabetes type 1 in minors and young adults), while also trying to answer calls for more quantitative and statistically reliable approaches to doing so. This in mind, we have first selected a highly quantitative case study on family dynamics and brittle diabetes [1] and reviewed and reanalyzed its raw data through implementation of a new statistical procedure increasing the coefficient of determination in the new model by factor ten (while also presenting new and clearer findings), in order to then, in a second step, discuss and compare our results to possibly the historically most well-known set of qualitative case studies on the topic [2].

We will start by briefly revisiting the literature on the psychosomatics of adolescent instable diabetes type 1, present a case vignette and basic data collection method of the original case study we reexamine (which may be skipped by those familiar with the work published by [1]), followed by a detailed description of our new statistical approach and its results, concluding with a clear clinically oriented graphical presentation of our findings and their discussion in light of Minuchin et al.'s [2] qualitative findings.

The Case of "Brittle" Diabetes. One out of 600 US or European school-age children suffers from insulin dependent diabetes mellitus [3, 4]. Just about 33 percent of diabetics between 13 and 19 years of age manage to maintain tolerable glycemic control and a HbA_{1c} below 8; 6.3 percent suffered at least one episode of major hypoglycemia within the last three months [5, 6]. The devastating immediate and long-term effects of poor diabetic control are widely known and feared. 44 percent of the variance in blood glucose control can be statistically explained by psychological variables in these patients and their parents [7]. A randomized controlled study further demonstrates how an intensive inpatient treatment program including psychoanalytic psychotherapy could effectively improve diabetic control in children [8]. These cases of glycemic instability with no somatic explanation have been termed "brittle diabetes" by some authors [9] and there is no doubt concerning the importance of further exploration of the causes and remedies surrounding this truly psychosomatic disease.

While various aspects of brittle diabetes have been explored in recent years, including its exact definition, there seems to be a gap in the literature in exploring how emotional variables of all individuals within the family system may interact to affect glycemic control of the diabetic adolescent, the "index patient" of a dysfunctional family system. The little research which has sought to fill this gap (i.e., [2, 10, 11]) is primarily qualitative in nature and must face similar critique as all such work, as will be discussed in the last section of this study.

The Case and Its Psychosomatic Background (adopted and revised from [1]). The adolescent index patient of this case study was diagnosed with diabetes type 1 at age of four (clinical clues were polyuria, polydipsia, loss of appetite, a fungal infection, HbA_{1c} of 9.1 per cent, antibodies against islet cells, and GAD65).

Family dynamics surrounding this classic family of three (biological parents, single child) appeared unsuspicious notwithstanding the girl's history of poorly controlled bronchial asthma and allergic diseases.

Yet at age of six, nocturnal hypoglycemia with loss of consciousness led to readmission to the hospital, during which another episode of profound hypoglycemia, this time in conjunction with a tonic-clonic seizure, occurred, thus further consolidating her parents' distress concerning hypoglycemia and hospital treatment. Once all educational efforts concerning the diabetic management were exhausted (including individual and family-based counseling, detailed and repetitive disease-specific education, and information about glycemic control mechanisms including the influence of nutrition, sport, and other aspects of blood sugar regulation), but a HbA_{1c} below 7 percent was never achieved, the family finally sought for psychosomatic family treatment. Psychodynamically based therapeutic analysis of the family dynamic suggested a conflict between the adolescent and her mother about who had control of the blood sugar levels. The mother's dominance seemed to have negative effects on her daughter's glycemic control. Fears of hypoglycemia were somewhat irrational with all three family members, including the father, who, at first sight, seemed rather more distant to the matter (literature proposes parental hypoglycemia avoidance behaviours to adversely affect glycemic control [12]).

Six family therapy sessions were undertaken on a biweekly schedule. The family's shock in relation to the diagnosis and mistrust of hospital personnel was discussed.

Finally, a therapeutic intervention confronted them with their specific type of collusion concerning (in-)dependence, in which both parents, in their manifest statements, advocated for more self-confidence and extended duties on the side of the daughter, but on a more latent level, gave hints to their "beloved little girl" not being ready to take control over the blood sugar monitoring by herself. This mostly unconscious conflict had culminated in cloudy paths of communication concerning glycemic control, in nebulous distributions of duties within the family members, and, as a result of the arrangement, in deep dissatisfaction over the failure of proper diabetic control.

2. Methods

2.1. Collecting Quantitative Data. While traditional case studies would focus on the qualitative data outlined above, we sought to amend such observations by a highly quantitative approach in order to produce more evidence based and reproducible results. Therefore, we aimed to statistically explore how specific basic affect states of all three individual family members may impact each other and the success of the diabetic management over a period of 120 days. To operationalize this quest, we drew on the standardized self-assessment manikin (SAM), as developed by Bradley and Lang (for details see [13, 14]), asking all three family members to individually record on a daily basis their valence (mood), arousal (high versus low), and dominance (a sense of presence in the current environment). In addition the index patient was asked to obtain at least three daily blood glucose measurements (or more if required by the disease) over the same period utilizing a common standardized technique. This form of diary based data collection is also referred to as ecological momentary assessment with many benefits in terms of accuracy and validity of measurements [15].

Standard deviations of the daily blood glucose measurements served as an indicator for glycemic variability, a measure which recent research has identified as the most precise predictor of diabetic control, followed by the HbA_{1c}-value in second place [16–19], due to it being the best known predictor for diabetic complications and microvascular derailments in particular [20].

Resulting from this data collection and primary analysis are ten time series: three time series for each of the three family members from the SAM, affective valence (happy, sad), arousal (excited, calm), and dominance (a sense of presence, distance to the current environment), as well as one time series recording glycemic variability (daily standard deviations of measurements). In contrast to Günther et al. [1], these ten time series were further analyzed by a completely new statistical approach to vector autoregressive (VAR) modeling. While past analysis of this same set of data (see [1]) has also relied on basic VAR analysis, there had been some common shortcomings to the validity and scope of results, which we were able to remedy here, thus solving statistical shortcomings while also presenting completely new results in a clearer more clinically oriented fashion. How we were able to achieve this, the presentation of a newly developed optimized multivariate lag selection process in VAR analysis, and a comprehensive review of the principles of vector autoregression will be presented next.

2.2. Reviewing Vector Autoregression as a Quantitative Approach to Time Series Data.

The use of vector autoregressive models (VAR) for the analysis of time series data in psychosomatic medicine (also widely used in neuroscience) allows treating a set of variables as jointly driven by the lagged values of all variables in the system with no a priori assignment of dependent and independent status being necessary. This technique seems particularly apt for research in psychosomatic medicine, where [21], among others, has long called for a more integrated (monistic) view on the complexity of dynamic dependencies and intertemporal reciprocal cause and effect relationships among different psychic as well as somatic variables.

Any VAR model requires the user to select a maximum number of lags, which, in more practical terms, refers to how far back in time the user wants to go in the search for past recordings of all variables to predict the present value of one variable. The farther back in time the user decides to go, the more explanatory variables (lags) need to be included in the model because it used to be improper to exclude past recordings of explanatory variables, which lay in-between the present value and the most historic one [22, 23].

Unfortunately including more explanatory variables (going back further in time) is a double edged sword, since this would provide a VAR model more representative of reality (goodness of fit), but would also endorse one with less explanatory power (lower adjusted R^2). The latter is due to the tremendous penalty inflicted by the large number of explanatory variables (lags) in the model resulting in high estimation variance [22, 23]. This substantial drawback weakened the substance of empirical findings derived from VAR models, because researchers would either present results through models with teeth chattering low R^2 values (see previously published results from the same raw data as one example) or adopt models only incorporating the effects of events preceding the predicted value of a variable by one day/one unit of time in the VAR (e.g., see [24]).

In order to alleviate this shortcoming of low adjusted R^2 values in the standard vector autoregressive modeling approach, we developed a computer code implementing a statistical procedure recently published in parts in Savin and Winker [25] and Winker [26, 27], referred to as the optimized multivariate lag selection process, which allows (contrary to previous practice) excluding such explanatory variables (lags) from the VAR model which add little to its goodness of fit (estimated representativeness of reality) while nonetheless reducing its explanatory power (adjusted R^2). This "admittance of holes" to the lag structure (equations organizing the explanatory variables) allows us to now present an entirely new model exhibiting more detailed dynamics with a smaller number of parameters, for the data in this case resulting in about tenfold increase of the adjusted R^2 value. Mathematical details of applying the optimized multivariate lag selection process to this VAR analysis of the ten time series of the data set at hand will be presented next (and may be skipped by the more clinically focused researcher).

2.3. Applying the Optimized Multivariate Lag Selection Process.

A standard vector autoregressive (VAR) model was constructed, using EViews 7.1 (QMS, Quantitative Micro Software, Irvine CA), based on the ten time series we mentioned above. In order to focus on the innovative aspects of our methodology we will not delve into the details of VAR model construction, which have been described at length in preceding publications (i.e., [1, 24]).

Given the large number of explanatory variables (the more lags, the more variables) and the limited number of observations, only a very limited number of lags (past days) could be considered while adjusted R^2 would still be low, if we were to follow the standard modeling approach [22, 23]. The novel contribution is to maximize the informational content of the model by minimizing an information criterion [25–27].

In more concrete terms, if we assume that any one value within the ten time series may have effects on any of the other values of all-time series with a delay of up to one week, a total of 710 parameters would have to be estimated. Given 120 observations in each time series, this results in tremendous estimation variance (very low R^2). Model selection criteria suggest using only one lag (assuming effects will take place within a day instead of within a week, which seems highly unrealistic but is a common approach adopted by other researchers in the field, including Wild et al., 2010) resulting in a total of only 110 parameters to be estimated with a still low R^2 value of 0.02 for the model explaining glycemic variance [1].

To resolve this dilemma, we drew on Winker [26, 27] and Savin and Winker [25] engaging in optimized multivariate lag structure analysis. Given the huge discrete search space of all possible lag structures, for example, for a maximum lag length of seven, heuristic optimization algorithms are used to this end. For this process, a computer code was developed using Matlab R2011b with an interface to EViews 7.1, which implements a Genetic Algorithm for the search of an optimized lag structure making use of information criteria (BIC) as in the standard selection procedure (see for more details [25]). By providing an approximation to the minimum of the information criterion, the resulting model exhibits an optimized tradeoff between a good fit to the multivariate dynamics of the data and model parsimony.

As a result, we obtained a model with only 70 parameters, but still cover effect delays up to one week. Since the maintained lags are selected based on their joint informational content (as measured by the information criteria), the procedure results in a model with much higher explanatory power (for predicting glycemic variability adjusted R^2 value of 0.20 as opposed to 0.02 for the standard model with only one lag) and a richer dynamic.

Given the rich dynamics between all variables of the model, besides considering single equations, the calculation of impulse response functions as in [1] would be of interest. However, the zero constraints of the VAR model with holes preclude the application of standard methods for the calculation of confidence bands.

Similarly, poor glycemic control (high glycemic variability) will correlate with low glycemic variability four days earlier, a calm mother three days earlier, an excited mother seven days earlier, a dominating mother four days earlier, a non-dominating mother seven days earlier (although statistically insignificant), a sad father both five and six days earlier, a calm father both three and seven days earlier, and a dominating father both two and five days earlier. High glycemic variability will also correlate with a sad child six days later, an excited mother three days later, and a dominating father one day later. For a graphical representation see Figure 2.

3. Results and Discussion

The optimized multivariate lag structure selection process provides one equation of seemingly unrelated multiple regression for each of the ten time series to be presented next. Three of them directly involve glycemic variability in addition to the one for glycemic variability itself, which shall be presented last (lags in parentheses):

> affective valence of the adolescent = α_1 glycemic variability (−6) + α_2 valence adolescent (−1) (R^2 = 0.25, adj. R^2 = 0.24);
>
> affective valence of the mother = α_3 dominance adolescent (−7) + α_4 valence mother (−5) + α_5 arousal mother (−6) + α_6 arousal father (−4) + α_7 arousal father (−6) (R^2 = 0.21, adj. R^2 = 0.18);
>
> affective valence of the father = α_8 valence adolescent (−3) + α_9 valence adolescent (−5) + α_{10} arousal mother (−5) + α_{11} dominance father (−3) (R^2 = 0.21, adj. R^2 = 0.18);
>
> arousal of the adolescent = α_{12} arousal adolescent (−1) + α_{13} arousal adolescent (−3) + α_{14} arousal adolescent (−7) + α_{15} valence mother (−4) + α_{16} arousal mother (−3) + α_{17} valence father (−2) + α_{18} valence father (−6) (R^2 = 0.30, adj. R^2 = 0.25);
>
> arousal of the mother = α_{19} glycemic variability (−3) + α_{20} arousal adolescent (−7) + α_{21} dominance adolescent (−5) + α_{22} arousal mother (−5) + α_{23} arousal mother (−7) + α_{24} dominance mother (−1) + α_{25} dominance father (−6) (R^2 = 0.29, adj. R^2 = 0.24);
>
> arousal of the father = α_{26} valence mother (−4) + α_{27} dominance mother (−6) + α_{28} arousal father (−1) + α_{29} arousal father (−2) + α_{30} arousal father (−6) + α_{31} dominance father (−1) (R^2 = 0.19, adj. R^2 = 0.15);
>
> dominance of the adolescent = α_{32} valence adolescent (−1) + α_{33} arousal adolescent (−5) + α_{34} arousal father (−1) + α_{35} dominance father (−1) (R^2 = 0.25, adj. R^2 = 0.22);
>
> dominance of the mother = α_{36} valence mother (−7) + α_{37} dominance mother (−1) + α_{38} dominance mother (−3) + α_{39} dominance father (−5) (R^2 = 0.65, adj. R^2 = 0.64);
>
> dominance of the father = α_{40} glycemic variability (−1) + α_{41} dominance child (−6) + α_{42} valence mother (−5) + α_{43} valence mother (−7) + α_{44} dominance mother (−4) + α_{45} dominance mother (−6) + α_{46} valence father (−1) + α_{47} valence father (−3) + α_{48} arousal father (−3) + α_{49} dominance father (−2) (R^2 = 0.34, adj. R^2 = 0.27);
>
> *glycemic variability* = ß_1 glycemic variability (−4) + ß_2 arousal mother (−3) + ß_3 arousal mother (−7) + ß_4 dominance mother (−4) + ß_5 dominance mother (−7) + ß_6 valence father (−5) + ß_7 valence father (−6) + ß_8 arousal father (−3) + ß_9 arousal father (−7) + ß_{10} dominance father (−2) + ß_{11} dominance father (−5) (R^2 = 0.28, adj. R^2 = 0.20).

The coefficients, their standard error, t-statistic, and probability referred to above, can be reviewed in Table 1.

The development of a novel statistical methodology allowed us to disentangle the data and generate statistically reliable results in the form of ten equations. The dynamic of the results pertaining to glycemic variability, (thereby, it has to be taken into account that additional dynamic interactions arise due to spillover between equations, which are not considered here), taking into account the direction of coefficients, can be summarized in the following words and graphical representations.

Low glycemic variability and, therefore, *good* diabetic control will correlate with the following: high glycemic variability four days earlier, an excited mother three days earlier, a calm mother seven days earlier, a non-dominating mother four days earlier, a dominating mother seven days earlier (although statistically insignificant), a happy father both five and six days earlier, an excited father both three and seven days earlier, and a non-dominating father both two and five days earlier. Low glycemic variability will also correlate with a happy child six days later, a calm mother three days later, and a non-dominating father one day later. For a graphical representation of this paragraph refer to Figure 1.

Similarly, poor glycemic control (high glycemic variability) will correlate with low glycemic variability four days earlier, a calm mother three days earlier, an excited mother seven days earlier, a dominating mother four days earlier, a non-dominating mother seven days earlier (although statistically insignificant), a sad father both five and six days earlier, a calm father both three and seven days earlier, and a dominating father both two and five days earlier. High glycemic variability will also correlate with a sad child six days later, an excited mother three days later, and a dominating father one day later. A graphical representation of this paragraph is presented in Figure 2

In clinical terms, this means, good diabetic control was preceded by attentive and alert (“high arousal,” excited) parents with a positive attitude (“happy father”), at the same time refraining from too much overwhelming presence (“low dominance”). Likewise, phases of good diabetic management

Table 1: Coefficients and their statistical properties.

(a)

	Coefficient	Std. error	t-statistic	Prob.
α_1	0.008371	0.002505	3.341682	0.0009
α_2	0.439050	0.071648	6.127902	0.0000
α_3	0.196661	0.072361	2.717768	0.0067
α_4	0.193472	0.070105	2.759765	0.0059
α_5	0.166062	0.072169	2.301002	0.0216
α_6	−0.093081	0.038780	−2.400229	0.0166
α_7	0.083885	0.023675	3.543200	0.0004
α_8	−0.133217	0.045307	−2.940347	0.0033
α_9	0.135556	0.044104	3.073571	0.0022
α_{10}	−0.096673	0.029864	−3.237170	0.0012
α_{11}	−0.220601	0.061646	−3.578496	0.0004
α_{12}	−0.083390	0.031821	−2.620595	0.0089
α_{13}	0.167024	0.043985	3.797288	0.0002
α_{14}	0.499978	0.148744	3.361336	0.0008
α_{15}	0.235265	0.063599	3.699206	0.0002
α_{16}	−0.118392	0.039810	−2.973946	0.0030
α_{17}	−0.177384	0.058985	−3.007251	0.0027
α_{18}	0.327619	0.062900	5.208601	0.0000
α_{19}	−0.006755	0.002888	−2.339111	0.0195
α_{20}	−0.516945	0.178245	−2.900191	0.0038
α_{21}	−0.973039	0.242951	−4.005083	0.0001
α_{22}	0.190612	0.063265	3.012915	0.0026
α_{23}	−0.212629	0.060467	−3.516477	0.0005
α_{24}	−0.560562	0.136662	−4.101828	0.0000
α_{25}	−0.464339	0.146477	−3.170045	0.0016
α_{26}	−0.090665	0.041861	−2.165871	0.0305
α_{27}	0.447149	0.069911	6.395994	0.0000
α_{28}	0.234203	0.065907	3.553560	0.0004
α_{29}	−0.225144	0.058588	−3.842809	0.0001
α_{30}	0.129774	0.038175	3.399442	0.0007
α_{31}	0.182089	0.037975	4.795004	0.0000
α_{32}	−0.077998	0.029281	−2.663826	0.0078
α_{33}	−0.325788	0.065003	−5.011909	0.0000
α_{34}	0.215753	0.065266	3.305758	0.0010
α_{35}	−0.259613	0.081614	−3.181004	0.0015
α_{36}	0.200644	0.061428	3.266334	0.0011
α_{37}	0.292372	0.060802	4.808558	0.0000
α_{38}	−0.186054	0.064022	−2.906069	0.0037
α_{39}	−0.233369	0.086570	−2.695740	0.0071
α_{40}	0.004900	0.001217	4.024947	0.0001
α_{41}	0.367140	0.102177	3.593182	0.0003
α_{42}	−0.128680	0.045575	−2.823477	0.0048
α_{43}	−0.111369	0.043503	−2.560006	0.0106
α_{44}	−0.186954	0.067466	−2.771067	0.0057
α_{45}	−0.187772	0.065392	−2.871465	0.0042
α_{46}	−0.192931	0.048915	−3.944164	0.0001

(a) Continued.

	Coefficient	Std. error	t-statistic	Prob.
α_{47}	−0.201673	0.062378	−3.233079	0.0013
α_{48}	−0.092639	0.048991	−1.890956	0.0589
α_{49}	0.154373	0.062922	2.453387	0.0143

Determinant residual covariance $9.14E-05$.

(b)

	Coefficient	Std. error	t-statistic	Prob.
β_1	−0.197322	0.076111	−2.592545	0.0097
β_2	3.639513	1.583793	2.297973	0.0218
β_3	−4.889116	1.647518	−2.967565	0.0031
β_4	22.52994	3.969363	5.675959	0.0000
β_5	−6.340918	3.554736	−1.783794	0.0747
β_6	9.565170	3.704850	2.581797	0.0100
β_7	9.249940	2.865721	3.227788	0.0013
β_8	7.562806	2.651011	2.852801	0.0044
β_9	10.96846	2.600148	4.218400	0.0000
β_{10}	13.04606	3.522259	3.703891	0.0002
β_{11}	11.03846	4.583850	2.408120	0.0162

Determinant residual covariance $9.14E-05$.

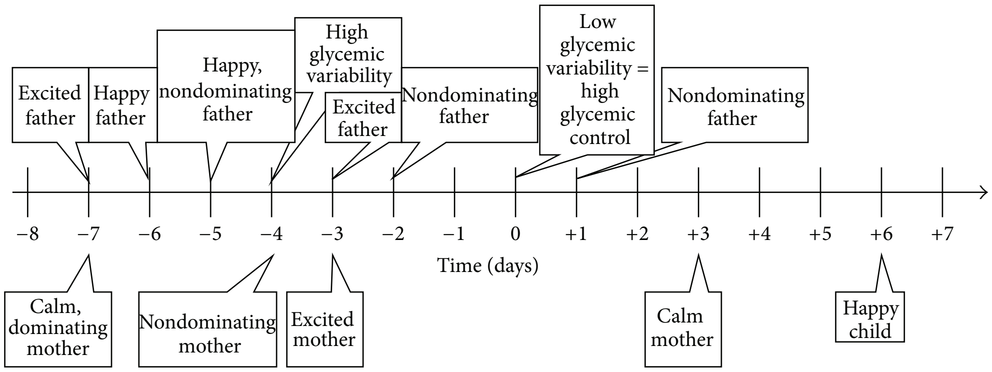

Figure 1: Timeline displaying effects correlating with high glycemic control. The graph depicts a psychosomatic cycle in which various emotional states of all involved family members influence glycemic variability of the adolescent patient and vice versa.

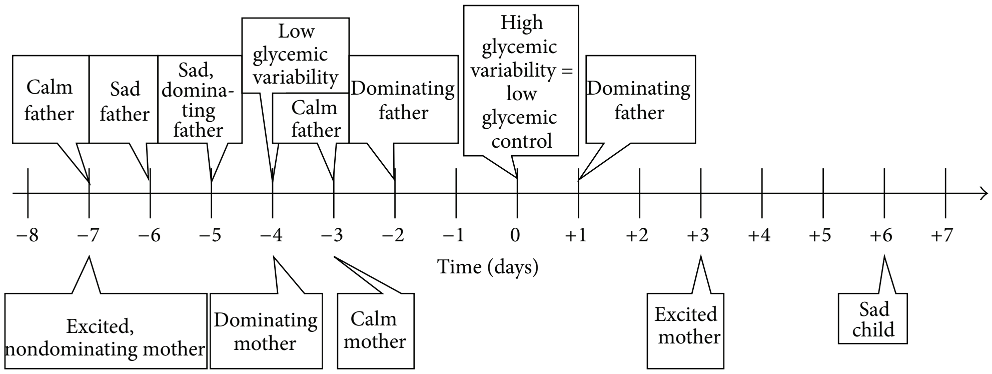

Figure 2: Timeline displaying effects correlating with poor glycemic control. The graph depicts a psychosomatic cycle in which various emotional states of all involved family members influence glycemic variability of the adolescent patient and vice versa.

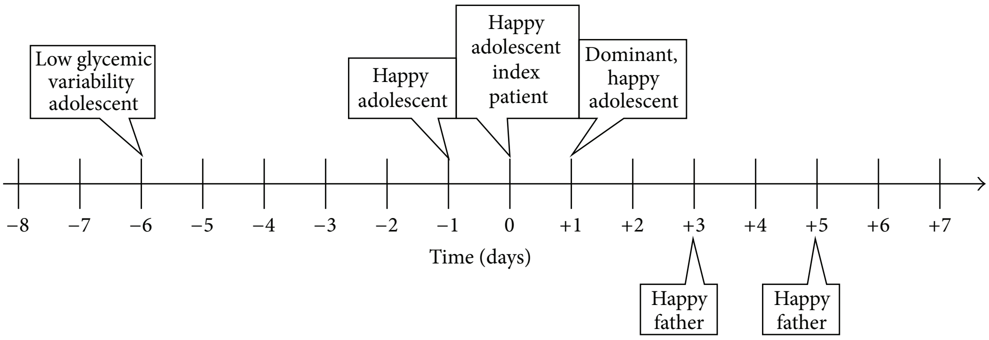

Figure 3: Timeline displaying effects correlating with affective valence in the adolescent index patient. The graph depicts a psychosomatic cycle in which various emotional states of all involved family members influence affective valence (pleasure) of the adolescent patient and vice versa.

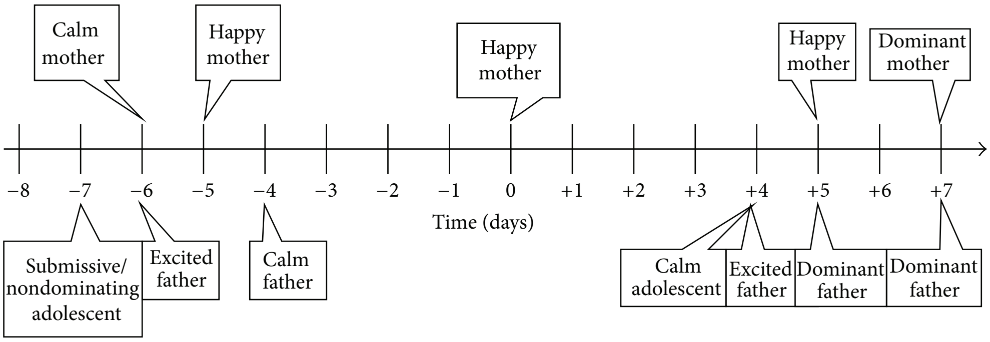

Figure 4: Timeline displaying effects correlating with affective valence in the mother of the adolescent index patient. The graph depicts a psychosomatic cycle in which various emotional states of all involved family members influence affective valence (pleasure) of the mother to the adolescent patient and vice versa.

were followed by a continuously distant father ("low dominance"), unfortunately a less alert mother ("low arousal"), and a content ("happy") adolescent index patient.

Similarly, mostly self-explanatory, graphical representations were constructed for the effects surrounding the affective valence of all three family members (see Figures 3, 4, and 5). We picked these three timelines for more detailed examination, because the appropriate measurement of depressive symptoms (which at least at a distance somewhat relates to affective valence) in diabetics in general, remains to be a topic of current debate in the literature [28].

4. Conclusions

In comparison to the results derived from the same set of raw data with a different statistical approach in an earlier publication [1], there are several improvements we were able to achieve:

(i) increasing the coefficient of determination R^2 for the model prediction of glycemic variability by factor ten (adjusted R^2 value of 0.20 as opposed to 0.02) while incorporating significant effects of explanatory variables (lags) stemming from a longer period of time preceding the predicted event;

(ii) presenting a more precise timeline of effects of various variables on each other, including glycemic variability and vice versa (e.g., "a nondominating mother four days prior to a set day will increase glycemic control" instead of "a nondominating mother somewhere up to four days prior to a set day will increase glycemic control");

(iii) isolating additional relationships between variables which did not reach statistical significance earlier or took more time to take effect than the time frame of the earlier models allowed for.

A more substantial contribution of this paper is the demonstration and practical application of the multivariate lag selection process to VAR analysis, resolving an essential shortcoming in VAR analysis of (relatively) small samples. Hence, this contribution to literature will have relevance beyond the case study approach but also to VAR-based studies of larger cohorts of patients (as e.g., [24]), significantly increasing either the number of effects analyzed (as in [24]) or the statistical reliability (i.e., the adjusted R^2) with which results are presented.

All in all, however, mathematically refined quantitative methodological approaches relying on modern computational technology can generate more specific, reproducible,

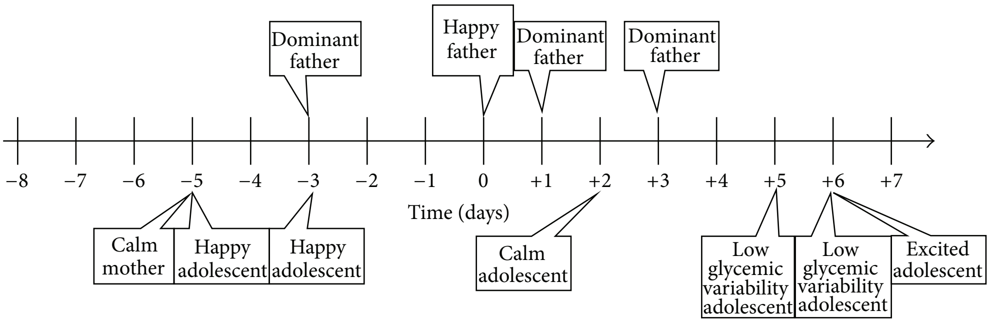

Figure 5: Timeline displaying effects correlating with affective valence in the father of the adolescent index patient. The graph depicts a psychosomatic cycle in which various emotional states of all involved family members influence affective valence (pleasure) of the father to the adolescent patient and vice versa.

and thus trustworthy results than purely qualitative (narrative) accounts, while still honoring the benefits of the case study approach aiming to explore previously unforeseen avenues fit for further vested inquiry (often costly to perform).

Yet, we have to ask ourselves critically if the added mathematical complexity honors the overall value of the results a case study approach can provide. Revisiting the opening comments of this report in the context of brittle diabetes, it seems interesting to note that particularly the most highly acclaimed and clinically widely trusted research on brittle diabetes has also been the most severely and broadly criticized. So, for instance, more than ten years after the initial publication of the pioneering work of Minuchin et al. in 1978 (on what they called "psychosomatic diabetes") entitled "Psychosomatic families" [2], critics commented as follows: "…as we conducted research and therapy with the families of diabetic children, we were impressed with both the limit of the formulation of the family's role in diabetes offered in 'Psychosomatic Families' and the uncritical acceptance that the book continued to enjoy" [29]. In their rather pointed article entitled "The 'psychosomatic family' reconsidered II: recalling a defective model and looking ahead" Coyne and Anderson [29] criticize Minuchin et al. [2] primarily for their bold, yet statistically (allegedly) poorly supported, statements on the "typical psychosomatic family" (Minuchin et al. [2] describe the "psychosomatic family" as featuring enmeshment, rigidity, overprotectiveness, and lack of conflict resolution and the children affected by brittle diabetes as having difficulty in handling stress, showing a tendency to internalize anger and being somewhat immature in their ability to cope with challenging situations) and their overgeneralizations of these overall "weak" findings on familial situations in one psychosomatic illness to various psychosomatic illnesses. More specifically, small sample sizes and poor documentation of methodology (or lack thereof) are being highlighted.

Reflecting on such valid criticism in light of our own extensive research both on the subject of brittle diabetes in adolescents and on the various shortcomings of contemporary statistical approaches to time series data in psychosomatic medicine, we believe there is a case for both sides. On the one hand, we must vigorously support critics (i.e., [29]) in their call for much more detailed and sophisticated reports on and publication of statistical methodology in such complex and intricate research situations as are present in multivariate time series analysis. The reason lies in the fact that there is vast room for pitfalls and error with this type of research, if left in the hands of the mathematically inexperienced. On the other hand, however, we found for fact, that with the change of statistical approach, the results drawn from a given set of data may change somewhat, despite both methodologies being perfectly valid and academically accepted. So one wonders how this (agreeably small) imprecision of highly quantitative research is any different from the (possibly but not necessarily larger) inaccuracy of qualitative research due to subjectivity. Noteworthy, and in taking up the cudgels for Minuchin et al. [2, 11], the one finding which we were able to observe clinically before conducting any statistical testing at all, namely, that of a dominating mother having a negative effect on glycemic control of her child, was also a finding that both of our methodologies were able to report at a high level of significance. (Amusingly, one might find what Minuchin et al. [2] described as overprotectiveness in families with brittle diabetes is very similar, if not the same, to what we were able to pinpoint in terms of exaggerated control of a mother over her glycemically out of control child.) Additionally, we also fear that critics of primarily qualitative case research (i.e., [2]) may not have realized the vastness of data inherent even in a small sample in time series analysis, an apprehension possibly supported by the fait accompli of not too many critics providing any statistically evidenced findings on the subject of brittle diabetes themselves (i.e., [29]). So in conclusion, we believe the careful observation of the clinically experienced therapist to be almost as valuable as the most substantiated and savvy statistical approach.

Appendix

See Table 1.

Abbreviations

VAR: vector autoregression/vector autoregressive.

Consent

Consent for the publication of this case report has been obtained from all individuals mentioned in the report (father, mother, and adolescent) as well as all authors of the paper.

Conflict of Interests

The authors declare that they have no competing interests.

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Clinical Study

Reduced Worries of Hypoglycaemia, High Satisfaction, and Increased Perceived Ease of Use after Experiencing Four Nights of MD-Logic Artificial Pancreas at Home (DREAM4)

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Aims. This study assesses the impact of using an AP-system at home on fear of hypoglycaemia. In addition, satisfaction and acceptance of the new technology are evaluated. *Methods.* In a multicentre, multinational study of 75 patients using the MD-Logic AP during four consecutive nights in home setting 59 of them (aged 10–54 years, 54% male, HbA1c 7.89 ± 0.69% [62.72 ± 7.51 mmol/mol], diabetes duration 11.6 ± 8.4 yrs) answered standardized questionnaires (HFS, adapted TAM, and AP satisfaction) before and after using the AP. *Results.* After experiencing the AP in home setting worries of hypoglycaemia were significantly reduced (before 1.04 ± 0.53 versus after 0.90 ± 0.63; $P = 0.017$). Perceived ease of use as a measure of acceptance with the AP significantly increased after personal experience (before 4.64 ± 0.94 versus after 5.06 ± 1.09; $P = 0.002$). The overall satisfaction mean score after using the AP was 3.02 ± 0.54 (range 0–4), demonstrating a high level of satisfaction with this technology. *Conclusions.* The four-night home-based experience of using MD Logic AP was associated with reduced worries of hypoglycaemia, high level of satisfaction, and increased perceived ease of use of the new technology in children, adolescents, and adults.

1. Introduction

Current research is focusing on the artificial pancreas (AP) or the so-called closed-loop systems (CLS) to optimize metabolic control in patients with type 1 diabetes mellitus (T1DM). An AP combines continuous subcutaneous insulin infusion (CSII) and continuous glucose monitoring (CGM) with a control algorithm to calculate insulin delivery in response to sensor data. Different artificial pancreas systems from various research groups have shown the superiority of the artificial pancreas compared to standard CSII therapy regarding overall glucose control and risk of nocturnal hypoglycaemia. These results were achieved during controlled conditions of an inpatient environment (review by [1]). Now first studies started to evaluate the AP system at the patient's home. The Diabetes Wireless Artificial Pancreas Consortium (DREAM-Project, [2]) assessed the MD-Logic artificial pancreas system [3, 4] outside hospital settings under real-life conditions. Meanwhile the safety and efficacy of the MD-Logic automated insulin delivery system was demonstrated in hospital setting [1] as well as in diabetes camps [2] and in home setting [5, 6]. Briefly, The MD-Logic is a wireless fully automated closed-loop system based on a fuzzy logic theory algorithm, a learning algorithm, a personalized system setting, and alerts module. The alerts module includes real-time alarms such as impending hypoglycaemia and long standing hyperglycaemia. The algorithm for alerts integrates information derived from past glucose levels and insulin delivery (time and dose) as well as models of insulin pharmacodynamics. The hypoglycaemia alarms are designed to operate in instances when impending hypoglycaemia cannot be avoided by holding insulin alone [4].

While the metabolic efficacy of the existing AP systems is impressing, its psychological impact remains to be evaluated. The majority of patients accept and use CSII continuously, but there are also reports of some patients who discontinued this technology [7, 8]. CGM use was less effective in adolescents due to the low rate of young people willing to use CGM continuously [9]. Barriers mentioned against CGM use were, for example, "technical aspects" like alarms and inaccurate readings and "body image concerns to wear two devices" [10]. Barriers like fear of hypoglycaemia and human factors like the emotional acceptance of wearing the devices and trusting the accuracy seem to play a leading part for the acceptance and efficacy of these technologies.

Until now the acceptance of CLS was rarely assessed. Elleri and colleagues [11] prospectively asked parents of children with T1DM if they would trust an AP-system. The majority (90%) reported secure feelings. A sample of 132 adults with T1DM also indicated positive attitudes towards the new technology [12]. However, these patients and parents had no real-life access to the system.

Little is known on the psychological impact of an AP system in the patient's home [13]. Systematic studies on fear of hypoglycaemia and satisfaction with and acceptance of an AP in children, adolescents, and adults with T1DM in the home setting have not yet been evaluated. In this study the impact of using an AP-system during four consecutive nights in a home setting regarding fear of hypoglycaemia is assessed among children, adolescents, and adults in a multicentre study. In addition, satisfaction and acceptance of this new technology are evaluated as main psychological predictors of a potential long-term use of the AP system.

2. Materials and Methods

2.1. Trial Design. This study on the psychological impact of using an AP for four consecutive nights in home setting is part of the DREAM Project (DREAM4) conducted in three multinational centres from Israel, Slovenia, and Germany. The main study focused on the feasibility, safety, and efficacy of the MD-Logic AP. It is a two-arm study, each arm covering four consecutive nights comparing the MD-Logic AP ("closed-loop" arm) with sensor-augmented pump therapy ("control" arm). Patients were randomly assigned either to "Group A" (first "closed-loop" and then "control" arm) or to "Group B" (vice versa) with a week washout between the two periods [5, 6]. Before intervention and after experiencing the MD-Logic AP participants answered structured questionnaires on fear of hypoglycaemia, satisfaction with the technology, and acceptance of the MD-Logic AP. The study was conducted in compliance with the protocol, the Declaration of Helsinki, and applicable regulatory and good clinical practice requirements. All patients and parents provided a written informed consent prior to trial initiation.

2.2. Participants and Eligibility Criteria. Overall 45 patients from the Schneider Children's Medical Center in Israel (Petah Tikva), 15 patients from the University Medical Centre-University Children's Hospital in Slovenia (Ljubljana), and 15 patients from the Kinder- und Jugendkrankenhaus AUF DER BULT in Germany (Hanover) were recruited between November 2012 and January 2014. Main inclusion criteria were type 1 diabetes (>1 yr since diagnosis), age ≥10 years and ≤65 years, CSII therapy for at least three months, experience in using CGM, HbA_{1c} ≥7% to <10% (53–86 mmol/mol), patients living with at least one other adult person, and an internet access at patient's home. Main exclusion criteria were concomitant diseases that influence metabolic control, participation in any other study, pregnancy, a history of diabetic ketoacidosis or severe hypoglycaemia within the last month, medications, or other conditions that may influence metabolic control, compromise safety, or prevent subjects from completing the study [5, 6]. For organisational reasons sixty participants were offered to answer psychological questionnaires, 30 from Israel, 15 from Slovenia, and 15 from Germany.

2.3. Psychological Assessment

Fear of Hypoglycaemia. Fear of hypoglycaemia was assessed with the Hypoglycaemia Fear Survey (HFS). The HFS is based on cognitive-behavioural theory of anxiety distinguishing emotional and behavioural components. Accordingly the HFS includes a Behaviour Subscale (HFS-B) and a Worry Subscale (HFS-W). The HFS adult-version consists of 10 behaviour or avoidance items (items 1–10) and 17 worry or affect items (items 11–27) to be answered on a 5-point Likert scale. Higher total scores reflect greater fear of hypoglycaemia. Higher scores on the behaviour subscale reflect a greater tendency to avoid hypoglycaemia and/or its negative consequences. Higher scores on the Worry Subscale indicate more worries concerning episodes of hypoglycaemia and its consequences. A study with 158 individuals with type 1 diabetes indicated good internal reliability: Cronbach's alpha for the entire scale was .90, for the Behaviour Subscale .60, and for the Worry Subscale .89. The instrument proved to have a high test-retest stability (after 6 weeks .89, .81, and .85 ($P < 0.001$)) and a good construct validity as the HFS covaries with elevated HbA_{1c} and is sensitive to a hypoglycaemia awareness training [14].

The HFS was adapted to be answered by children with T1DM. The final pediatric HFS (C-HFS) questionnaire consists of 10 behaviour or avoidance items (items 1–10) and 15 worry or affect items (items 11–25) to be answered on a 5-point Likert scale. A study with adolescents demonstrated adequate internal consistency for the C-HFS-Total Score and the C-HFS-W Score (.86, .91), with a lower Cronbach's alpha for the C-HFS-B Score (.54) [15]. Green reported similar results [16]. Construct validity was demonstrated by a significant correlation between State-trait Anxiety Inventory for children scores and C-HFS-Total scores and C-HFS-W Scores [15].

TABLE 1: Baseline patient characteristics.

	Children (10–14 yrs) ($n = 20$)	Adolescents (14–18 yrs) ($n = 20$)	Adults (>18 yrs) ($n = 19$)	P value	Israel ($n = 29$)	Slovenia ($n = 15$)	Germany ($n = 15$)	P value	All ($n = 59$)
Age (years), mean (SD)	12.3 (1.17)	15.6 (0.86)	31.22 (9.96)		17.45 (6.43)	22.07 (12.00)	20.96 (12.96)	0.286	19.51 (9.98)
Male (%)	50	60	52.6	0.806	55.2	46.7	60.0	0.757	54
HbA_{1c} (%), mean (SD)	7.97 (0.72)	7.93 (0.76)	7.78 (0.58)	0.679	8.03 (0.71)	7.89 (0.74)	7.63 (0.53)	0.184	7.89 (0.69)
HbA_{1c} (mmol/mol, IFCC), mean (SD)	63.50 (7.90)	63.15 (8.33)	61.44 (6.32)		64.17 (7.78)	62.78 (8.13)	59.84 (5.75)		62.72 (7.51)
Diabetes duration (years), mean (SD)	7.25 (3.06)	8.78 (3.31)	19.24 (10.82)	0.000	9.21 (5.42)	13.92 (12.29)	14.03 (7.85)	0.094	11.63 (8.44)
CSII duration (years), mean (SD)	5.68 (3.35)	6.32 (2.82)	8.96 (5.58)	0.036	5.77 (3.52)	7.45 (3.24)	8.74 (5.70)	0.075	6.95 (4.24)
Regular sensor use (%)	65	55	26.3	0.044	62.1	53.3	20.0	0.028	49.2

Acceptance of the Artificial Pancreas. The acceptance of an artificial pancreas was assessed with the adapted TAM Questionnaire. This instrument developed by van Bon et al. [12] is based on the Technology Acceptance Model (TAM). The questionnaire consists of two items assessing “Intention to Use” (items 1-2), eight items on “Perceived Usefulness” and its determinants (items 3–10), three items on “Perceived Ease of Use” (items 11–13), and one item on “Trust” (item 14). The items are answered on a 7-point Likert scale. Higher scores indicate a higher degree of acceptance of the AP. In a study with 132 patients with T1DM Cronbach’s alpha was .91, reflecting a good internal consistency.

Satisfaction with Use of an Artificial Pancreas. The questionnaire was developed and validated specifically for closed-loop studies [17]. The questionnaire consists of 14 items (e.g., item 1: “in general to which extent were you satisfied with using the artificial pancreas system?”). Items are answered on a 5-point Likert scale. A higher score indicates a higher degree of satisfaction with the AP.

All questionnaires were translated linguistically in patients’ native language; the validation of the translation was performed by each study centre.

Sociodemographic characteristics (age, gender, and family status) and clinical characteristics (HbA_{1c}, onset of diabetes, start of CSII, and sensor use) were collected from patients’ files. Metabolic control was assessed by DCA 2000 in all centres.

2.4. Statistical Methods. All analyses were performed with SPSS for Windows version 22. The descriptive statistics are reported as percentages or means and standard deviations (SD). Comparison between pre- and postassessment was performed using paired Fisher-t-test or Wilcoxon signed-rank test. Effects of age-group, gender, or regular sensor use were analysed by using ANOVA or Kruskal-Wallis H test. Associations between fear of hypoglycaemia, acceptance, satisfaction and HbA_{1c}, diabetes duration, and pump duration were calculated via Spearman’s rho. Cronbach’s alpha was performed by analyses of reliability. Varimax rotated factor analyses were applied to assess the structure of the questionnaires. Two-sided P values ≤ 0.05 were considered statistically significant.

3. Results

3.1. Study Sample. Overall 59 patients (54% male, age 19.9 ± 9.9 yrs, diabetes duration 11.6 ± 8.4 yrs, HbA_{1c} 7.89 ± 0.69% [62.7 ± 7.5 mmol/mol]) answered the questionnaires before and after using the AP for four consecutive nights at home (29 patients from Israel, 15 from Slovenia, and 15 from Germany). One additional patient withdrew consent. Baseline demographic and diabetes characteristics were similar over centres. CGM use turned out to differ between centres (Table 1). Patients from Germany had previous continuous CGM use less often (3 versus 12) compared to Israel (18 versus 11) or Slovenia (8 versus 7). Overall, significantly fewer adult than younger patients had used the device continuously at baseline (Table 1).

3.2. Fear of Hypoglycaemia. This questionnaire was completed by 58 participants.

Internal Consistency. For the total scale of the adult version Cronbach’s alpha was .88, suggesting a high level of reliability. The Behaviour Subscale had an alpha of .61, and the Worry Subscale had an alpha of .90, comparable to the results published by Cox and colleagues [14]. Cronbach’s alpha for the pediatric version was .69, demonstrating an adequate reliability. As reported elsewhere the Behaviour Subscale shows consistently a lower internal consistency [15, 16].

At study entry overall HFS items’ mean score was 1.33 ± 0.41; for the Behaviour Subscale it was 1.78 ± 0.49 and for the Worry Subscale was 1.04 ± 0.53 (range 0–4). After four nights on the AP, the HFS Worry Score decreased (1.04 ± 0.53 versus 0.90 ± 0.63; $P = 0.017$). The HFS Total Score and HFS Behaviour Score remained on a low level of anxiety (Figure 1).

There were no significant differences among all HFS scales at study entry or at follow-up in relation to the patients’ demographic or diabetes characteristics (each $P > 0.1$).

Table 2: Acceptance of an artificial pancreas analysis.

		Pre	Post	Delta	*P* value
Total acceptance	All	4.69 (0.87)	4.76 (1.06)	0.07 (0.77)	0.501
Intention to Use	All	4.7 (1.25)	4.76 (1.64)	0.01 (1.44)	0.964
Perceived Usefulness	All	4.66 (0.91)	4.67 (1.07)	0.01 (0.86)	0.940
Perceived Ease of Use	All	4.64 (0.94)	5.06 (1.09)	0.42 (0.95)	0.002
Total acceptance	Children ($n = 17$)	4.54 (1.04)	4.54 (1.15)	−0.00 (0.67)	
	Adolescents ($n = 19$)	4.69 (0.77)	4.88 (1.18)	0.19 (0.86)	
	Adults ($n = 19$)	4.81 (0.82)	4.83 (0.86)	0.01 (0.80)	

Values are expressed as mean (SD).

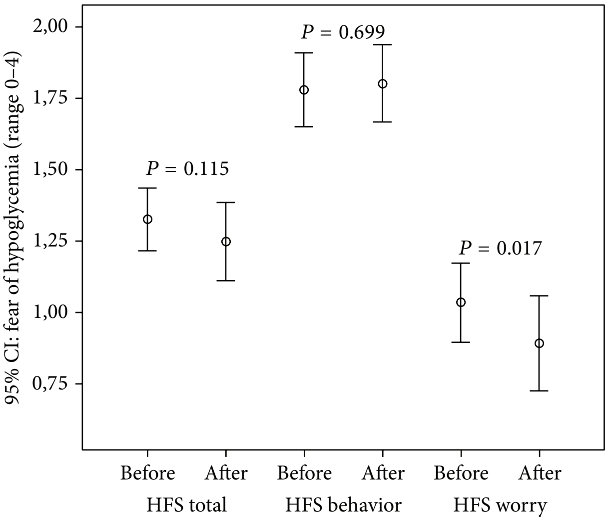

Figure 1: Hypoglycaemia Fear Survey (HFS) before and after 4 nights with the MD-Logic artificial pancreas in home setting ($n = 58$).

3.3. Acceptance of the Artificial Pancreas. 55 patients answered all items of the TAM questionnaire.

Internal Consistency. For the total scale Cronbach's alpha was .90, reflecting a good internal consistency. The "Intention to Use" subscale had an alpha of .83 and the "Perceived Usefulness" subscale revealed a Cronbach's alpha of .87, reflecting an adequate reliability. The "Perceived Ease of Use" subscale had an alpha of .71.

Factor Analysis. The principal components analysis revealed the presence of four components with eigenvalues exceeding 1, explaining 43.7%, 9.8%, 8.6%, and 7.2% of the variance.

The overall TAM score at study entry was 4.69 ± 0.87; for the "Intention to Use" subscale it was 4.75 ± 1.25, for the "Perceived Usefulness" subscale was 4.66 ± 0.91, for the "Perceived Ease of Use" subscale was 4.64 ± 0.94, and for the "Trust" item was 4.86 ± 1.24 (range each 0–6). After four nights on AP at home the "Perceived Ease of Use" score increased (4.64 ± 0.94 versus 5.06 ± 1.09; $P = 0.002$). The other subscales of TAM remained on a high level (Table 2) with no significant association to age, diabetes duration, gender, or metabolic control (each $P > 0.1$).

Patients using CGM continuously reported a higher acceptance of AP on all TAM scales compared to those with no regular use (Table 3). Accordingly there were significant centre-differences on TAM "Intention to Use" subscale ($P = 0.032$) and TAM "Perceived Usefulness" subscale ($P = 0.038$) with lower scores in the German sample compared to the ones from Slovenia and Israel.

3.4. Satisfaction. The satisfaction questionnaire was completed by 57 patients.

Factor Analysis. The principal components analysis revealed the presence of five components with eigenvalues exceeding 1, explaining 34.47%, 11.59%, 9.98%, 8.08%, and 7.47% of variance. Every item has only one high correlation with one factor, ranging from .56 to .87. Five scales can be identified: scale 1 "Perceived Usefulness of Alarms" (items 8, 9, and 12); scale 2 "Trust" (items 2, 6, and 11), scale 3 "Ease of Use" (items 3, 5, and 7); scale 4 "Satisfaction" (items 1, 13, and 14), and scale 5 "Freedom" (items 4, 10).

Internal Consistency. For the total scale Cronbach's alpha was .84, reflecting a good internal consistency. Only if item 10 would have been deleted there is an increase in Cronbach's alpha to .85. The "Perceived Usefulness of Alarms" subscale showed an alpha of .75, "Trust" subscale had an alpha of .73, "Ease of Use" subscale had an alpha of .72, "Satisfaction" subscale had an alpha of .77, and "Freedom" subscale had an alpha of .56 reflecting a lower internal consistency.

The overall satisfaction score was 3.02 ± 0.54; for "Perceived Usefulness of Alarms" subscale it was 2.82 ± 0.77, for "Trust" subscale was 3.07 ± 0.79, for "Ease of Use" subscale was 3.26 ± 0.73, for "Satisfaction" subscale was 3.16 ± 0.77, and for "Freedom" subscale was 2.66 ± 0.91 (range 0–4). There were significant differences of "Ease of Use" subscale ($P = 0.004$) between the age groups with significant lower mean scores in children than in adolescents/adults (Table 4).

Significant differences of overall satisfaction mean score, "Perceived Usefulness of Alarms" subscale, "Satisfaction" subscale, and "Freedom" subscale according to regular sensor use with significant higher mean scores in patients using CGM continuously were observed ($P = 0.001$, $P = 0.002$, $P = 0.005$, and $P = 0.009$).

There were no significant centre differences on overall satisfaction scores and all subscales.

Table 3: Association between acceptance of an artificial pancreas and regular sensor use initial.

		Regular sensor use Yes	Regular sensor use No	*P* value
Total acceptance	All	5.07 (0.59), *26*	4.34 (0.93), *29*	0.000
Intention to Use	All	5.20 (1.01), *28*	4.33 (1.32), *30*	0.007
Perceived Usefulness	All	5.02 (0.67), *27*	4.34 (0.98), *30*	0.004
Perceived Ease of Use	All	5.03 (0.77), *25*	4.28 (0.96), *27*	0.004
Total acceptance	Children	5.05 (0.81), *10*	3.80 (0.90), *7*	
	Adolescents	5.09 (0.42), *11*	4.14 (0.81), *8*	
	Adults	5.07 (0.49), *5*	4.72 (0.90), *14*	

Values are expressed as mean (SD), *n*.

Table 4: Satisfaction scores after 4 nights with the MD-Logic artificial pancreas in home setting.

	Children	Adolescents	Adults	*P* value
Total satisfaction	2.96 (0.52)	3.06 (0.60)	3.04 (0.53)	0.848
Perceived Usefulness of Alarms	2.84 (0.88)	2.74 (0.80)	2.87 (0.64)	0.872
Trust	2.95 (0.70)	3.22 (0.80)	3.07 (0.88)	0.600
Ease of Use	2.85 (0.83)	3.35 (0.60)	3.60 (0.55)	0.004
Satisfaction	3.15 (0.69)	3.25 (0.91)	3.07 (0.75)	0.804
Freedom	3.03 (0.66)	2.58 (0.95)	2.37 (1.01)	0.068

Values are expressed as mean (SD).

4. Discussion

This analysis of the psychological impact of using the automated closed-loop MD-Logic system under real-life conditions in the patients' home demonstrated reduced worries of hypoglycaemia with the artificial pancreas. Among children as well as adolescents and adult patients with T1DM alike there was a high level of satisfaction and increased acceptance of controlling nocturnal blood glucose automatically.

Hypoglycaemia, especially at night, is a major concern of patients and parents. It can impair well-being and is generally accepted as major obstacle to reach near-normoglycaemia [18, 19]. New technologies like CSII and CGM can improve glycemic control but still cannot solve the problem of nocturnal hypoglycaemia sufficiently [20]. Recent studies of our group and others with a night-time closed-loop system demonstrated that the closed-loop system is effective reducing the rate of nocturnal hypoglycaemia and increasing time within range in the home setting [5, 6, 21]. The present results confirm that these positive clinical results translate into positive psychological well-being with the MD-Logic system reducing worries of hypoglycaemia and increasing acceptance and satisfaction with this new technology in all age groups under real-life conditions.

It should be noted that fear of hypoglycaemia scores at study entry were already relatively low in all age groups but comparable to those reported in the literature for adults [22, 23], adolescents [24], and children [15]. This low HFS level had to be expected as patients with a particular history of severe hypoglycaemia were not included in the study for safety reasons. Nevertheless, despite the already low baseline level of HFS, a significant reduction in the Worry Subscale after using the AP system was found. This scale is known to reflect the cognitive level of fear of hypoglycaemia. Thus these findings may relate to AP patients experiencing less and even more reliable alarms compared to using sensor-augmented pump therapy (SAP). A significant reduction of hypoglycaemia and a lower rate of hypoglycaemia alarms during the closed loop nights with the MD-Logic AP versus control nights were demonstrated in the interim findings of the main study [5]. This may reinforce patients' trust in CLS and reduce their worries concerning episodes of hypoglycaemia. Our current findings are in contrast to another study on short-term use effects of CGM on fear of hypoglycaemia [25]. Without automated closed-loop insulin adjustment no reduction of fear of hypoglycaemia was observed with CGM alone. The authors argued that this finding may have been related to the low CGM accuracy and a high rate of false alarms. Adolescents especially reported frequent alarms as a barrier to using CGM continuously [26].

In our study the Behaviour Subscale of HFS remained unchanged on a low level. This can be explained due to the short time of the study. After only four nights it is unlikely that a major behaviour change can be observed. In another study after a two-month blood glucose awareness training, which focused on behavioural aspects, both scales were significantly reduced [27]. Currently 60-day studies with the MD-Logic under home conditions are underway. It will be interesting to analyse if such a longer period will eventually lead to changes in behavioural parameters. Nevertheless, our findings indicate an improvement in well-being in patients with T1DM using the MD-AP with less worries concerning episodes of hypoglycaemia and its consequences.

Satisfaction with the CLS has been assessed with a newly developed questionnaire to assess CL-satisfaction. The CL-satisfaction questionnaire demonstrated good internal reliability. In general, satisfaction with CLS has been relatively high in our study, with a mean score of about 3 (on a 0- to 4-point scale). CL-satisfaction was related to age, with lower satisfaction regarding "Ease of Use" of the AP in children than in adolescents and adults. This finding raises the issue that children (10–14 yrs) need the support and positive motivation of their caregivers for managing their diabetes tasks with the CLS. As a practical consequence, the developments of age appropriate education materials and specific curricula for children and their caregivers before starting the AP need to be implemented.

Despite the considerable technical prerequisites of using the CLS, the barriers of CLS in daily life were rated very low, especially in patients with regular CGM use. Potential hassles concerning the interpretation of a lot of data are considered a major barrier to CGM use. Therefore previous regular CGM experience at baseline may have given the patient sufficient knowledge to understand the more complex issues related to the CLS (e.g., sensor information and alarms). The CLS finally allows them to profit from the benefits of real-time CGM without the need for making sense of fluctuating glucose levels. Similar results were seen in a study comparing CGM before starting CSII versus CGM after using CSII. The group with CGM use before the start of CSII eventually turned out to use CGM more frequently [28]. A potential recommendation for future success with the CLS may be implementing a longer CGM experience prior to starting CLS.

The level of acceptance of CLS has been assessed with the adapted TAM questionnaire [12]. In general, acceptance of an AP has been relatively high in all age groups even before participants had any experience with the CLS overnight at home, with mean score of about 4 (on a 0 to 6 scale). After 4 nights with an AP participants reported significantly higher "Perceived Ease of Use" of the AP independently of age. Likewise the other acceptance scales remained on a high level. These findings demonstrate high acceptance before and after CL experience. Similar to the satisfaction results participants with regular sensor use reported significant higher acceptance scores of an AP than participants without regular sensor use. It can be summarized that patient satisfaction with and acceptance of the AP have been relatively high, and patients who used CGM regularly before starting AP reported higher satisfaction with and higher overall acceptance of an AP.

Recently a study was published regarding the psychosocial impact of overnight CLS at home for 15 adolescents with T1DM by Cambridge Group [13]. High satisfaction with the closed-loop system and a decrease of the mean HFS total score were reported to be similar to our data. However, inferential statistical analysis and comparison to our data were not possible due to the small sample size of the Cambridge Group.

The major strength of this study is that it provides evidence of the psychological effect of a CLS under real life conditions for different age groups. As the patients are asked to wear two devices (sensor and pump) as well as a laptop with the algorithm this high acceptance level of the system by patients is reassuring. Long-term adherence to CLS tasks will be necessary for the efficacy of this new technology. In CSII users with poor adherence to CSII tasks the efficacy of CSII in youth is limited [29]. Clearly CLS may reduce the burden of several diabetes tasks and could provide a significant benefit to the patients. They will be relieved from giving boluses, adjusting the basal rate or calculating insulin-to-carb ratios. Nevertheless, the patients' involvement in some of the diabetes management tasks will remain when using the CLS. They will still need to treat (rare) hypoglycaemia with carbohydrates, change the insulin catheter and sensor, or check the blood glucose for sensor calibration. Thus, in spite of the potential ease in diabetes management through the CLS, the human factor still needs to be taken into consideration.

The study covered a total period of 4 nights with the CLS. Important short-term effects of the MD-Logic AP on fear of hypoglycaemia and satisfaction with and acceptance of an AP were demonstrated. Several limitations of the present study have to be kept in mind. This study may not be adequately powered as the psychological aspects were not the primary end points. Also, the pediatric participants may not be able to provide all answers correctly. In a next step the psychological effect of an AP during long-term overnight and day-and-night use will be studied. Moreover, this study included only subjects without DKA or recent severe hypoglycaemia, but previous studies have shown that patients in poor metabolic control benefitted to a much greater extent from new technologies like SAP [30]. Thus it will be a future challenge to evaluate if the AP technology could also provide a significant step forward for subgroups with frequent acute diabetes complications.

5. Conclusions

In conclusion, this study demonstrated the positive psychological effect of an AP system in patient's home on fear of hypoglycaemia and satisfaction with and acceptance of an AP in children, adolescents, and adults with T1DM. By using the MD-Logic AP for four consecutive nights in home setting worries of hypoglycaemia were reduced in all age groups. In addition high satisfaction with and increasing acceptance of this new technology were reported after using the MD-Logic AP in home setting. This may predict an effective long-term use of the AP system by the patients in the future.

Abbreviations

AP:	Artificial pancreas
CGM:	Continuous glucose monitoring
CLS:	Closed-loop system
CSII:	Continuous subcutaneous insulin infusion
DREAM:	Diabetes Wireless Artificial Pancreas Consortium
HFS:	Hypoglycaemia Fear Survey
SAP:	Sensor-augmented pump therapy
TAM:	Technology Acceptance Model
T1DM:	Type 1 diabetes mellitus.

Disclosure

Moshe Phillip is a member of the Advisory Board of AstraZeneca, Sanofi, Animas, Medtronic, and Bayer Health

Care and Board Member of C.G.M.3 Ltd., Consultant of Bristol-Myers Squibb, D-medical, Ferring Pharmaceuticals, and Andromeda Biotech. The Institute headed by Moshe Phillip received research support from Medtronic, Novo Nordisk, Abbott Diabetes Care, Eli Lilly, Roche, Dexcom, Sanofi, Insulet Corporation, Animas, Andromeda, and Macrogenics. Moshe Phillip has been paid lecture fees by Sanofi, Novo Nordisk, Roche, and Pfizer. He is a Stock/ Shareholder of C.G.M.3 Ltd. and DreaMed Diabetes Ltd. Moshe Phillip reports two patent applications. Tadej Battelino is a board member of Novo Nordisk, Sanofi, Medtronic, and Bayer Health Care and Consultant of Spring. Tadej Battelino's institution received research grant support, with receipt of travel and accommodation expenses in some cases, from Abbott, Medtronic, Novo Nordisk, GluSense, Sanofi, Sandoz, and Diamyd. Tadej Battelino received honoraria for participating on the speaker's bureaux of Eli Lilly, Bayer, Novo Nordisk, Medtronic, Sanofi, and Roche. Tadej Battelino and Nataša Bratina were supported in part by the Slovenian National Research Agency Grant no. P3-0343. They are shareholder of DreaMed Diabetes Ltd. Thomas Danne received honoraria for consulting, speaking engagements from Sanofi, Novo Nordisk, Eli Lilly, Medtronic, Roche, Abbott, Dexcom, GSK, Cellnovo, Bayer Diabetes Care, and Johnson & Johnson. He is shareholder of DreaMed Diabetes Ltd. Olga Kordonouri received honoraria for scientific lectures from PriMedia, consulting fees and travel reimbursement from Sanofi and Roche Diagnostics. She is shareholder of DreaMed Diabetes Ltd. Karin Lange received honoraria for consulting and scientific lectures from Bayer Diabetes Care, Berlin Chemie, Eli Lilly, Merck, MSD, Novo Nordisk, Roche Diagnostics, and Sanofi.

Conflict of Interests

Claudia Ziegler, Alon Liberman, Revital Nimri, Ido Muller, Simona Klemenčič, Sarah Bläsig, and Kerstin Remus declared no conflict of interests. There is no other potential conflict of interests relevant to this paper.

Authors' Contribution

This study was an investigator-initiated trial. The study and protocol were designed by the investigators Tadej Battelino, Moshe Phillip, Olga Kordonouri, and Thomas Danne. Claudia Ziegler and Karin Lange contributed to the study concept and design, researched the data, contributed to the statistical analysis and data interpretation, and wrote and edited the paper. Moshe Phillip and Revital Nimri coordinated the study, codesigned and implemented the glucose controller, and participated in data analysis and interpretation. Alon Liberman, Ido Muller, Simona Klemenčič, Nataša Bratina, Tadej Battelino, Thomas Danne, Olga Kordonouri, Sarah Bläsig, and Kerstin Remus contributed to the study concept and design, supervised the study, researched data, participated in data analysis and interpretation, and reviewed and edited the paper. The first (Claudia Ziegler) and last authors (Karin Lange) had full access to the data of the study and take responsibility for the accuracy of the analysis and integrity of the work as a whole. All authors reviewed and accepted the final version of the paper.

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