

# Health Literacy, Diabetes Prevention, and Self-Management

Guest Editors: Joanne Protheroe, Gill Rowlands, Bernadette Bartlam,  
and Diane Levin-Zamir





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Journal of Diabetes Research

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## Editorial

# Health Literacy, Diabetes Prevention, and Self-Management

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## 1. Introduction

In the last few decades, focus on how to achieve and support maintenance of optimal glycemic control has become a well-established research area. It is well known and accepted that the degree of blood glucose control, especially in diabetes mellitus type 2, is linked with the risk of developing complications such as heart disease, stroke, renal failure, and blindness [1, 2]. Patients' knowledge about diabetes mellitus, their attitudes towards self-management, and self-management skills, together with lifestyle choices, are central to achieving and maintaining glycemic control, both in the short term and long term. The World Health Organization defines health literacy as "the personal characteristics and social resources needed for individuals and communities to access, understand, appraise and use information and services to make decisions about health" [3]. Health literacy is known to be associated with health outcomes, including chronic disease and diabetes [4]. Among people with type 2 diabetes, inadequate health literacy is independently associated with worse glycemic control, higher rates of retinopathy, and lower self-rated health [5, 6]. Inadequate health literacy may contribute to the disproportionate burden of diabetes-related problems among disadvantaged populations [6, 7]. A variety of measures have been developed to assess health literacy depending upon context, as reflected in the articles in this special issue.

Needing to understand this association in more depth and to explore potential interventions to improve diabetes health outcomes and quality of life was the basis for dedicating a special edition of this journal to such issues. The intention is

to contribute to an evidence base that better informs diabetes treatment and prevention planning for patients, clinicians, and health policy decision-makers

The main themes highlighted in this issue are health literacy and lifestyle in relation to diabetes, including studies exploring behavior change and motivation; mechanisms, moderators, and mediators of change; interventions to promote healthy lifestyles with respect to diabetes; self-care and self-management including health promotion aspects of diabetes care; health literacy; the role of family, peer support, and other care-givers, social networks, and distributed health literacy; and health systems navigation and management. The 12 studies included reflect a global reach, with research from six countries across four continents.

(a) *Feasibility and Outcome Measures of Self-Management Interventions.* In their study from Spain, G. Moreno and colleagues describe their feasibility study conducted in a range of primary care clinics and show that the implementation of their diabetes self-management programme was feasible. However, it was shown that while self-efficacy, blood pressure, physical activity, and some dietary habits improved, glycemic control was not achieved, perhaps due to the short-term duration of the intervention in the context of a feasibility study. In another study, J. F. Graumlich and colleagues report on their randomized control trial testing the effectiveness of a medication planning tool implemented via an electronic medical record to investigate the improvement of people's medication knowledge, adherence, and glycemic control as compared to usual care. They found that people with diabetes type 2 who used the tool had greater knowledge of medication



indication; however, there was no improvement in adherence nor in glycemic control. Yet it is reported that the tool supported patient-provider collaboration in the clinic and the authors hypothesize that results may be improved by extending the tool to home and community settings. In two linked papers reporting a feasibility randomized control trial into the use of Lay Health Trainers (LHTs) to support self-management in a population with low health literacy, J. Protheroe and colleagues show that the intervention was associated with improved mental health, and illness perception, in addition to better self-management skills and QALY profile at 7-month follow-up, while B. Bartlam and colleagues report on the mixed methods process study evaluation of the trial. They note that the intervention proved feasible and offered important insights for a follow-up randomized control trial, as well as further training to support the LHTs skills for counselling older people with diabetes. These studies further emphasize the difficulties with, and the importance of, recruiting participants with low health literacy into trials exploring the development of new interventions to improve self-management. Failure to include participants with low health literacy into such trials may in fact inadvertently worsen the disproportionate burden of diabetes-related problems among disadvantaged populations [6].

*(b) Culturally Sensitive and Ethical Aspects of Diabetes Risk and Self-Management Interventions among Special Populations.* Cultural considerations and appropriateness in the management of type 2 diabetes have been shown to be critical in offering appropriate care, particularly due to the cultural influences on lifestyle and self-management [8]. Several articles in this special issue focus on cultural aspects of diabetes management. E. Wilkinson et al. offer a literature review that examines the topic of older people with diabetes from ethnic minorities in the UK. They highlight emerging themes from the literature including cultural competency (health care providers understanding and taking account of the importance of social and cultural influences of patient health beliefs and behaviors) and comorbidity, with ramifications for “culturally intelligent” and individualized care. N. Patel et al. describe the pilot testing of a cross-cultural tool, adapting a self-assessment risk tool to the Indian Gujarati language in order to achieve an equivalent score, using a multicomponent translation model. In addition, C. T. Ing et al. report on a study in which Native Hawaiians and other Pacific Islanders who had received a culturally tailored, community based self-management intervention program (Partners-in-Care, PIC) were then randomized to social support groups or control to see if social support improved maintenance of the benefits of the intervention over time. While both the control and social support groups maintained their initial improvements over 6 months, the authors explore the further potential benefits of social support.

*(c) Age and Gender Considerations.* The importance of individual background characteristics such as age and gender has also attracted the attention of researchers with regard to health literacy and diabetes self-management, as seen in two articles in this special issue. D. Goeman et al. have applied the

Optimizing Health Literacy Access (Ophelia) approach for codesigning interventions based on tool for assessing health literacy specific needs of people/organizations. As reported in this issue, the method was successfully applied among older people with diabetes, through a home care nursing service in Australia. Gender issues regarding diabetes self-management have also been researched and are presented in this special issue. S. T. Hendriks et al. used the Patient Activation Model (PAM) to investigate gender differentiation and patient activation. Their findings showed no gender difference after adjusting for cofounders with regard to patient activation, while certain self-management factors in fact were related to gender.

*(d) Health Literacy, Behavioral and Mental Health Risk Factors for Diabetes.* The behavioral risk factors for diabetes and the significance of lifestyle changes on the etiology of diabetes and on glycemic control are also critical issues for research [9–12]. Y.-T. Sung and colleagues explore the significance of smoking and smoking cessation on the incidence of diabetes. The findings showed that even up to 2 years subsequent to smoking cessation, ex-smokers still had a higher risk of diabetes. K. Friis et al. noted that, among people with diabetes in a Danish sample, lifestyle behaviors, namely, nutrition and physical activity were positively associated with health literacy, after controlling for cofounders. Yet no such association was found between alcohol and tobacco consumption and health literacy. In the final article of this thematic area, D. Maneze et al. examined the influence of depression and health literacy on diabetes self-management and found that, among a sample in Australia, depressed mood predicted low health literacy and lower self-management. They concluded with a recommendation to screen for depression while helping also to support self-management among people with low literacy.

In summary, the articles in this special edition highlight important issues and emerging research in health literacy and in self-management in diabetes. This issue includes a particular focus on measurement and the cultural and ethical issues of self-management in populations at risk of poor outcomes, with examples from around the world. The importance of including these at risk populations in future trials of interventions, especially those designed to support self-management in diabetes, cannot be overemphasized. Further research is needed to ensure that the benefits for patients, communities, and societies can be achieved through enhanced self-management strategies, and hence reduced risks of morbidity and mortality can be realized by all groups in societies, in diverse cultural settings.

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Gill Rowlands  
Bernadette Bartlam  
Diane Levin-Zamir

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## Research Article

# A Pilot Study to Assess the Feasibility of the Spanish Diabetes Self-Management Program in the Basque Country

**Estibaliz Gamboa Moreno,<sup>1</sup> Lourdes Ochoa de Retana Garcia,<sup>2</sup> Maria Emma del Campo Pena,<sup>2</sup> Álvaro Sánchez Perez,<sup>3</sup> Catalina Martinez Carazo,<sup>3</sup> Juan Carlos Arbonies Ortiz,<sup>4</sup> Maria Angeles Rua Portu,<sup>5</sup> Koldo Piñera Elorriaga,<sup>6</sup> Amaya Zenarutzabeitia Pikatza,<sup>7</sup> Miren Nekane Urquiza Bengoa,<sup>8</sup> Tomás Méndez Sanpedro,<sup>9</sup> Ana Osés Portu,<sup>10</sup> Lourdes Gorostidi Fano,<sup>10</sup> Miren Bakarne Aguirre Sorondo,<sup>11</sup> Kalliopi Vrotsou,<sup>11</sup> and Rafael Rotaecche Del Campo<sup>12</sup>**

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**Purpose.** The purpose of this study was to assess the feasibility of the Spanish Diabetes Self-Management Program (SDSMP) in the primary care setting of the Basque Health Service and offer initial estimations of the randomized controlled trial (RCT) effects. **Methods.** Ten health centers (HCs) participated in a single-arm pilot study with a 6-month follow-up period between February 2011 and June 2012. Recruitment was performed via invitation letters, health professionals, and the local media. Each intervention group consisted of 8–15 people. The ability of each HC in forming up to 2 groups, participants' compliance with the course, and coordination and data collection issues were evaluated. Glycated haemoglobin (HbA1c) was the main outcome variable. Secondary outcomes were cardiovascular risk factors, drugs consumption, medical visits, quality of life, self-efficacy, physical exercise, and diet. **Results.** Two HCs did not organize a course. A total of 173 patients initiated the program, 2 dropped out without baseline data, and 90% completed it. No pre-post HbA1c differences existed. Certain improvements were observed in blood pressure control, self-efficacy, physical activity, and some dietary habits. **Conclusion.** The SDSMP is feasible in our setting. Our experience can be of interest when planning and conducting this program in similar health settings. The trial is registered with ClinicalTrials.gov identifier NCT01642394.

## 1. Introduction

Diabetes is one of the most prevalent chronic diseases, with 422 million people worldwide having diagnosed diabetes in 2014 [1]. It is estimated that the prevalence of diagnosed and undiagnosed type 2 diabetes (T2DM) in Spain may reach as high as 12% in people above 30 years of age [2]. T2DM is associated with an increased morbidity and mortality and it is thought to be responsible for 1.5 million deaths in 2012 [3]. What is more, the direct and indirect costs of the disease between 2011 and 2030 will reach US \$ 1.7 trillion [3]. It is estimated that diabetes accounts for between 6.3 and 7.4% of the costs in our health system [4].

Above all, T2DM is associated with cardiovascular system conditions, such problems being the cause of death in three-quarters of the patients. In the Basque Country, 44% of people with diabetes are obese [4] and 22% have diabetic macroangiopathy [5]. The diabetes control is improving in our setting, although 64% of patients have HbA1c levels below 7% and only 50% have blood pressure readings under 140/80 mmHg [5].

Patients' education can play an important role in improving glycemic control and reducing cardiovascular risk [6]. The current Basque Country clinical practice guideline (GPC) for T2DM recommends offering a structured educational program in order to empower the patients and encourage their active participation in the management of their condition [6]. Patient activation is defined as understanding one's own role in the care process and having the knowledge, skills, and confidence to take on that role [7].

Research indicates that activated patients are more likely to adhere to treatment regimens, get preventive care, and participate to a greater degree in decisions about their care [8]. They are also more likely to engage in healthy lifestyle behaviors, to seek out health information, and to make less use of healthcare services. Interventions that provide peer support for patients and improve their problem-solving skills have also been shown to increase patient activation and improve health outcomes [8].

Like other chronic illnesses, diabetes requires patients to take responsibility for their own health (self-care) to minimize long-term complications. Among programs on patient self-management, the most widely used structured approach is the Chronic Disease Self-Management Program (CDSMP) [9] developed at Stanford University. The CDSMP has different versions, among which is the Diabetes Self-Management Program (DSMP), specifically adapted for T2DM patients and its Spanish language version (SDSMP) [10]. These self-management programs are based on Albert Bandura's self-efficacy theory of behavioral change [11], which states that the key predictive variables for successful change are confidence (self-efficacy) in the capacity for carrying out an action and the expectation of achieving a particular goal (outcome expectation). Many studies support that self-efficacy and changes seen in the latter are associated with changes in health behavior and health status [12].

Successive systematic reviews have been published on the efficacy of various educational models in self-care and patient

activation [13–16]. These reviews indicate great variety in the results of the interventions attributable to differences in the length of the follow-up, the modality of the interventions, and the target populations.

In Spain, the few data available on self-management programs suggest favorable results, but the latter have not been assessed through prospective studies or compared with usual care [17]. The Department of Health of the Basque Country has launched a new strategy for providing care to chronic patients based on the Chronic Care Model [18]. One of the cornerstones of this model is the promotion of self-care and population education. In this context, one of the trainings that offers the Active Patient Program ("*Paciente Activo*") follows the SDSMP methodology and has been proposed as an instrument to promote self-care in people with T2DM. In our health system, these educational interventions take place in the primary care health centers. These centers mainly host general practitioners, pediatricians, and nurses, with the latter bearing the responsibility of most educational activities.

A single-arm pilot study was conducted for assessing the feasibility of this educational intervention in our context [19]. Acceptability, participation, and satisfaction with the educational intervention were studied. Furthermore, the obtained data served to estimate the subsequent clinical trial sample size [19], while offering initial estimations of the expected effects for the main and secondary outcomes [19]. Finally, the experiences and lessons learned during this phase helped the investigators to better prepare, organize, and control all aspects of the subsequent clinical trial [20].

## 2. Objectives

The feasibility aspects assessed by the pilot study were the interest of the target population in the proposed educational program and the enrollment rate; compliance with the program's schedule; adequacy of the battery of the administered questions, and finally participation and coordination of several health centers (HCs).

In addition, the main and secondary outcome pre-post effects were estimated. The standard deviation (SD) estimation of the main outcome of interest (HbA1c) was implemented in the sample size estimation of the clinical trial. All primary and secondary derived effects offer an initial idea of the results that may be expected in the clinical trial.

## 3. Methods

This preliminary research was a prospective pre-post pilot study without a control group. Recruitment took place in 10 participating HCs across 4 healthcare organizations (i.e., primary care districts of Araba, Gipuzkoa, Ezkerraldea-Enkarterri, and Bidasoa Integrated Healthcare Organization) in the Basque Country (Spain) from February 2011 to June 2012. Between 2 and 9 health professionals (HPs) participated per center.

Patients with T2DM between the ages of 18 and 79 years were included. Individuals with mental health problems (bipolar disorder, psychosis, schizophrenia, Alzheimer's



disease, or other forms of dementia) or other health problems, that might have affected their ability to participate in the study, were excluded.

Recruitment was carried out in several ways. Invitations letters were sent to 120 T2DM subjects of each participating HC, fulfilling the age criteria. These subjects were selected via a computer generated random numbers sequence. In addition, the participating HPs were instructed to inform and invite patients to the study. Finally, awareness about the program was also spread in the local media. All the patients who agreed to participate gave written informed consent, after receiving information about the purpose of the research project.

Sociodemographic and baseline clinical data were collected on age, sex, years since diagnosis, and comorbidities. Assessed comorbidities were hypertension, heart disease, macroangiopathy (coronary, cerebrovascular, or peripheral artery disease), microangiopathy (renal, retinopathy, or neuropathy), depression, asthma, chronic obstructive pulmonary disease, and cancer.

#### 4. Description of the Intervention

Self-efficacy enhancement was the key element of the applied educational intervention. The teaching process was structured to include the following four self-efficacy components: performance mastery, which shows participants how to make specific action plans; modeling, which can be accomplished by involving peers as instructors of self-management programs; symptom interpretation, helping patients to form alternative interpretations of their physiological symptoms, as such interpretations can subsequently lead to new self-management behaviors; and, finally, social persuasion, which refers to the positive effect experienced by the majority of the group members and the way in which this can influence other group members [12]. On the other hand, the content of the self-management program addressed three tasks, medical or behavioral management, role management, and emotional management, and five core skills, problem solving, decision-making, resource utilization, forming a patient/healthcare provider partnership, and taking action [21]. The intervention consisted of 6 group sessions lasting 2.5 hours each, once a week for 6 weeks. Sessions were structured with the objective of enabling participants to acquire knowledge and skills related to the disease and its management, placing emphasis on tools for enhancing proactive self-care to achieve healthier lifestyle behaviors (improvements in diet, physical activity patterns, emotional management, and medication adherence among others).

Patients were trained to set their own targets, solve problems related to their condition, and communicate more effectively, with their relatives and healthcare professionals, by sharing their feelings, in order to enable them to play a more active role in the management of their disease. The final goal of all this was to promote changes towards healthier lifestyles.

All sessions were supported by educational material specifically developed for the program: books, leaflets, and CDs. Each group was supervised by two leaders previously

trained and certified in the SDSMP. At least one of the leaders was required to be a T2DM patient or a caregiver for a person with this condition, while the other was allowed to be a HP. These leaders introduced themselves to participants as SDSMP leaders, not referring to their professional position, promoting the concept of peer-learning, as recommended in the implementation manual of the SDSMP. Patients not attending at least four sessions were considered not to have completed the program.

#### 5. Outcomes

**5.1. Feasibility Assessment.** The recruitment capacity of the centers and their ability in forming up to 2 intervention groups each was assessed. Each center was asked to recruit between 8 and 30 subjects. For the needs of this study, 8 and 15 were the minimum and maximum acceptable number of participants in any group. At least 65% of the participants initiating the intervention were expected to complete it [15]. Each center was responsible for and should be successful at managing all program related aspects and data collection. The actual educational intervention was delivered by the same investigators across all centers. Finally, the principal investigators attended interested patients, corresponding to nonparticipating HCs, organized the details related to baseline data information, and referred those subjects to the most convenient participating HC for receiving the educational intervention. The adequacy and understanding of the battery of questions would be judged by the frequency of missing data, while at the same time this would also inform about appropriate patient follow-up. A manual with detailed instructions related to the pilot study project was given to all participating HPs.

##### 5.2. Clinical Outcomes

**5.2.1. Primary Outcome Variable.** Glycated haemoglobin (HbA1c) level was a primary outcome variable.

##### 5.2.2. Secondary Outcome Variables

**Cardiovascular-Related Factors.** The factors are body mass index (BMI), systolic and diastolic blood pressure (SBP and DBP), and total and HDL cholesterol levels. Cardiovascular risk was assessed with the *Registre Gironí del COR* (REGI-COR) score, an adaptation of the original Framingham risk score for Mediterranean populations, calculated for persons between 35 and 74 years of age [22].

**Use of Medications.** Antidiabetes, antihypertensives, and antiplatelets were studied.

**Quality of Life.** The Spanish version of the self-administered instrument, Audit of Diabetes-Dependent Quality of Life (ADDQoL-19), was used [23]. This scale is specific for patients with diabetes and consists of 19 items assessing leisure activities, relationships, and living conditions. All items are addressed from two perspectives: the way diabetes affects the patient's life and what a patient's life might be like

if they did not have diabetes. Replies range from 1 (excellent) to 7 (very poor).

**Self-Efficacy.** The Spanish Diabetes Self-Efficacy Scale developed at Stanford University [24] was administered. It consists of 8 items assessing diet, physical activity, and control of the disease. Items are rated on a Likert-type scale from 1 to 10 (minimum to maximum). A total score and scores for the three aforementioned areas were obtained.

**Physical Exercise.** Physical exercise was assessed with the 7-Day Physical Activity Recall (PAR) interview [25, 26]. This is a semistructured interview concerning the intensity of physical activity performed in the previous week. Exercise intensity in metabolic equivalents (METs) in hours/week is estimated considering the hours of moderate, intense, and very intense exercise. PAR also assesses whether the exercise reported by the patients is suitable for their age.

**Diet.** Diet quality was examined using the food frequency questionnaire of the PREDIMED study [27]. This questionnaire assesses frequency consumption of olive oil, fruit, vegetables, dairy products, cereal, red and white meat, fish, pasta or rice, legumes, commercial sweets, and beverages.

**Patient Satisfaction with the Program.** It was measured with an anonymous specific satisfaction survey consisting of 10 questions related to sociodemographic and process variables, 20 satisfaction questions rated on 5-point Likert-type scale ranging from 1 = minimum to 5 = maximum and 3 open questions. Questions were divided into three sections referring to the material presented, organization of the program, and behavior change (see Supplementary Material available online at <http://dx.doi.org/10.1155/2016/9145673>).

**Use of Healthcare Services.** Number of visits to the general practitioner and nurse, number of visits to the emergency department, and number of times of hospitalization are compared during a 6-month period before and after the intervention. Only cardiovascular morbidity and diabetes-related complications (e.g., renal insufficiency, hypoglycemia, and ketoacidosis) were considered for the emergency department visits and hospital admissions.

Patients were assessed twice, 1 month before starting the intervention and 6 months after the end of the intervention. Sociodemographic and self-report questionnaires were given to patients to fill in, in their own homes. All participating HPs, previously trained by the research team, were in charge of collecting the following data. Medication consumption and clinical visits were assessed from the electronic clinical history files and corroborated by the participants. Body mass index (BMI) and systolic (SBP) and diastolic blood pressure (DBP) were recorded, while HbA1c and cholesterol levels were assessed by blood samples. These samples were extracted in participants' HCs and were analyzed in the reference laboratories of the four participating health districts of the Basque Health System (Osakidetza). When necessary, the referring HP helped the participants complete the questionnaires.

Finally, the 7-Day PAR and PREDIMED questionnaires were administered over the telephone by trained interviewers from a centralized call center.

## 6. Statistical Analysis

Categorical variables were expressed as frequencies ( $n$ ) and percentages (%) and continuous variables as means and standard deviations (SD) when normally distributed or as medians and interquartile ranges (Q1, Q3) when they did not follow a normal distribution.

The comparisons between categorical variables before and after the intervention were carried out with McNemar's test. Comparisons between continuous variables were performed with Student's  $t$  test for paired samples or the nonparametric Wilcoxon signed-rank test. All the differences were calculated as postintervention minus preintervention values. For normally distributed variables, differences are presented as means with 95% confidence intervals (CI), while, for nonnormally distributed variables, such as the number of visits, differences are expressed as medians and their corresponding 95% CI. Comparisons were considered as statistically significant when  $p < 0.05$ . For the needs of this study, all results are based on available data. Statistical analyses were carried out using the SAS v.9.3.

## 7. Ethical Considerations

The research protocol was approved by the Clinical Research Ethics Committee of the Basque Country (Ref. number: 11/2010).

## 8. Results

**8.1. Feasibility Assessment.** The participating HCs recruited between 3 and 27 patients each, while 5 patients corresponded to nonparticipating HCs. Five of the centers obtained two program groups; three centers obtained one group, while patients recruited in two centers (i.e.,  $n = 3$  and 5) had to follow the program in a different HC, for being less than the required minimum for a course. The 5 additional subjects were absorbed without affecting the respective number of program groups. Of the 1200 invitation letters sent, 46 were undelivered. Many patients visited their corresponding HP with an invitation letter and requested more details on the program. However, frequency of patients who responded to the letter's invitation, of patients who showed initial interest, and of patients informed exclusively by the HP was not registered.

A total of 174 patients signed an informed consent, 173 initiated the program, and 2 dropped out after the first session, without providing baseline data. One hundred and fifty-five patients (90%) completed the training program (Figure 1).

Between 1 and 9% of the self-reported questions were not answered at baseline. At the postintervention assessment, the main outcome of interest, along with other cardiovascular data, was missing for 5 of the 171 participants, while the



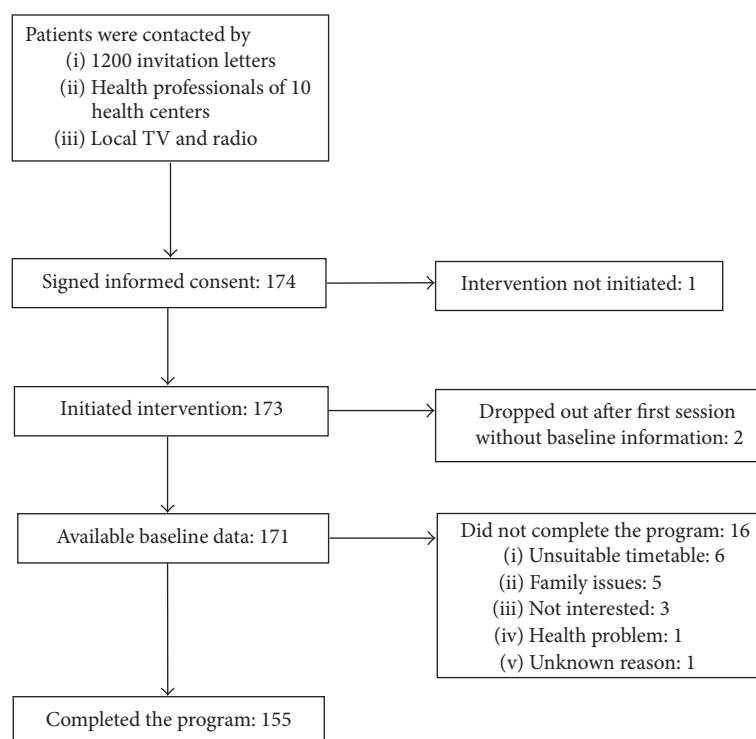


FIGURE 1: Flowchart of pilot study participants.

amount of missing data of the self-reported variables had increased.

**8.2. Baseline Characteristics of Participants.** Overall, 52% of the sample were male, with mean (SD) age of 63.4 (8.1) years. Among the most common comorbidities were hypertension (57%) and heart disease (26%), while 25% and 14% of the participants had a history of macro- and microangiopathy, respectively. Baseline data are summarized in Table 1.

**8.3. Pre-Post Differences.** HbA1c levels at the two pilot study moments were 7.3% (1.1) and 7.4% (1.3), respectively, with the mean difference between the measurements being 0.1% (95% CI: -0.1 to 0.2;  $p = 0.348$ ) (Table 2). It was additionally assessed whether patients with poorer initial control, defined as a baseline HbA1c  $\geq 7\%$ , presented greater reductions in this variable, but no differences were observed neither in patients with HbA1c  $\geq 7\%$  (diff: 0.01 (95% CI: -0.21 to 0.22);  $p = 0.960$ ;  $n = 94$ ) nor in patients with HbA1c  $\geq 8\%$  (diff: -0.06 (95% CI: -0.54 to 0.42);  $p = 0.791$ ;  $n = 38$ ) between the two time points. Further, no differences in BMI, total cholesterol levels, or cardiovascular risk were found (Table 2).

In terms of blood pressure, a reduction was seen after the intervention. The mean changes in SBP and DBP were -3.3 mmHg (95% CI: -5.4 to -1.3;  $p = 0.002$ ) and -1.3 mmHg (95% CI: -2.5 to -0.1;  $p = 0.032$ ), respectively. These reductions were also reflected in an increased percentage of patients who simultaneously achieved good control of both SBP and DBP (SBP < 140 and DBP < 90 mmHg) after the intervention, with 10% (95% CI: 3 to 18;  $p = 0.010$ ) of the participants improving the control of their blood

TABLE 1: Baseline characteristics of participating patients.

Baseline information	<i>N</i> = 171
Age in years; mean (SD)	63.4 (8.1)
Sex; <i>n</i> (%)	
Male	89 (52)
Female	82 (48)
Years with diabetes; mean (SD)	9.7 (7.2)
Smoking status; <i>n</i> (%)	
Smoker	30 (18)
Nonsmoker	141 (82)
Comorbidities; <i>n</i> (%)	
Hypertension	97 (57)
Heart disease	44 (26)
Macroangiopathy	43 (25)
Microangiopathy	24 (14)

*n* (%) = frequency (percentage) and SD = standard deviation. Comorbidity data indicate frequency of the “yes” category.

pressure during the study. However, this improvement was not reflected in a coronary risk reduction (Table 2).

In addition, the pilot study participants reduced by 1 both general practitioner ( $p = 0.005$ ) and primary nurse visits ( $p < 0.0001$ ). Frequency of emergency department visits and hospitalization remained 0 at both time points. Finally, no differences were seen neither in the total number of medications per patient nor in the percentage of patients taking antidiabetics, antihypertensives, or antiplatelets drugs (Table 2).

TABLE 2: Cardiovascular clinical variables and number of medical visits and times of hospitalization at baseline and 6 months after the intervention.

Variables	<i>n</i>	Preintervention	Mean difference (95% CI)	<i>p</i> value
<i>Cardiovascular data</i>				
HbA1c level	166	7.3 (1.1)	0.1 (−0.1, 0.2)	0.348
HbA1c < 7%; <i>n</i> (%)		72 (43)	3 (−4, 9)	0.465
BMI	167	30.4 (5.3)	−0.1 (−0.3, 0.1)	0.461
Total cholesterol	164	197.8 (37.9)	−3.2 (−7.6, 1.2)	0.158
REGICOR score	145	7.2 (3.8)	−0.2 (−0.6, 0.3)	0.466
SBP	166	137.1 (16.6)	−3.3 (−5.3, −1.2)	0.002
DBP	166	79.2 (9.9)	−1.4 (−2.5, −0.2)	0.024
Good blood pressure control SBP < 140 & DBP < 90; <i>n</i> (%)	166	88 (53)	10 (3, 18)	0.007
<i>Medication consumption</i>				
Antidiabetics; <i>n</i> (%)	171	133 (78)	1 (−2, 4)	0.479
Antihypertensives; <i>n</i> (%)		98 (57)	0 (−4, 4)	1.000
Antiplatelet drugs; <i>n</i> (%)		56 (33)	1 (−5, 2)	0.527
Number of medications; median (Q1, Q3)		3 (1, 4)	0 (0, 0)	0.763
<i>Number of medical visits; median (Q1, Q3)</i>				
General practitioner	165	3 (2, 5)	−1 (−1, 0)	0.005
Primary care nurse		4 (2, 5)	−1 (−1, −1)	<0.0001
Emergency department		0 (0, 0)	0 (0, 0)	0.815
Hospital admissions		0 (0, 0)	0 (0, 0)	0.278

Data are mean (standard deviation), unless otherwise stated. *n* (%) = frequency (percentage). The “*n*” column reports frequencies of available data at both time points. REGICOR estimates cardiovascular risk for patients between 35 and 74 years of age. Differences were calculated as postintervention minus preintervention values. CI: confidence interval. Q1, Q3: 25th and 75th percentiles. HbA1c: glycated haemoglobin. BMI: body mass index. SBP: systolic blood pressure; DBP: diastolic blood pressure. Mean difference for categorical variables corresponds to differences in paired proportions and their respective 95% CI and for ordinal variables (i.e., total number of medications and medical visits) to median differences with their respective 95% CI. Reported *p* values are based on paired *t*-tests for continuous variables, McNemar's test for binary variables, and the Wilcoxon signed-rank test for ordinal variables. Medical visits were assessed for the intervals of 6 months before and after intervention. Only diabetes-related complications were considered for the emergency department visits and hospital admissions.

When replying to the general item of the ADDQoL-19 “In general, my present quality of life is...” participants rated their quality of life as being better 6 months after the pilot study (*p* = 0.027). On the other hand, no differences were observed in the general item, “If I did not have diabetes, my quality of life would be...” (*p* = 0.263) or in the total ADDQoL-19 score (*p* = 0.877) between the two moments (Table 3).

Self-efficacy significantly improved both overall and in the different areas, namely, diet, physical activity, and control of the disease. The observed changes ranged from 0.5 (95% CI: 0.1 to 0.9) to 0.8 (95% CI: 0.5 to 1.2) (Table 3).

The percentage of participants who reached the recommended levels of physical activity for their age increased 6 months after the intervention by 12% (95% CI: 4 to 21%; *p* = 0.007), while this improvement was not captured when physical activity was measured in minutes and METs (Table 3). Regarding dietary habits, a 10% increase was observed in the percentage of patients eating five or more portions of fruit and vegetables after the intervention (*p* = 0.020) and cold cured meats consumption was reduced (*p* = 0.035). However, none of the other main dietary habits was altered (Table 3).

As far as satisfaction with the course was concerned, a total of 149 patients replied to these questions. In 19 of the 20 questions, the median score was 5 (95% CI: 4-5), with

only one item “This course is going to help me to manage my emotions better,” having a lower median score of 4 (95% CI: 4-5).

## 9. Discussion and Conclusion

**9.1. Discussion.** Based on the current pilot study, we concluded that performing a randomized clinical trial (RCT) for evaluating the effectiveness of an educational program for diabetic patients was feasible in our context. Results were acceptable as far as overall recruitment, course participation, and patients' satisfaction and collaboration across various centers was concerned.

However, several important observations were also made. Two of the participating centers, with 3 HPs collaborators each, did not manage to fulfill the minimum number of required participants. The number of involved staff, their motivation, and understanding of the study goals were important aspects to consider in the future RCT. This was seen as a key aspect for the successful RCT fulfillment, especially considering that the latter would involve a great number of centers dispersed over the whole Basque Country. Therefore, it was decided that at least 5 or 6 HPs per center should be achieved for the future study. In addition, during the RCT informative sessions for capturing participating HPs, more effort should be made on highlighting the positive

TABLE 3: Variables related to self-efficacy, quality of life, diet, and physical exercise at baseline and 6 months after the intervention.

	<i>n</i>	Preintervention	Mean difference (95% CI)	<i>p</i> value
<i>Spanish Diabetes Self-Efficacy Scale</i>				
Diet	131	6.5 (2.2)	0.5 (0.2, 0.9)	0.006
Physical activity	137	6.7 (2.2)	0.7 (0.3, 1.1)	0.0003
Disease control	136	6.2 (2.1)	0.8 (0.5, 1.2)	<0.0001
Total score	128	6.5 (1.7)	0.6 (0.3, 0.9)	<0.0001
<i>Quality of life, physical activity</i>				
ADDQoL score	145	−1.4 (1.4)	−0.02 (−0.2, 0.2)	0.877
Moderate and vigorous activity minutes/week	137	539 (776)	−13 (−144, 117)	0.840
Moderate and vigorous activity MET hours/week	137	5.5 (7.7)	0.01 (−1.4, 1.4)	0.984
Met physical activity recommendations for their age; <i>n</i> (%)	137	79 (58)	12 (4, 21)	0.007
<i>Dietary habits; n (%)</i>				
Fruit & vegetables: ≥5 pieces p/d	141	37 (26)	10 (2, 18)	0.020
Olive oil: ≥3 soup spoons p/d	142	28 (20)	−4 (−12, 5)	0.398
Red meat: <2 portions p/w	139	47 (34)	3 (−6, 11)	0.505
Cold cured meat: <2 portions p/w	131	64 (49)	11 (1, 20)	0.035
Legumes: ≥2 plates p/w	139	97 (70)	−4 (−13, 4)	0.304
Commercial sweets: <2 pieces p/w	125	87 (70)	3 (−5, 12)	0.465
Beverages: <1 can p/d	124	107 (86)	−2 (−8, 3)	0.405

Data are mean (standard deviation), unless otherwise stated. *n* (%) = frequency (percentage). The “*n*” column reports frequencies of available data at both time points. ADDQoL: Audit of Diabetes-Dependent Quality of Life. MET: metabolic equivalent. Meat portions were 100–150 grams for red meat and 4–5 slices or 80 grams for cold cured meat. p/w and p/d indicate per week and per day, respectively. Differences were calculated as postintervention minus preintervention values. Mean difference for categorical variables corresponds to differences in paired proportions and their respective 95% CI. Reported *p* values are based on paired *t*-tests for continuous variables and McNemar's test for binary variables.

aspects of the educational intervention; this was expected to improve patients' health control and relieve, in the long term, the workload of the professionals themselves. It was also thought that the HP motivation would increase, if pilot study patients participated actively in those informative sessions.

During the pilot study many participating HPs complained that their workload did not allow them to devote any time to the current project. For this reason, HPs participating in the RCT were going to be allowed (by Osakidetza) a certain amount of working hours devoted exclusively to the needs of that study.

It was also observed that missing information, especially on subjective and patient self-reported data, increased at six months postintervention, compared to baseline. This fact was taken into consideration when estimating the RCT sample size, but also it indicated the need for a closer patient follow-up during the RCT data collection.

The pre-post differences obtained in the current single-arm study may offer an initial estimation of the expected RCT results. The baseline characteristics of the current sample were comparable to those of the average diabetic patient in the Basque Country [4], except in that they were slightly younger and had lower levels of total cholesterol.

Changes in several dimensions including improvements in the self-efficacy scale, levels of exercise, and diet were observed. However, these changes were not accompanied by a greater glycaemic control in terms of HbA1c levels or changes in other variables, related to vascular morbidity, like coronary risk for example. The good initial control of the local T2DM

population and the short follow-up of the pilot study could be possible explanations of this lack of difference. It is recognized that diabetic people with poorer HbA1c levels have a greater room for improvement and tend to respond better to any type of intervention [4]. However, this phenomenon has not been observed consistently in the context of the Stanford Self-Management Programs [28–31]. This very hypothesis will be tested in the RCT study, where a greater number of subjects will be followed for a longer period of time.

It is important to note that although the target HbA1c level is the most widely used variable to date for assessing diabetes interventions, its use as the only method is currently being questioned. Recent evidence has shown that lower HbA1c levels are not always accompanied by a decrease in cardiovascular morbidity and mortality, especially in older patients or those with comorbidities [32]. Hence, it may be necessary to adapt the selection of variables to assess diabetes control to baseline levels of HbA1c, the length of time since diagnosis of the disease, and the presence of risk factors and cardiovascular morbidity [33]. The following RCT study of this group will explore the HbA1c level as its main outcome, in order to confirm or refute the prior theories, after a 2-year follow-up period, in our context.

The pilot study results suggested a reduction in blood pressure, similar to that obtained using nondrug approaches, such as a salt-free diet and physical exercise, and this was reflected to a significant increase in the percentage of patients with good blood pressure control, without changing the prescription of antihypertensives. The effect on blood

pressure has not been included in any of the evaluations of the DSMP we identified in our review of the literature [28, 34, 35]. Given the high prevalence of hypertension in people with diabetes and the importance of decreasing blood pressure for reducing cardiovascular morbidity and mortality, this potentially promising finding should be confirmed in future prospective studies, while the influence of a blood pressure reduction in the cardiovascular risk should also be further explored [20].

An improvement in scores on the specific self-efficacy questionnaire is a common finding in all evaluations on diabetes self-management [15, 36, 37]. However, in many occasions, the significant progress achieved was not followed by an improvement in quality of life [15]. On the other hand, people with diabetes, who improve their disease knowledge and self-management skills, are more independent and use fewer healthcare resources. This well-documented finding [15, 36, 37] was also observed in our sample.

The effects seen in the current study cannot be generalized and no causal relationship can be claimed between those effects and the applied educational intervention. The fact that the DSMP has been assessed in other populations and contexts, resulting in modest short-term positive results in outcomes such as depression, dietary habits, exercise, medication adherence, symptoms of hypoglycemia, communication with physicians, and health status [34–36], make us believe that the RCT findings will be in line with the a priori positive expectations.

This pilot study has certain limitations. Firstly, its single-arm nature was not a replicate of the future RCT study. However, its design permitted testing the feasibility of the educational program, in terms of participation and multiple-sites coordination. Even though the minimum number of participants was met overall, great variability was seen among participating HCs. Motivation and time availability of participating HPs are issues that will be treated more carefully in the follow-up RCT study. What is more, exact patient participation rates cannot be calculated. On one hand, the invitation letters were sent to T2DM patients, irrespective of whether or not they were fulfilling any other inclusion criteria than the age. This was due to the data confidentiality, which did not permit access to further medical information of the population of interest. Furthermore, no records of interested patients and patients informed exclusively by the HPs were kept. However, given the number of the participating centers, health professional and recruitment approaches, such a record would have been very difficult to manage. Finally, missing data information, especially at 6 months, is another important limitation. Patients that were not satisfied may have been more reluctant to reply after the intervention and thus the initially obtained and presented results may have been biased. Given the importance of missing and the effect they can have on the study's conclusions, a closer patient follow-up, at all stages, should be assured in the RCT.

**9.2. Conclusion.** The Spanish Diabetes Self-Management Program is feasible in our health system and well accepted by patients. The single-arm pilot study results suggest that the program may induce improvements in self-efficacy and blood

pressure, but its effectiveness will have to be confirmed by a RCT.

## 10. Practice Implications

The current pilot study could contribute to the debate on the most adequate outcome variables, for evaluating diabetic patients' interventions. In addition, the experiences and lessons learned during this phase will serve for better coordinating the future RCT study. Avoiding organizational and communicational flaws, motivating HPs, improving patients' follow-up, and refining the study manual will result in enhancing the RCT quality at all levels. Finally, the experience and lessons learned may be beneficial to similar health settings for planning and conducting diabetes self-management programs.

## Competing Interests

The authors declare that they have no competing interests.

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## Research Article

# Lay Health Trainers Supporting Self-Management amongst Those with Low Health Literacy and Diabetes: Lessons from a Mixed Methods Pilot, Feasibility Study

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This article reports a mixed methods process evaluation of a pilot feasibility randomised controlled trial comparing a Lay Health Trainer (LHT) intervention and usual care for those with poorly controlled Type 2 Diabetes Mellitus (T2DM). Set in a deprived area in the UK, this research explores patient and health care practitioner (HCP) views on whether a structured interview between a patient and a Lay Health Trainer (LHT), for the purpose of developing a tailored self-management plan for patients, is acceptable and likely to change health behaviours. In doing so, it considers the implications for a future, randomised controlled trial (RCT). Participants were patients, LHTs delivering the intervention, service managers, and practice nurses recruiting patients to the study. Patients were purposively sampled on their responses to a baseline survey, and semistructured interviews were conducted within an exploratory thematic analysis framework. Findings indicate that the intervention is acceptable to patients and HCPs. However, LHTs found it challenging to work with older patients with long-term and/or complex conditions. In order to address this, given an ageing population and concomitant increases in those with such health needs, LHT training should develop skills working with these populations. The design of any future RCT intervention should take account of this.

## 1. Introduction

In the last 30 years the number of people in the world aged 60 or above has doubled from 378 million in 1980 to 759 million in 2010. It is projected to more than double again in the next 40 years, rising to two billion by 2050. In addition, the older population is itself ageing; currently, the “oldest old,” those aged 80 and above, represent 13% of the global population aged 60 and over; yet projections indicate that by 2050 that proportion will have grown to 20% [1]. Long-term conditions (LTCs) are more prevalent in older populations (58 percent of people over 60 compared to 14 percent under 40) and in more deprived groups (people in the poorest social class have a 60 percent higher prevalence than those in the richest social class and 30 percent more severity of disease). In the United Kingdom (UK), the number of people with more than

one LTC is expected to rise from 1.9 million in 2008 to 2.9 million in 2018 and this increasing prevalence is considered to be one of the biggest challenges facing the National Health Service (NHS) [2]. In the light of the increasing pressures on health and social care created by an ageing population, the UK House of Lords recently called for an urgent revision of how care is delivered, arguing for a move toward more integrated, person-centred care [3].

Diabetes is an example of a LTC and the number of adults across the globe living with it has quadrupled since 1980 to 420 million people [4]. In the UK it is the fourth most prevalent LTC and has increased by 25 percent from 1,962,000 people in 2007 to 2,456,000 people in 2011 [2]. Factors driving this increase are largely lifestyle related, that is, obesity because of poor nutrition and a lack of physical activity [4]. Good clinical management of diabetes

is critical as poor control can result in complications such as blindness, renal failure, neuropathy leading to impotence, and foot disorders that can result in amputation, stroke, and heart disease [5]. It may be that inadequate health literacy is a significant factor in the disproportionate burden of diabetes and diabetes-related complications in more socioeconomically disadvantaged populations [6]. Moreover, those with low health literacy have lower levels of good self-management of chronic disease, including poorer diabetes self-management [6, 7]. Health literacy can be defined as “the personal characteristics and social resources needed for individuals and communities to access, understand, appraise and use information and services to make decisions about health” [8].

As a part of the response to the growing number of people living with long-term conditions, a number of which relate to health behaviours, many countries have developed the role of health-related lifestyle advisors (HRLAs) [9]. In the UK the term Lay Health Trainer (LHT) has been adopted. LHTs are people living in the local community, intended to be demographically similar to those with whom they work, offering “support from next door” rather than “advice from on high” and taking a holistic approach. They are trained to a minimum of UK National Qualification Framework (NQF) level three in using techniques based on psychological and behavioural theories to help change behaviours (<https://www.gov.uk/what-different-qualification-levels-mean/overview>). The role emerged as a result of the UK Department of Health’s “Choosing Health” public health White Paper [10], which had as its aim the reduction of health inequalities by targeting disadvantaged groups in order to increase healthy behaviours and create opportunities for employment and training. LHTs have been found to be effective in engaging with less heard groups and supporting them to make and maintain lifestyle changes. They aim to promote affordable and sociocultural relevant lifestyle advice within communities. However, they were not designed to work with specific health conditions and little work has explored their efficacy in chronic long-term condition management, such as diabetes [11, 12]. Nonetheless, Pennington and colleagues, in their systematic review of the effectiveness, cost-effectiveness, equity, and acceptability of different types of HRLA role, identified some evidence that lay-led self-management interventions can be both effectual and cost-effective [9].

## 2. The SHIPS Randomised Controlled Feasibility Pilot Trial

Given that self-management of Type 2 diabetes is dependent on healthy lifestyle choices, the Study of Health Trainer Improved Patient Self-management (SHIPS) was a randomised controlled feasibility pilot trial (RCT) to develop and then compare a LHT intervention to improve patient self-management with usual care for those with low health literacy and poorly controlled Type 2 diabetes mellitus (T2DM). Patients with HbA1c > 7.5 or 58 mmol/mol in at least the last two measures were eligible to be recruited from a socioeconomic disadvantaged population [13] (see

TABLE 1: Summary of data.

Interviews	
Patients	14 one-to-one interviews (mean 30 mins)
Health Trainers	4 interviews
	3 follow-up telephone interviews (mean 30 mins)
Service managers	2 x one dyadic interview (1 hr 50 mins)
	1 follow-up telephone interview (24 mins)
Practice nurses	4 telephone interviews (mean 25 mins)

Protheroe, Rathod, Bartlam, Rowlands, Richardson, and Reeves, this issue).

The feasibility, pilot RCT took place in a UK local government council authority funded health promotion service. This local service employed four LHTs to offer information and support to help individuals improve their lifestyle and general health, and it was overseen by two service managers. The service was located in a Victorian gate-lodge to a large public park, two miles from the town centre, with a bus every half an hour. The aim of not being located in an obvious health built environment, such as a clinic, was to emphasise supporting health and well-being from within the community. However, patients could be seen elsewhere if other venues were more convenient to them, including their local primary care centre or their own home.

The SHIPS study was a complex intervention and, in line with Medical Research Council guidance [14], the process evaluation reported here had three research objectives:

- (1) To explore if the intervention was considered acceptable to patients, health care practitioners (service managers and practice nurses), and LHTs
- (2) To explore whether patients, health care practitioners, managers, and LHTs considered the intervention likely to change health behaviours
- (3) To consider the implications of findings for any future RCT

SHIPS was reviewed and approved in the UK by the National Research Ethics Service Committee East Midlands-Derby 2: 11/EM/0294.

## 3. Methods

The qualitative methods reported here form part of a mixed methods approach to pilot RCTs, and both sampling and analysis were integrated with some of the baseline data from the pilot RCT (Table 1) [15].

Semistructured interviews (in person or by telephone) were carried out with patients in the intervention arm, the LHTs delivering the intervention, and the service managers and practice nurses (practice nurse is the term applied to nurses working as part of a primary care team within a family physician/general practice setting in the UK) recruiting patients to the study. The intervention consisted of a structured interview with the LHT, development of an individualised self-management plan with the identification

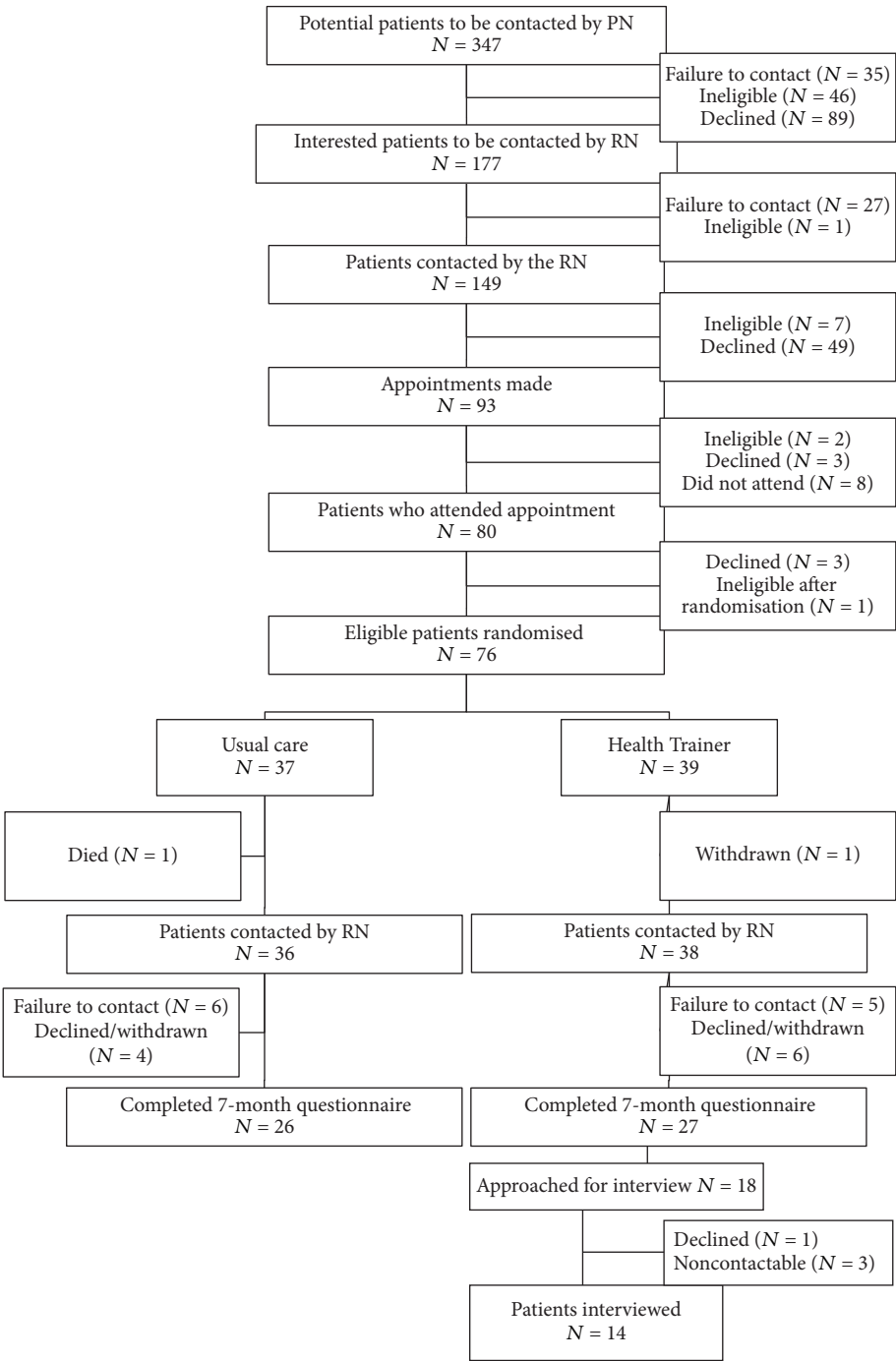


FIGURE 1: Patient recruitment process.

of specific agreed goals, and up to three support telephone calls from the LHT for a maximum of six months. In addition, a self-management pamphlet on T2DM was developed which the LHTs gave to patients. This differed from usual LHT care, in which the LHTs in the study would normally work on a one-to-one basis with patients for up to 12 months. It also differed from usual practice in the UK, where LHTs generally work with patients over a six-to-twelve-week period [11].

**3.1. Recruitment.** Recruitment of patients took place once the study team research nurse had completed the seven-month trial follow-up. This was to ensure sufficient time had lapsed for them to have had experience of the intervention. As part of this follow-up, they were asked to consent to further contact for the purposes of an interview exploring their views about the LHT service (Figure 1).

As previously mentioned, drawn from the baseline demographics in the pilot trial, a purposive sampling strategy based

on an iterative analysis concurrent with data collection was used to ensure balance for factors likely to influence outcome such as diabetic control, length of time since diagnosis, age, and gender. Health literacy levels were also taken into account, using the Newest Vital Sign (NVS)UK. The NVS asks six questions based on a food label: a score of less than four is taken as indicating less than adequate health literacy [16]. In addition, scores on the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) were considered. The WEMWBS scores range from a minimum of 14 to a maximum of 70, with higher scores indicating better mental well-being. The WEMWBS population mean for England in 2012 was 52.4, with men scoring slightly higher than women [17]. Low WEMWBS scores are consistently associated with lower socioeconomic status [18].

The LHTs, service managers, and practice nurses involved in the trial were also invited to interview. Follow-up interviews also took place with the LHTs and service managers toward the end of the pilot trial, with the aim of checking if their views or experiences had changed since the initial interview. The practice nurses were interviewed after referring patients to the LHT service, so a follow-up interview was not deemed necessary. Since patients were interviewed once the seven-month follow-up with the research team nurse had taken place, this was considered sufficient time to capture change in views within that group.

All participants were offered a choice of interview format and, in case of a face-to-face interview, a choice of location. Patients received a Patient Information Leaflet (PIL) at the time of their seven-month follow-up, ahead of deciding whether to consent to contact about a possible interview. Having been contacted by the qualitative researcher, and agreeing to be interviewed, they were sent a further copy of the PIL ahead of the interview as an additional reminder and explanation. The information encouraged them to discuss the study with family or friends ahead of deciding whether or not to continue. The written information was developed in collaboration with the Patient and Public Involvement research user group within the Research Institute for Primary Care and Health Sciences at Keele University. This two-arm approach to informed consent was not considered necessary for the health professionals collaborating in the trial, who were familiar with the PIL/purpose of the interview study in order to answer any questions patients might have and who consequently received one set of information prior to their interview. Information to all interview participants emphasised that any quotes that might be used in publications would be anonymised, and names and personal details would not be used in such publications. Written consent was obtained from all participants.

**3.2. Interviews.** Interview topic guides were developed from the research objectives. Those for patients explored their overall health, the history of their diabetes, and their experience of the information they had received since diagnosis in terms of enabling them to understand and manage their condition. The interviews also explored their expectations, experiences, and views of working with their LHT and the

extent to which they had changed their self-management as a result. The guide evolved in the light of emerging findings, which also informed the continuing sampling strategy. The questions to the LHTs, practice nurses, and service managers focused on their experiences of working with this particular patient population and what they considered the challenges and opportunities. They also explored aspects of practice and service provision—including the intervention—seen as useful, or not, in supporting behaviour change.

The steps outlined in the PIL on data anonymity and participant confidentiality were highlighted again before beginning the interview, and consent checked both at the start and end of the interview. The written information and consent forms for the LHTs, service managers, and practice nurses also highlighted both of these issues, providing a framework for discussion and checking. All discussions were digitally recorded and transcribed. All transcripts were anonymised and participants were given a unique numeric identifier. In addition, patients were given pseudonyms. Interviews lasted approximately half an hour, except for the dyadic interview with the two service managers which lasted one and a half hours, because of the more co-constructed nature of the discussion. Data collection with all four sets of participants took place between April and October, 2013.

**3.3. Analysis.** An exploratory thematic framework was adopted for the analysis, with emergent findings checked out in subsequent interviews across all four groups of participants in an iterative cycle. To maximize the benefits of being an interdisciplinary team, the two coders brought differing perspectives to bear on the data (Bernadette Bartlam, social science; Joanne Protheroe, family medicine). To ensure intercoder reliability, each independently coded a random selection of interviews as part of reaching agreement on the coding frame, which was then applied across the whole data set by Bernadette Bartlam, checking for consistencies and confounding cases [19–21].

## 4. Results

**4.1. Participants.** In total, 24 participants were interviewed: 14 patients with poorly controlled T2DM, two service managers, four LHTs, and four practice nurses. Follow-up interviews also took place with three of the LHTs and one service manager, giving sufficient data to ensure that no issues had been overlooked. This gave a total of 28 interviews.

**4.1.1. Health Trainers.** Three of the LHTs delivering the intervention were men, with one woman. One person had been in post six years, two for five years, and one for three years. All had undertaken the Royal Institute of Public Health “Understanding Health Improvement” course, NQF level two qualification, together with the City & Guilds Health Trainer course, NQF level three. In addition, they had all undertaken a variety of short courses on motivational interviewing and they all came from the local area. Three had previous backgrounds in health and fitness, and one had been a delivery driver. Their ages ranged from 26 to 34 years.

TABLE 2: Summary of patient participant characteristics.

	Women	Men	Overall
Gender (N)	6	8	14
Age (years) (mean, range)	73 (61, 86)	59 (43, 73)	70 (43, 86)
NVS (Mean)	2.5 (0, 5)	3 (0, 6)	0–6
Number of years living with T2DM (mean, range)	13 (1, 25)	10 (3, 18)	12 (1, 25)
Self-reported health			
Poor	2	1	3
Fair/good	4	5	9
Very good/excellent	0	2	2
WEMWBS score (mean, range)	22.5 (15.3, 32.6)	23.6 (13.3, 28.1)	23.0 (13.3–35.0)

**4.1.2. Service Managers.** One manager was a nurse with degree level education in public health who had been responsible for originally commissioning the LHT service. The other had been the day-to-day manager of the service since its inception in 2007 and had degree level education in Nutrition, Health, and Exercise, and in Voluntary and Third Sector Management.

**4.1.3. Practice Nurses.** The four practice nurses recruiting patients to the study had been trained and working as primary care nurse specialists in diabetes for between six and eight years.

**4.1.4. Patients.** Seventy-six patients were randomised into the pilot trial, 39 to the intervention arm. There was a follow-up rate at seven months of just under 70%, resulting in 27 patients available for invitation to interview. Twenty-two of these consented to recontact for a possible interview. The reasons for refusing were poor health of self or partner and having other commitments. Based on the sampling strategy, contact was attempted with 18 participants, three of whom were noncontactable—one person's phone number was "invalid" and it was not possible to contact the other two people, despite five attempts at different times on different days. One person that was contacted declined participation because of a recent bereavement (Figure 1).

Of the patients interviewed, six were women and eight were men. Ten participants were aged over 60 years; the age range was 43–86 years, with men being generally younger than the women (mean of 59 compared to 73 years). From the baseline data in the pilot RCT, the average length of time living with T2DM was 12 years. Although there was a considerable range in this (from one year to 25 years), the majority of participants (11) had lived with the condition for ten years or more. All participants were also living with at least one additional LTC, and the majority rated their own health as fair or good. However, with a mean score on the WEMWBS of 23, participants' mental well-being was very much lower than the UK population norm of 52.4 [17], with men scoring slightly higher overall. There was a spread of scores across the NVS, with the mean for women (2.5) being slightly lower than that for men (3) (Table 2). It is also worth noting that a number of participants who had low scores on the NVS self-reported their health as good or excellent.

**4.2. Key Themes.** Three key interrelated themes emerged from the analysis: health literacy and understanding of diabetes, responses and coping strategies, and motivation to change. In what follows we present details of these using illustrative quotations, before turning to look at the implications. Interviewer comments are in italics.

**4.2.1. Theme: Health Literacy and Understanding of Diabetes.** The relationship between health literacy and people's understanding of their condition was immediately apparent, as this excerpt from the interview with Beth illustrates; she was an 86-year-old lady, diagnosed with diabetes for 12 years and with a low NVS score of two:

*I really don't feel it's as serious as they try to make out. . . The younger sister, she's abandoned all pills [for T2DM]. She doesn't have any.*

*And would you recommend the Health Trainer Service to her. . . ?*

*Well, no, she has no problems. She does eat well. . . but she does drink a little bit too [laughs]. . . We can tell when she falls over that she's had a little bit too much [laughs], and she smokes. . . but she's healthy, you know.*

Similarly, Fred, a 72-year-old man with a low NVS score of one, who had lived with diabetes for 18 years, found it difficult to accept even general advice on health, as this excerpt shows:

*It says giving up smoking is one of the most positive things you can do to improve your health, right? Well, when I stopped smoking, just over two years ago, my diabetes became uncontrollable, so I disagree.*

This lack of health literacy was reflected in the interviews with the LHTs, as this account by LHT3 illustrates:

*One client was told by someone at the gym that he needed to be on a higher protein diet and cut out his carbohydrates, lose weight, and when I explained the Eat Well Plate to him, he wouldn't have it.*



Linked to this lack of clarity was a lack of understanding about the role of LHTs in supporting self-management of the condition, as these excerpts from the interview with LHT1 illustrates when reflecting on the people seen in the trial:

*They don't know who we are... they've had the condition for so many years and why haven't they addressed it before they've come to us? And they're so set in their ways now that they don't want to, there's quite a lot of resistance.*

Such lack of clarity could result in unrealistic expectations on the part of patients and of other health professions of what the service might offer, given the level of training and expertise amongst LHTs, as this interview with practice nurse 1 indicates:

*I think a Health Trainer would look at more like the whole person and the whole thing, whereas when we refer them to different services. They're either just looking at the weight loss, or they're just looking at smoking cessation, or they're just looking at alcohol, whereas there's a lot of other factors that come into the whole person.*

It was also apparent that the SHIPS pilot trial was recruiting patients who would not generally fall within the age range targeted by the service employing the LHTs, as Service Manager 2 clarifies:

*Just one thing that I noticed from this group from the SHIPS study that we don't tend to have with the people that we regularly support, is the age group. So when you said "Do you tend to deal with over 65?" and it might be so many, but after that we don't tend to have those older age groups... and so straightaway you've got issues around the fact that they've obviously had... the condition for a long time... the behaviour's so engrained... And it's a group that, although we deal with that group, it's not a large age category that's supported by health trainers usually.*

**4.2.2. Responses and Coping Strategies.** Patients' lack of understanding of their condition was reflected in their self-management, as Beth's description of her diet illustrates:

*When you're old you can't possibly eat five portions of fruit and vegetables a day.*

Despite a score on the WEMWBS of 23.21, and even though she had multiple coexisting chronic health problems, Beth reported her own health as good.

The sense of already doing what was necessary to live well with diabetes was reflected throughout the interviews, as this excerpt from the interview with Tom, a 54-year-old man, diagnosed with diabetes for 14 years and with an NVS score of three, shows:

*The things they've got in the book [pamphlet] I eat anyway. I always have. I don't like MacDonald's, I can't be doing with that kind of rubbish.*

Jane, a 62-year-old woman living with diabetes for 20 years, with an NVS score of four, also felt she was managing well despite poor glycaemic control:

*I do consider myself a bit of an expert because I've been diabetic for quite a while.*

However, this was not exclusively the case, as John, a 67-year-old man with a low NVS score of one and who had lived with diabetes for 15 years, illustrates when he responds to the question on the ways in which he found the LHT helpful:

*First of all I think what [LHT] done really, I started looking at what I eat because [LHT] explained everything... was very... not complicated, if you know what I mean?*

*Straightforward?*

*Straightforward and just said "If you want to control it you've got to do this. Without doing this, it won't work." Simple as that. But very plainly told me what's the score.*

*Okay, and you found that helpful?*

*Very helpful, yes.*

Fred, too, despite his earlier scepticism over health advice, reported finding the consultation with the LHT helpful:

*[LHT] completely changed and broadened, in effect, what I was eating. And I feel a lot better as a result of that.*

The degree to which participants found the intervention helpful appears to be directly related to communication within the consultation.

**4.2.3. Motivation to Change.** Motivation and capacity for change also emerged as an important factor, as Beth indicates when asked what she first thought when the LHT was suggested:

*I think it was a bit of a waste of time, at my age, when I've had it for so long... I've had no problems.*

However, despite this she did feel that the intervention had brought some benefit:

*Do you recall setting goals with him?*

*Yes, when I knew I had to record what I was eating, it did make me eat better, because I had to put it down what I'd had, you know? I couldn't just say, "Oh, a couple of biscuits," or something, you know, for a meal [yeah]. I did make the effort to eat properly while I was recording, you know.*

Whilst Jane recognised that her glycaemic control was poor, she reported not finding the LHT consultation helpful, echoing issues around long-established conditions and coping strategies and age:



*[LHT was] on about me doing more exercise than I do, and I do exercise [laughs] everyday. It's laughable really... I felt as though I was wasting his time. Then [LHT] was on about the food I was eating. Well, you go through this so many times. That's all they seem to think; because you've got a little bit of weight on, you need to lose weight. I hardly eat anything. I don't eat bread at all now. I don't buy crisps... And [LHT] says, "I can organise some cookery lessons for you." I thought; "I'm 63, what do I want to do with cookery lessons at my age?"... So I said in the end, I say, "I think we're wasting our time here".*

Jane's reluctance to engage with the LHT reflects her sense of herself as expert and also may be a reflection of her self-reported poor health status and her low score on the WEMWBS of 15.32. She clearly had complex health needs: throughout the interview she also spoke of her chronic heart condition, and the high impact that was having on her life. Shortly before participating in the trial she lost her mother and was finding it difficult to come to terms with that. Nonetheless, she spoke positively of the LHT as an individual: "He was excellent, really, it just didn't suit me..."

However, John, clearer in his understanding of his condition as a result of meeting with the LHT, reported being highly motivated to change, as this response to being asked whether he had identified particular goals shows:

*Lose weight [Laughing]. That's the number one... So I thought yes, I'll just follow what [LHT] said. And that's it. I lost two and a half stones. I put my control over diabetes into motion, really, and I figure that it's thanks to that LHT.*

John had one of the highest scores amongst participants on the WEMWBS, 28.13, and reported his health as good even though he too had coexisting LTCs.

Other factors, such as working conditions appeared to play a part in capacity for change, again illustrated by this response from Tom, a long-distance lorry driver, when asked about his views on the LHT service:

*He was nice lad everything, explaining like, this might help and that might help... It's all right now because I'm not working, I said, but as soon as I go back to work everything just goes out the window again... I sometimes miss my dinner-time tablets, because you start at daft times...*

*Did you just go and see him the once then?*

*Yes, because [LHT] said "due to your lifestyle there's not a lot you can do about it really", you know?*

As the earlier excerpt illustrated, Tom felt that his diet was good. It was managing the medication and the complexity of his other health conditions that he found challenging, and which left him with a sense of being overwhelmed and unable to change. This was reflected in his WEMWBS score of 13.33,

the lowest of all participants, and he reported his health as poor.

Fred highlights the importance of timing and early intervention after diagnosis, and the usefulness of the pamphlet the LHTs used to explain how to live well with diabetes

*So you've been living with it for a long time?*

*Oh, yeah, but not living with it correctly [laughs].*

*So are you coming across stuff in [the pamphlet] that's new?*

*No. No, not really, no. [Pause] No, I mean, I am aware...*

*Of everything that's there?*

*Yeah.*

*But this would be something that you think would be useful for folk?*

*Oh, yes. If I'd have been given something like this in the early days, it would have been a much greater help than that which I received.*

*Right, in terms of understanding?*

*Yes, and making it plainer. You see, pictures are a better way of telling the story.*

*Yes, than just lots of words?*

*Yeah, because people tend to get a bit bored of lots of words, particularly if they're not presented well.*

Again, this was reflected in the interviews with the LHTs, as this quote from LHT4 indicates:

*I think the kind of patients that need to come in need to be people who want to change and are ready to change. It's perhaps better to get them when they've just been diagnosed.*

The challenge in how best to address the complexity with which patients could present, and their prioritisation of their needs, was also evident in the interviews with the LHTs:

*So when I was dealing with [patient name], there was lots of issues and a lot of the time was spent just listening and trying to help her deal with these issues... because her health and lifestyle was really poor... It was very hard to get her to engage in the topic of what we were looking at without her going off on a tangent. She kept apologising for the fact that she was doing all this talking, and she was talking about all this other stuff, which, it had some relevance, but it's not relevant for what we're trying to achieve. So she was aware that, you know, the study was to help with managing diabetes, and she wasn't allowing me to do that, and she wasn't able to engage in that. (LHT3)*

Finally, location of the LHT service was also something that emerged as an influencing factor on people's motivation and capacity to engage:

*I think location can make a difference to people, if it's hard for them to get to the service. That does sometimes figure as a factor in them not turning up for appointments. (LHT4)*

## 5. Discussion

People with long-term conditions can and do self-manage complex medical regimes every day including medicine taking, self-injecting, and dressing wounds as well as dealing with their many challenges of everyday living. They need help to have the confidence and knowledge to know what they can do effectively and safely for themselves and when to seek professional help. (Dr. Patricia Wilkie, President and Chairman National Association for Patient Participation [2].)

This study had three research objectives: first, to explore if the intervention was considered acceptable to patients with low health literacy and T2DM and to practitioners; second, to explore whether they considered if the intervention was likely to change health behaviours; and finally to consider any implications for a future main trial.

Given the complex characteristics of the study population, it is important to note that the SHIPS pilot trial results indicate that the intervention is feasible and should be carried forward into a main trial. Moreover, the pilot trial results indicate that the LHTs had a positive impact on the mental health of participants in the intervention arm compared to those in the control arm (see Protheroe et al., this issue, for full details of the pilot trial results). However, as the qualitative findings here indicate, and as to be expected, the picture is more nuanced than the trial findings alone suggest, with patients experiencing a range of responses in terms of the acceptability of the intervention and the likelihood of it resulting in behaviour change. Findings must be interpreted with caution given that participants were drawn from a small pilot study located in one specific area in the UK. Moreover, the data is cross-sectional and does not allow for follow-up over time. Finally, participants in this study all scored well below the population mean of the WEMEBS of 52.4, with a range of 13.33–35, despite most self-reporting their health as good. However, it is worth noting that older people have been found to be significantly less likely to partially or not respond to the tool [17], and more work is needed to establish its reliability in older populations and amongst those with low health literacy. Nonetheless, despite these limitations, these findings suggest that a full RCT intervention could be enhanced if attention were paid to a number of issues.

First, in keeping with the work of authors such as Carollo [22], relationships and communication emerged as critical. Even those patients who did not find the intervention helpful spoke of their experience of engaging with the LHT in

positive terms, which itself is important in terms of likelihood of accessing support in the future. Whilst the LHTs and health care professionals in the study found the intervention acceptable, not all patients did so. This may be for a number of reasons. Key to engaging patients in behaviour change is clarity around roles and responsibilities. Whilst the LHTs and managers interviewed were very clear about the role, other health care professionals, and in particular patients, appeared less so, leading to unclear expectations for some patients. Greater promotion of the LHT service would improve patient and public understanding of what it can, and cannot, offer. With its emphasis on reaching those patients less likely to access services, careful thought needs to be given as to the ways in which such information is delivered [23]. In addition, there may be something in the title “Health Trainer” that may hold less appeal to older people who have been living with their condition(s) for protracted lengths of time. It may also be that, given the training and qualifications outlined here, the term “Lay Health Trainer” no longer reflects the original emphasis on amateur peer support from “next door.”

It was also clear from this work that LHTs appear to be effective for those patients who are already motivated to change health behaviours. However, they may be less effective with those patients who have a more established view of their condition, and those with complex health needs, for example, multiple LTCs, and those who are older [24]. Moreover, there remains a dearth of evidence around the relationship between adherence and older adults with low health literacy [25].

The LHT service in this study tended not to work with those over 65 years. In addition, most LHT services aim to recruit a high proportion of their staff from similar backgrounds to their clients [26] and it may be that the disparity in the average age of the LHTs in this study compared to participants (30 versus 64 years) had an impact on the potential therapeutic impact of the intervention. Given the ageing population and the concomitant increase in those growing older with more than one LTC, having the skills needed to engage such individuals will become more necessary. Such skills need to include an understanding of developmental ageing, in particular the challenges of later life [27, 28], as the individual psychosocial context within which any intervention is delivered.

Finally, location also emerged as an issue in this feasibility pilot RCT, with some LHTs and patients reporting challenges in accessibility, despite the efforts to offer a range of settings. Emphasising the message that a variety of consultation settings are available is something a future RCT should take account of. In addition, whilst this service was located in an urban environment, thought should also be given to how to best reach people living in rural areas, which are experiencing the fastest growth amongst older populations [13].

## 6. Conclusions

This work suggests that LHTs appear to be effective for those patients already motivated to change health behaviours but that they may be less effective with those who are older and have a more established view of their condition and how best to self-manage. However, recent systematic reviews

indicate that, whilst interventions are potentially effective, there remains a paucity of evidence on this topic [25, 29, 30]. Further research is needed on the association between health literacy and general health behaviour and on the effectiveness of interventions such as those in the SHIPS pilot RCT. In particular, work is needed that can take into account the complexity of diverse populations, including issues such as environment, culture, gender, and life-course perspectives and which can allow for a longitudinal follow-up to evaluate the effectiveness of interventions. These qualitative findings highlight the importance of expanding LHT practice to develop skills around working with older populations. They also contribute to the argument for the inclusion of mixed methods, qualitative research in RCTs.

## Disclosure

The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health. SHIPS is registered with the current controlled trials database, ISRCTN, reference: ISRCTN 08022935.

## Competing Interests

The authors declare that they have no competing interests.

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## Research Article

# The Feasibility of Health Trainer Improved Patient Self-Management in Patients with Low Health Literacy and Poorly Controlled Diabetes: A Pilot Randomised Controlled Trial

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Type 2 diabetes mellitus is most prevalent in deprived communities and patients with low health literacy have worse glycaemic control and higher rates of diabetic complications. However, recruitment from this patient population into intervention trials is highly challenging. We conducted a study to explore the feasibility of recruitment and to assess the effect of a lay health trainer intervention, in patients with low health literacy and poorly controlled diabetes from a socioeconomically disadvantaged population, compared with usual care. *Methods.* A pilot RCT comparing the LHT intervention with usual care. Patients with HbA1c > 7.5 (58 mmol/mol) were recruited. Baseline and 7-month outcome data were entered directly onto a laptop to reduce patient burden. *Results.* 76 patients were recruited; 60.5% had low health literacy and 75% were from the most deprived areas of England. Participants in the LHT arm had significantly improved mental health ( $p = 0.049$ ) and illness perception ( $p = 0.040$ ). The intervention was associated with lower resource use, better patient self-care management, and better QALY profile at 7-month follow-up. *Conclusion.* This study describes successful recruitment strategies for hard-to-reach populations. Further research is warranted for this cost-effective, relatively low-cost intervention for a population currently suffering a disproportionate burden of diabetes, to demonstrate its sustained impact on treatment effects, health, and health inequalities.

## 1. Introduction

Diabetes mellitus (DM) is a disorder of glucose metabolism suffered by over 4 million UK people, 90 per cent of whom have Type 2 diabetes [1, 2]. Type 2 diabetes is more common in middle-aged or older people and greatest in deprived communities [3]. The risk of developing Type 2 diabetes can be reduced by lifestyle modification [4]. Deprivation is strongly associated with increased levels of obesity, physical inactivity, unhealthy diet, smoking, and poor blood pressure

control, all potentially modifiable factors and all associated with an increased risk of developing diabetes or the risk of developing complications in people with diabetes [5]. The risk of developing complications such as heart disease, stroke, renal failure, and blindness is strongly linked to the tightness of glycaemic control [6, 7]. Patients' knowledge about diabetes and how to manage it, together with lifestyle choices, is central to the tightness of glycaemic control [8, 9].

Limited health literacy and numeracy skills are more common in areas of socioeconomic deprivation [10]. If this is

linked with evidence that low health literacy is independently associated with worse glycaemic control and higher rates of diabetic complications, inadequate health literacy may be a significant factor in the disproportionate burden of diabetes and diabetes-related complications in more socioeconomically disadvantaged populations [11]. Studies have shown that people with low health literacy have lower levels of self-management of chronic disease, including poorer diabetes self-management [12–14].

Individuals with inadequate health literacy are less likely to be recruited into research studies or randomised controlled trials of healthcare interventions [15, 16]. This selection bias common to trials of interventions, may have implications for the likelihood of uptake of traditional diabetes educational interventions [17, 18]. In summary, we have a population of people with Type 2 diabetes and low health literacy at increased risk of complications who may be ill-served by the currently available diabetes educational self-management programmes.

Lay health trainers (LHTs) are a UK government initiative using peer or lay educators, living in the local community, designed to reduce health inequalities by engaging with and focusing on deprived or hard-to-reach populations [19, 20]. They are intended to promote affordable, practical, socioculturally relevant lifestyle advice within communities.

This study aims to

- (1) develop a LHT intervention to encourage patients to make healthy lifestyle choices in the management of Type 2 DM. This intervention is intended to improve patient self-management of their diabetes;
- (2) to explore the feasibility of recruitment of patients, with low health literacy and poorly controlled diabetes from a socioeconomic disadvantaged population, to a trial of a LHT intervention;
- (3) to collect data on a range of outcome measures and look for provisional indications of effectiveness and cost-effectiveness of the LHT intervention, in order to inform the design of a subsequent large-scale randomised controlled trial.

## 2. Participants and Methods

**2.1. Sample.** We conducted a pilot randomised controlled trial comparing the LHT intervention with usual care. Patients were recruited from six family doctor practices in Blackpool, from October 2012 to September 2013. Blackpool is the 6th most deprived local authority area in England and has a high prevalence of diabetes Type 2 (8.3%) compared with a national average of 5.8% [21, 22]. Patients who were aged over 18 years with poorly controlled diabetes ( $HbA_{1c} > 7.5$  or  $58 \text{ mmol/mol}$  in at least the last 2 measures) were eligible to be recruited. Those who were deemed ineligible by the practice staff (usually because of being too ill or too cognitively impaired to participate) were excluded.

Patients were identified and contacted by the practice nurse and informed about the study. Interested patients then had their contact details forwarded to the study research

nurse. The research nurse contacted the patient to arrange an appointment to discuss the trial in depth at a face-to face meeting, either at home or at the practice as preferred by the patient. Consenting participants completed the baseline questionnaire and were randomised to one of the two trial arms (usual care or LHT).

Initially, potential participants were identified by the practice nurse at their routine review appointment from four family doctor practices. This yielded a poorer than expected recruitment and so the recruitment method was changed such that the practice nurse identified all potentially eligible patients and telephoned them to see if they would be interested in the study, rather than seeing the patient opportunistically at their routine check-up. Furthermore, an additional two family doctor practices were recruited to the trial.

**2.2. Intervention.** The intervention consisted of a structured interview with the LHT and development of an individualised patient self-management plan, plus up to three two-monthly support phone calls from the LHT (depending on agreements between the patient and the LHT) for a maximum of 6 months.

The structured interview supported the patient to identify areas where they could improve their health and used a locally developed menu (by collating existing locally available options) of support options available to that patient. Literacy skills teaching was not part of the intervention, but the LHT had information to enable them to, on request, signpost patients towards basic skills courses in their locality. The LHT did not provide medical or nursing advice. If the patient asked the LHT medical questions, patients were referred back to the practice nurse or family doctor. The LHTs had received training from the research team on evidence based diabetes care and appropriate lifestyle advice. In addition to providing information and advice aimed at changing key beliefs such as perceptions of risk from diabetes and the advantages and disadvantages of behaviour change, the LHTs advised them about essential health care tests and checks they should receive regularly as advised by Diabetes UK (blood pressure, cholesterol, feet and eye examinations, etc.). Using expertise from the research team, NHS Blackpool and Diabetes UK, the Wellness Service, employing the LHTs, developed a pamphlet designed for individuals with low health literacy to manage their diabetes [23].

Patients randomised to the control group received usual medical care. In the UK, usual care management of diabetes involves the family doctor practice keeping a register of all patients diagnosed with diabetes and usually inviting those patients into the practice for a review at least every 12 months. At this yearly review, usually led by the practice nurse, patients will be monitored and the following care processes should be undertaken: BMI measurement; BP measurement; haemoglobin A1c ( $HbA_{1c}$ ) measurement; cholesterol measurement; record of smoking status; foot examination; albumin: creatinine ratio; serum creatinine measurement.

**2.3. Data Collection and Outcome Measures.** To reduce the burden on the participant, the baseline demographics and



outcomes were collected face-to-face by a research nurse who entered responses directly onto a security encrypted laptop. Outcomes were assessed at 7 months after randomisation via a telephone call from a different research nurse. Baseline demographics collected were age, gender, deprivation, health literacy, marital status, employment, ethnicity, and education. One aim of the pilot trial was to assess a broad spectrum of outcome measures (several of which overlap in health domains) for the purpose of selecting the most suitable subset for a larger trial in this population. Outcome measures included validated measures of diabetes self-care and quality of life, diabetes services and checks, EQ5D, mental well-being, illness perception, mental and physical health, resource use, and HbA1c values.

*Deprivation.* The index of multiple deprivation (IMD) 2010 is a measure of deprivation for small areas in England. It ranks areas from 1, the most deprived area, to 32,482 the least deprived area. The rank of deprivation is based on seven weighted domains: income; employment; education, skills, and training; health and disability; crime; barriers to housing and services; and living environment. Based on the participants' residential postcode, the rank of deprivation was obtained and then categorised into five groups with 1 being the most deprived area and 5 being the least deprived area in England [24].

*Health Literacy.* The Newest Vital Sign UK, validated for use with a UK population, was used to assess health literacy [25]. Participants were asked 6 questions based on a food label and a score of  $\geq 4$  was deemed to indicate adequate health literacy and a score  $< 4$  was deemed as less than adequate.

*Diabetes Self-Care.* It was measured using the Summary of Diabetes Self-Care Activities Measure [26]. This is a validated brief self-report questionnaire of diabetes self-management that assesses general diet, specific diet, exercise, blood-glucose testing, foot care, and smoking.

*Diabetes Quality of Life.* It was assessed using The Diabetes Quality of Life Brief Clinical Inventory [27]. This is a short 15-item scale that covers a broad range of issues ranging from patient satisfaction with their diabetes regimen to worries over diabetes symptoms and consequences.

*Diabetes UK Scale Items.* It is based on 9 questions (those applicable to primary care) out of 15 from Diabetes UK, relating to how many services and checks patients received to manage their diabetes; a total number of services and checks received was created [28].

*Health-Related Quality of Life.* It was assessed using the EQ5D which provides a measure of generic health-related quality of life [29]. This instrument enables the calculation of QALYs (quality adjusted life years), a composite measure of health obtained by weighing each period of follow-up time by the value corresponding to the health-related quality of life (HRQoL) during that period [30]. The values of the weights typically lie on a scale between zero (equivalent to death) and one (equivalent to full health), although negative values for

states rated worse than dead are possible. This captures effects on both the quality and quantity of life used in assessment of health interventions in the UK health service [31]. The use of the QALY enables comparisons of the relative cost-effectiveness of interventions to be made across a range of conditions.

*Warwick-Edinburgh Mental Well-Being.* It was assessed using the short version of the Warwick-Edinburgh Mental Well-Being scale which consists of 7 items to assess mental wellness [32].

*Illness Perception.* This was assessed using the Brief Illness Perception Score to assess the cognitive and emotional perceived illness [33].

*Health Status Measure.* It was assessed using the physical and mental health components of the SF12, which is a validated measure of overall health and daily activities [34].

*Resource Use.* It is the self-reported service use of family doctor and hospital care.

*Haemoglobin A1c Values.* Haemoglobin A1c values were extracted from the medical records. The closest available readings prior to date of randomisation and after 7 months were taken.

*2.4. Sample Size.* The primary aim of this pilot trial was to inform the design of a subsequent large-scale randomised controlled trial. Accordingly, the sample size was set to provide sufficient data to make reasonably accurate estimates of the underlying recruitment rate, statistical properties of the outcome measures, and some indication that the intervention has benefit for patients. On this basis, the target sample was set at 120 participants, allowing percentage recruitment to be estimated with an error of at most plus/minus 9% and the standard deviations of outcome measures to be between 0.89 and 1.14 times the actual value, with 95% confidence. With regard to patient benefit, although not powered to provide convincing evidence for a treatment effect (i.e.,  $p < 0.05$  is unlikely to be found), low  $p$ -values on some of the major outcomes can be viewed as supporting the intervention's likely effectiveness. Allowing for 25% attrition, a follow-up sample of 90 patients would give 80% power to yield a  $p$  value (two-tailed test) of 0.15 or less given a moderate to large effect size of the intervention (Cohen's  $d$  of 0.5 or greater). The above calculations do not take account of clustering of outcome scores within practices but do give a general indication of sample adequacy.

*2.5. Randomisation.* Participants were randomly allocated on a 1:1 basis to either the LHT intervention or usual care. For each family doctor practice, a computer generated block randomisation list using block sizes of 2, 4, and 6 was produced by the statistician who was blind to treatment allocation. The sequence of treatment allocation was then sealed in opaque envelopes to be given to the participant from the research nurse once baseline data had been collected.

Participants allocated to the intervention group were then given an appointment with the health trainer for commencement of the intervention. To avoid the risk of “contamination” between members of the same household if more than one person had diabetes, only 1 person was recruited per household. To maintain allocation concealment, the follow-up outcome data was collected by a different researcher at Keele University who was blind to treatment allocation.

**2.6. Statistical Analysis.** A consort flow diagram is presented (Figure 1). Descriptive statistics were used to assess whether the study had successfully recruited participants with low health literacy from a socioeconomic disadvantaged population. Descriptive statistics were used to assess balance of baseline characteristics between the trial arms and the distributional properties of each outcome measure. Analyses of the effectiveness of the LHT intervention at 7-month follow-up were conducted using an intention to treat approach within a linear regression framework. The primary analysis adjusted for baseline outcome scores only. To account for possible baseline differences on key prognostic factors, a sensitivity analysis was then performed adjusting also for age, gender, health literacy, family doctor practice, and length of time with diabetes. The assumptions of linear regression were verified. As this was an exploratory analysis looking solely for indications of effectiveness, imputation of missing values was not applied and all analyses were based on complete cases. All analyses were conducted in STATA v14.

**2.7. Ethical Approval.** Ethical approval was granted by the East Midlands, Derby National Research Ethics Service Committee on 16 August 2011, reference 11/EM/0294.

### 3. Results

**3.1. Feasibility of Recruitment.** Target recruitment was set at 120 patients; however, only 76 patients were recruited. Failure to reach target was due to the initial way potential participants were identified by the practice nurse with one family doctor practice failing to identify any potential participants.

Figure 1 is the consort flow diagram illustrating the flow of patients recruited to the trial. In summary, of the 290 eligible patients, 76 (26.2%) were randomised, 37 to usual care and 39 to the LHT arms. One ineligible Type 1 diabetic patient was randomised and was removed from analysis. The overall follow-up rate at 7 months was 69.7% (53/76); the follow-up rates in the usual care and LHT arms were 70.3% (26/37) and 69.2% (27/39), respectively, indicating drop-out was not related to trial allocation.

**3.2. Descriptive Statistics.** Patient characteristics are summarised in Table 1. There were some differences between the two groups; the LHT arm was slightly older, had more females, had less retirees, and had diabetes for a longer period of time. The majority of the patients had poor health literacy and had come from a socioeconomic disadvantaged population. 46 (60.5%) had less than adequate health literacy skill. Nationally, 20% of the UK population reside in each

deprivation quintile. Compared to the rest of England, 75% of the study sample resided in the most deprived areas of England, higher than the expected national level of 40%.

**3.3. Evaluation of Health Outcome Measures.** Table 2 describes the distribution of each outcome at baseline and 7 months. With the exception of the EQ5D and Diabetes UK Score, the rest of the outcomes demonstrate good performance in having wide variation but only small floor or ceiling effects. The EQ5D and Diabetes UK Score show substantial floor and/or ceiling effects at baseline and/or 7 months: over 60% of patients have an EQ5D score in the top 20% of possible scores; and up to 40% have a Diabetes UK Score in the top 20% of possible scores. This suggests that the EQ5D and Diabetes UK Score may not be suitable outcomes to use in a further full trial as they have limited ability to detect change at the top end of the scale.

There were good indications that the LHT can improve patients' mental health; at 7 months, participants in the LHT (intervention) arm on average had a higher mental component score (mean difference between arms = 5.46, 95% CI: 0.02, 10.89,  $p = 0.049$ ) and a less negative view on illness perception (−5.74, 95% CI: −11.19, −0.29,  $p = 0.040$ ). Both of these results reached the conventional level of statistical significance of  $p < 0.05$ . In terms of direction of change, participants in the LHT (intervention) arm had improved patient self-care management, received more health services and checks, and had better QALY profile but had worse haemoglobin A1c (all nonsignificant, but with  $p$  values close to 0.2). However, there was less evidence for any impact on the physical health, well-being, and diabetes quality of life (Table 3). The pattern of results was essentially unchanged under sensitivity analysis adjusting for prognostic factors (Table 3), with the exception of haemoglobin A1c where the adjusted  $p$  value suggested little effect on HbA1c over the length of this study.

**3.4. Resource Use.** The intervention was associated with lower resource use across all categories at 7-month follow-up. Results are presented in Table 4. The inpatient stay was lower in the LHT arm, though there were very few responses. It was assumed in the first case that missing values were in fact zero. However, conducting an analysis on those who completed the questionnaire and provided values for the first and/or second stay showed consistent results (inpatient stay mean for first stay was 13 days in usual care and 5.67 in LHT intervention and 8.5 and 0 for second visit). All of these results were not significant at conventional levels.

### 4. Discussion

This was a pilot randomised controlled trial of a lay health trainer (LHT) intervention to encourage patients to make healthy lifestyle choices in their self-management of Type 2 diabetes. The trial focused on the feasibility of recruitment of patients with low health literacy and poorly controlled diabetes from a socioeconomically disadvantaged population and evaluating its effect on diabetes self-management with

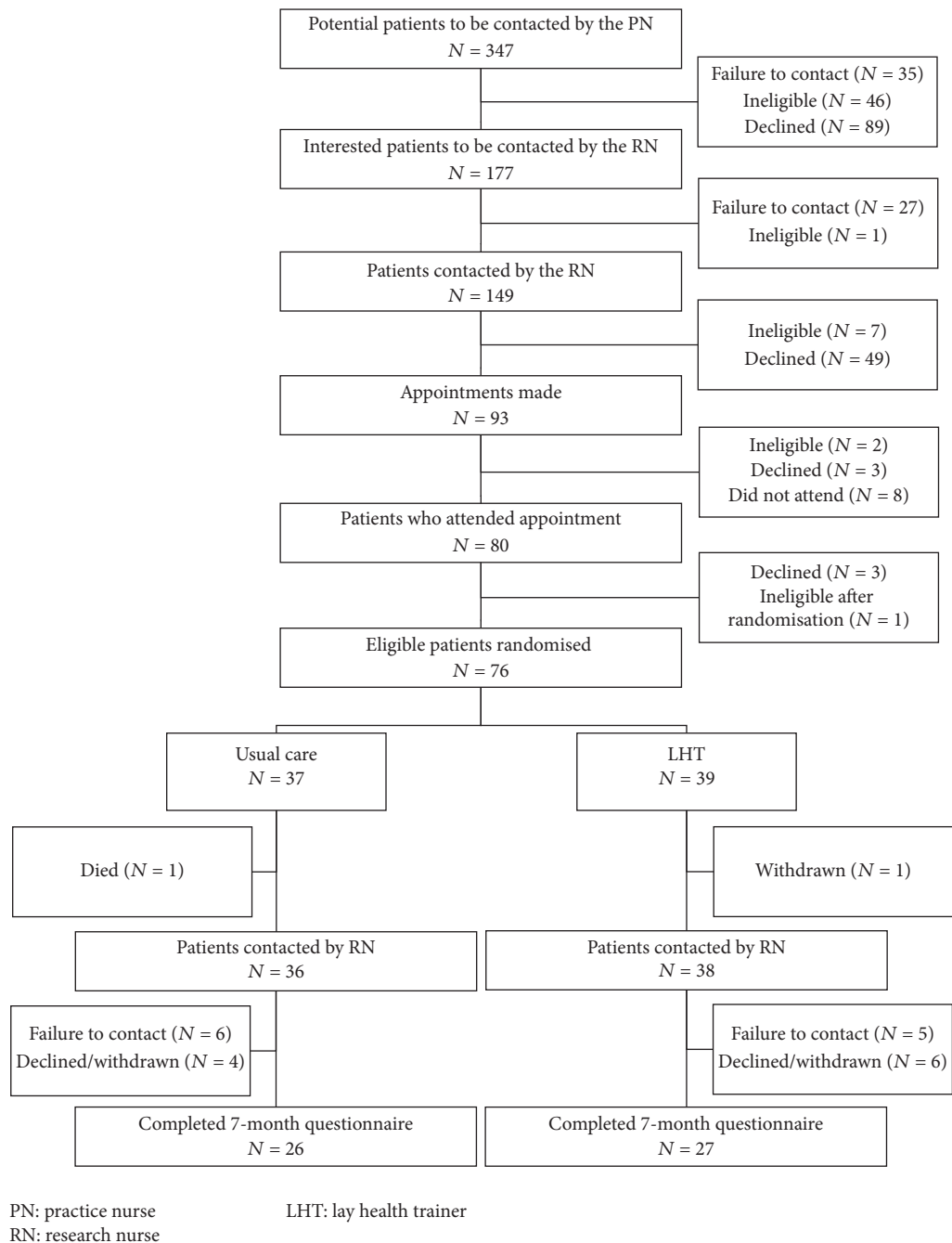


FIGURE 1: Consort diagram.

a preliminary assessment of cost-effectiveness of the LHT intervention.

**4.1. Recruiting from Disadvantaged Populations.** As expected, recruiting participants with low health literacy from a socioeconomically disadvantaged population was challenging and required alterations to our recruitment strategy. At the outset, we had made the decision not to use postal written information as we were particularly interested in recruiting patients with low health literacy for whom written information might be less accessible. We had felt that personal contact from the

practice nurse when the patient attended for their regular review would be more appropriate. However, this method proved to be slower in recruiting patients than was expected. When the study team explored this with our recruiting practices, it appeared that there were two reasons in particular for this; first, amongst all the clinical tasks that she was performing, often the practice nurse would fail to remember to mention the study and, second, the patients who were in this most at risk group were poor attenders of their review appointments. When we changed our recruitment strategy to support the practice staff to directly contact eligible

TABLE 1: Baseline patient characteristics between usual care and health trainer.

Patient characteristic	Usual care N = 37	Health trainer N = 39
Age (mean (SD))	61.5 (10.1)	64.7 (11.2)
Sex		
Male	22 (59.5)	16 (41.0)
Female	15 (40.5)	23 (59.0)
Deprivation		
Most deprived	11 (29.7)	13 (33.3)
2nd most deprived	16 (43.2)	17 (43.6)
Mid-deprived	8 (21.6)	5 (12.8)
2nd least deprived	2 (5.4)	4 (10.3)
Least deprived	0 (0)	0 (0)
Employment status		
Paid work	13 (35.1)	15 (38.5)
Retired	17 (46.0)	15 (38.5)
Long-term sick/disabled	6 (16.2)	6 (15.4)
Seeking employment/volunteer work/looking after home or family	1 (2.7)	3 (7.7)
Marital status		
Never married	7 (18.9)	4 (10.3)
Married/civil partnership	21 (56.8)	21 (53.9)
Separated/divorced/widowed	9 (24.3)	14 (35.9)
Lives alone		
Yes	9 (24.3)	10 (27.0)
No	28 (75.7)	27 (74.0)
How long patient had diabetes (years)		
<5 years	11 (29.7)	4 (10.3)
≥5 years	26 (70.3)	35 (89.7)
Number of comorbidities		
0-1	8 (21.6)	12 (30.8)
2-3	18 (48.7)	21 (53.9)
4-5	11 (29.7)	6 (15.4)
Highest qualification obtained		
School level including O-level/CSEs/GCSEs/School certificate or none	9 (26.5)	21 (53.9)
A-level or vocational including NVQ/HNC/HND/professional qualification/other	22 (64.7)	16 (41.0)
University (first or higher education)	3 (8.8)	2 (5.1)
Health literacy		
Adequate	17 (46.0)	13 (33.3)
Inadequate	20 (54.0)	26 (66.7)
Socioeconomic status		
Higher managerial administration and professional occupations	9 (24.3)	10 (25.6)
Intermediate occupations	10 (27.0)	12 (30.8)
Routine and manual occupations	18 (48.7)	17 (43.6)
Feeling down, depressed, or hopeless (QOF depression screen 1)		
Yes	16 (43.2)	15 (38.5)
No	21 (56.8)	24 (61.5)
Little interest or pleasure in doing things (QOF depression screen 2)		
Yes	17 (46.0)	16 (41.0)
No	20 (54.1)	23 (59.0)

TABLE 2: Adequacy of outcome measures.

Outcome measure	Number of patients answering all scale items N (%)	Range of possible scores	Mean score (SD)	Range of observed scores	Number of patients with minimum possible score N (%)	Number of patients with maximum possible score N (%)	Number of patients scoring in the bottom 20% of possible scores N (%)	Number of patients scoring in the top 20% of possible scores N (%)
Baseline: SDSCAM	76 (100)	0, 7	3.83 (1.48)	0.22, 6.89	0 (0)	0 (0)	4 (5.3)	7 (9.2)
7 months: SDSCAM	52 (98.1)	0, 7	4.01 (1.24)	0.89, 6.78	0 (0)	0 (0)	1 (1.9)	5 (9.6)
Baseline: SWEMWBS	76 (100)	7, 35	22.93 (5.30)	13.30, 35.00	0 (0)	3 (4.0)	0 (0)	8 (10.5)
7 months: SWEMWBS	52 (98.1)	7, 35	22.81 (4.22)	7.00, 30.70	1 (1.9)	0 (0)	1 (1.9)	2 (3.8)
Baseline: PCS	76 (100)	0, 100	36.90 (10.64)	9.94, 56.15	0 (0)	0(0)	6 (7.9)	0 (0)
7 months: PCS	53 (100)	0, 100	35.36 (13.04)	7.89, 56.15	0 (0)	0 (0)	5 (9.4)	0 (0)
Baseline: MCS	76 (100)	0, 100	45.44 (12.76)	15.36, 65.63	0 (0)	0 (0)	3 (9.2)	0 (0)
7 months: MCS	53 (100)	0, 100	49.16 (12.12)	17.36, 74.12	0 (0)	0 (0)	1 (1.9)	0 (0)
Baseline: DQL	76 (100)	0, 100	34.12 (24.05)	0, 100	2 (2.6)	2 (2.6)	19 (25)	5 (6.6)
7 months: DQL	48 (90.6)	0, 100	39.06 (25.98)	0, 100	2 (4.2)	1 (2.1)	9 (18.8)	4 (14.6)
Baseline: BIPS	76 (100)	0, 80	38.46 (12.80)	11, 63	0 (0)	0 (0)	3 (3.9)	0 (0)
7 months: BIPS	52 (98.1)	0, 80	38.33 (12.01)	12, 68	0 (0)	0 (0)	2 (3.8)	2 (3.8)
Baseline: DUKS	76 (100)	0, 9	6.97 (1.15)	3, 9	0 (0)	1 (1.3)	0 (0)	27 (35.5)
7 months: DUKS	52 (98.1)	0, 9	7.15 (1.24)	4, 9	0 (0)	8 (15.5)	0 (0)	21 (40.4)
Baseline: Hb1Ac	76 (100)	—	78.04 (15.17)	56, 121	—	—	—	—
7 months: Hb1Ac	61 (80.3)	—	72.64 (16.71)	41, 117	—	—	—	—
Baseline: EQ5D	76 (100)	−0.59, 1	0.59 (0.35)	−0.24, 1.00	0 (0)	12 (15.8)	0 (0)	47 (61.8)
7 months: EQ5D	52 (98.1)	−0.59, 1	0.64 (0.28)	−0.02, 1.00	0 (0)	7 (13.5)	0 (0)	31 (59.6)

Summary Diabetes Self-Care Measure (SDSCAM); Short Warwick-Edinburgh Mental Well-Being Score (SWEMWBS); SF-12 Physical and Mental Component Scores (PCS & MCS); Diabetes Quality of Life (DQL); Brief Illness Perception Score (BIPS); Diabetes UK Score (DUKS); EuroQuol Health questionnaire (EQ-5D).

patients by telephone and discuss their potential participation in the trial, we were more successful in recruiting this disadvantaged population. This finding adds weight to the argument that it is not the particular population that is problematic but the failure to adopt recruitment strategies sensitive to contributing factors that may have an impact on participation [35]. With this method, as can be seen from the consort diagram in Figure 1, only 89 out 347 (25%) declined to be contacted further. However, the numbers of patients declining to participate once they spoke to the study team and failure to make contact with participants for follow-up were quite significant in this population.

Despite these substantial challenges, this method of recruitment was successful in recruiting a study population, 75% of whom were from the most deprived areas of England and over 60% had low health literacy (as measured by the NVS) [25]. This compares well to other studies of LHTs which were less successful in this aspect and tended to recruit more affluent populations [36].

*4.2. Effect of Intervention.* Given that this was a feasibility pilot trial and powered accordingly, nonetheless, these provisional results show that the LHT had a significant



TABLE 3: Effectiveness of the health trainer arm.

Outcome measure	Usual care N = 26		Lay health trainer N = 27		Mean difference adjusted for baseline 95% CI	Sensitivity analysis: mean difference adjusted for baseline, gender, health literacy, PCP, and time with diabetes 95% CI	p value
	Baseline	7 months	Baseline	7 months			
SDSCAM: higher scores reflect better management of diabetes	4.00 (1.44)	3.85 (1.02)	4.00 (1.29)	4.18 (1.42)	0.33 (−0.21, 0.87)	0.33 (−0.24, 0.91)	0.249
PCS: higher scores reflect better physical function	35.90 (9.35)	35.68 (12.81)	35.42 (11.83)	35.06 (13.49)	−0.27 (−6.13, 5.60)	0.83 (−5.60, 7.26)	0.796
MCS: higher scores reflect better mental function	48.59 (9.73)	47.23 (11.08)	45.86 (13.57)	51.02 (12.98)	5.46 (0.02, 10.89)	6.61 (0.54, 12.68)	0.034
SWEMWBS: higher scores reflect better mental well-being	22.14 (4.39)	22.44 (2.86)	23.88 (5.59)	23.19 (5.27)	−0.17 (−2.13, 1.80)	−0.26 (−2.43, 1.92)	0.814
BIPS: higher scores reflect patients viewing their diabetes as more life threatening	33.46 (11.26)	38.76 (10.87)	39.26 (12.40)	37.93 (13.17)	−5.74 (−11.19, −0.29)	−5.91 (−11.89, 0.08)	0.053
DQL: higher scores reflect worse quality of life	28.21 (21.21)	39.02 (23.24)	33.70 (23.56)	39.10 (28.55)	−4.24 (−16.34, 7.87)	−3.13 (−16.58, 10.33)	0.641
DUKS: higher scores reflect patients were offered more health services to help manage their diabetes	7.27 (0.87)	6.96 (1.43)	7.19 (0.74)	7.33 (1.04)	0.40 (−0.27, 1.06)	0.29 (−0.41, 0.98)	0.414
HbA1c: higher scores reflect worse control of blood sugars	78.38 (13.86)	66.19 (18.60)	77.37 (16.54)	72.88 (14.82)	5.17 (−2.53, 12.88)	1.42 (−7.18, 10.02)	0.740
EQ5D: higher scores reflect better health	0.67 (0.26)	0.61 (0.27)	0.56 (0.36)	0.68 (0.28)	0.10 (−0.03, 0.24)	0.13 (−0.02, 0.27)	0.082

Summary Diabetes Self-Care Measure (SDSCAM); Short Warwick-Edinburgh Mental Well-Being Score (SWEMWBS); SF-12 Physical and Mental Component Scores (PCS & MCS); Diabetes Quality of Life (BDQL); Brief Illness Perception Score (BIPS); Diabetes UK Score (DUKS); EuroQol Health Questionnaire (EQ-5D).

TABLE 4: Resource use by group (number of contacts) at 7 months based on complete cases.

	Usual care N = 26 Mean (SD)	Lay health trainer N = 27 Mean (SD)	Unadjusted difference (95% CI)	p value
Inpatient (number of nights)*	3.12 (8.34)	1.26 (3.40)	-1.86 (-5.35, 1.63)	0.291
A&E attendance	0.54 (1.03)	0.46 (0.86)	-0.08 (-0.60, 0.45)	0.771
Outpatient visits	1.19 (1.86)	0.65 (0.89)	-0.54 (-1.35, 0.27)	0.188
GP at surgery	2.58 (2.16)	1.65 (1.60)	-0.92 (-1.98, 0.13)	0.086
GP at home	0.04 (0.20)	0 (0)	-0.04 (-0.12, 0.04)	0.322
Practice nurse	2.12 (2.10)	1.73 (1.15)	-0.38 (-1.33, 0.56)	0.417

\* Based on the assumption that missing values were zeros.

impact on the mental health of participants in the intervention arm, both in terms of the mental health component of the SF12 and in patients having a less negative self-perception of their condition. There may be a variety of reasons underlying this; research evidence suggests that patients with low health literacy can be especially anxious about medication use and dissatisfied with information that they receive about diabetes [37]. Additionally, other research has suggested that enhanced social support (signposted to or directly provided by the LHT) may improve diabetes self-care [38]. Furthermore, although not achieving conventional statistical significance in this small sample size, the results suggest that participants in the LHT arm had improved patient self-care management and received more health services and checks, all of which are likely to positively impact participants' mental health and their perceptions of their condition. This is supported by a relatively large increase in quality adjusted life years (QALYs) over a short seven-month period.

The LHT intervention in this pilot trial did not lead to improvements in physical health or blood-glucose control as measured by the HbA1c, but the sample was not powered to investigate changes in HbA1c and it is likely that an intervention of this nature, designed to improve patient self-management by encouraging patient behaviour change, would need longer than the short follow-up of this study to demonstrate an impact on physical health.

**4.3. Preliminary Cost-Effectiveness.** The LHT intervention was associated with lower resource use across all categories (primary and secondary care) at follow-up. While none of these differences were clinically significant, these results add weight to the possibility that the relatively minimal costs of the intervention may be offset by reductions in downstream costs. In addition, the intervention was associated with a better QALY profile than the control group. While this difference was small (and nonsignificant), it supports the

general results of this study that the intervention may provide good value for money and may even save money while improving outcomes.

Research evidence on the cost-effectiveness of lay health advisors, which would include LHTs, is mixed, but an evidence synthesis by Carr et al. suggests that they can be cost-effective in chronic care and smoking cessation, both important for diabetes self-management [39].

**4.4. Limitations of This Study.** Despite relatively successful efforts to recruit a disadvantaged population of patients with poorly controlled diabetes and low health literacy, from socioeconomically deprived areas, there remains the possibility that the trial participants are still underrepresentative of those who are most disadvantaged and most at risk. Such individuals may be less motivated to respond to the LHT intervention and less willing to respond to supported self-management to improve their poorly controlled diabetes.

Being a pilot, the trial was not fully powered for the detection of intervention effects and the inclusion of a wide range of outcomes implies a high chance of one or more falsely significance results; hence, the findings on effectiveness must be treated as purely provisional until validated by further, larger, studies. A further limitation is the short length of follow-up. This is particularly relevant to interventions which are intended to lead to change in outcome measures through behaviour change, which will likely need a reasonable length of time to make an impact. This would need to be evaluated in a full-size RCT with longer follow-up.

**4.5. What This Study Adds.** This study adds to the body of evidence regarding recruiting disadvantaged participants, specifically those with low health literacy, living in socioeconomically disadvantaged areas. We would support recruitment strategies that keep written information to a minimum and recruit using personal contact by someone known to the potential participant. As previously mentioned, a future full-sized RCT would need to aim for longer follow-up of 12–18 months to be confident about sustained improvements in mental health and the possibility of improvements in patient self-management leading to significant improvements in physical health. As discussed in the results, follow-up in this study at 7 months was just under 70%, so collecting longer term follow-up data will be challenging and may require the use of other more innovative practices such as the use of text messaging and social media to collect data, keeping in mind health literacy limitations.

## 5. Conclusion

Despite the initial low response to recruitment using practice nurses, changes in our recruitment strategy led to this pilot trial recruiting the population that it set out to achieve. To our knowledge, this is the first pilot trial to provide evidence for recruiting patients with low health literacy from disadvantaged backgrounds and to demonstrate the feasibility of a LHT RCT in a primary care setting for this population that is usually excluded from RCTs by nature of their poor

response to invites to research. Adding to this the likely cost-effectiveness of this relatively low-cost intervention to a population currently suffering a disproportionate burden of diabetes and diabetes-related complications, we would support a large, robust RCT to demonstrate the treatment effect and its sustained impact on health and health inequalities.

## Disclosure

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

## Competing Interests

The authors declare that they have no competing interests.

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## Review Article

# Meeting the Challenge of Diabetes in Ageing and Diverse Populations: A Review of the Literature from the UK

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The impact of type 2 diabetes on ageing societies is great and populations across the globe are becoming more diverse. Complications of diabetes unequally affect particular groups in the UK older people, and people with a South Asian background are two population groups with increased risk whose numbers will grow in the future. We explored the evidence about diabetes care for older people with South Asian ethnicity to understand the contexts and mechanisms behind interventions to reduce inequalities. We used a realist approach to review the literature, mapped the main areas where relevant evidence exists, and explored the concepts and mechanisms which underpinned interventions. From this we constructed a theoretical framework for a programme of research and put forward suggestions for what our analysis might mean to providers, researchers, and policy makers. Broad themes of cultural competency; comorbidities and stratification; and access emerged as mid-level mechanisms which have individualised, culturally intelligent, and ethical care at their heart and through which inequalities can be addressed. These provide a theoretical framework for future research to advance knowledge about concordance; culturally meaningful measures of depression and cognitive impairment; and care planning in different contexts which support effective diabetes care for aging and diverse populations.

## 1. Introduction

Although longevity in the UK is increasing, average increases mask important differences within the population [1–3]. Furthermore as the UK population as a whole grows older, the demographics within it are changing (see Figure 1). Currently most ethnic minorities have younger populations than the majority White British population. However by 2051, the ethnic groups with the highest proportions of people, aged 50 and over will be “Other White,” Chinese, “Other Asian,” Indian, “Other,” and White Irish alongside White British. In the “non-White” ethnic group alone, there will be 2.7 million people aged 65 and over and 1.9 million people aged 70 and over [4]. Whilst ethnic minorities already make up around half the local population in some parts of the country, by 2056 they will make up 43 percent of the total national population [5]. Together these changes highlight the need to focus attention to commissioning health services for an increasingly multiethnic older population.

The purpose of this research was to review the evidence to guide a programme of applied research to address the key areas and processes for reducing inequalities in diabetes care for older people from ethnic minority groups. We focussed in this instance on South Asians in the UK as this group has an established history in the UK (making up fifty percent or more of the population in some UK locations) and so would be likely to feature in the relevant research literature.

We define ethnicity as a consciousness of belonging to a particular group based on commonality of family origin and culture of shared values and beliefs which is socially constructed [6] and loosely related to country of birth, ancestral country of birth, language spoken at home, nature of geographical origin, racial group, and religion [4]. The broad South Asian ethnic group descriptor used in this review (unless otherwise stated) refers to the majority South Asian populations in the UK: Indian Punjabi, Indian Gujarati, Bengali, Pakistani, and Sri Lankan.



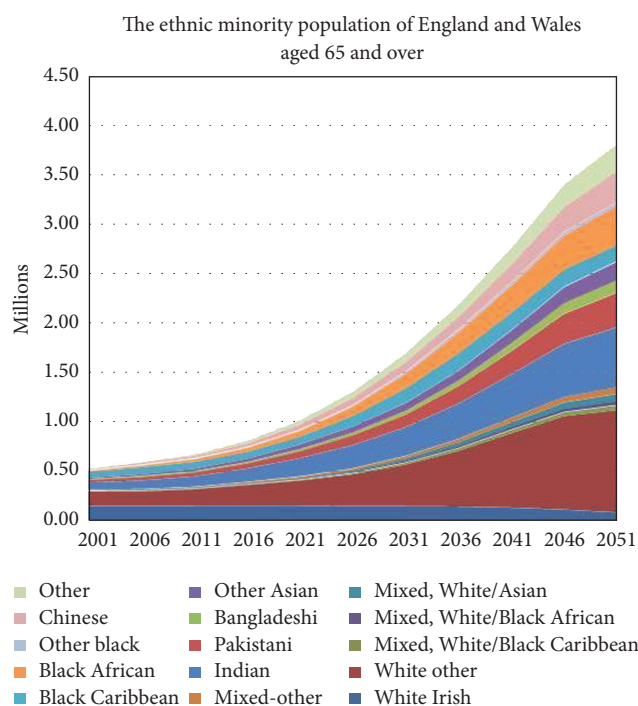


FIGURE 1: Ethnic minority population projections to 2051, England and Wales from Lievesly, 2010 [4].

The term “older people” is used variously according to context and different age-related dimensions: chronological, biological, functional, psychological, and social. In western societies, it broadly aligns with age of retirement 60 or 65+ [7, 8] but this is a socially constructed time point which does not take into account other factors relevant to diabetes care and ethnicity such as the onset of complications; and we account for this in our strategy for searching the literature.

This study’s principal interest was diabetes care and prevention in relation to inequality, ethnicity, and the older population rather than the aetiology of diabetes per se, although this was necessarily touched on where it related to clinical practice and management of older people who are living with diabetes. Diabetes care in the UK is a context specific and complex activity because it takes place across NHS settings through consultations in primary and secondary care and in people’s home through self-management and care support.

Inequality was the main lens through which the literature review was conducted. The starting point was that our previous research in related areas had found inadequate care of older people with diabetes particularly those being cared for in residential settings [9]; that providing equitable care through the diabetes care pathway was a challenge for care providers [10]; and that people with a South Asian background and diabetes can be doubly disadvantaged by having increased risk of developing diabetes compared to people with a White European background in the UK and additional access barriers [11]. These separate but related findings suggested to us that it was important to look at the

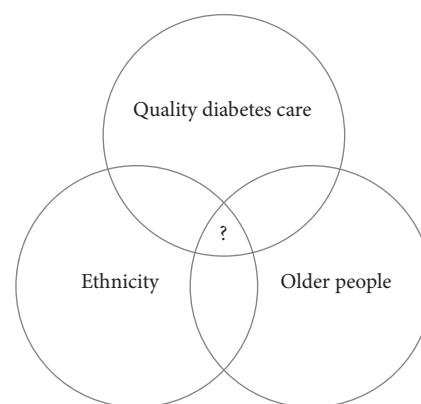


FIGURE 2: Areas for literature review.

evidence as a whole and to understand the processes which could help inform action on inequalities.

Although familiar with some of the concepts associated with reducing inequalities in access to diabetes care, such as cultural competency and concordance [12], we had not considered these specifically in relation to older people and the increasingly diverse and ageing UK population before. This was the first review, as far as we were aware, to do so and it was by nature and design exploratory. We used a realist review methodology to help us search the literature and to start to build a theoretical base for our research programme.

The review had two parts: Part 1, a mapping phase where we thematically synthesised the relevant studies into the main areas of research evidence; and Part 2, a theory building phase where we hypothesised, by abstracting from the evidence, a theoretical framework for moving forward from this base. As the work was early stage the emergent theory raised further questions which will help test and refine the theory in the future. As it stands however the review highlights a number of issues for policy makers, providers, and researchers concerned with reducing and preventing inequalities in diabetes care and these are summarised at the end of this paper.

## 2. Methodology and Methods

We reviewed literature at the intersection of three areas: quality diabetes care, older people, and ethnicity (see Figure 2). The review was conducted by a multidisciplinary team comprising researchers with interest and expertise in public health, diabetes, gerontology, and diversity research.

Following an initial exploratory phase we decided to apply a realist approach to review the literature. This methodology was considered the most appropriate because it accommodated the broad research question; was compatible with the complex and context related nature of diabetes care; was sympathetic to the usage of a multimethod, multidisciplinary evidence base; and would facilitate the exposition of theory through emerging and generalisable mechanisms [13]. This could inform our programme of research but also be useful to policy makers and practitioners working with other ethnic minority groups in the UK.

**2.1. Literature Search.** We conducted an initial scoping phase in which we hand-searched for research publications and tested different search strategies with available electronic databases. We made a number of decisions about the search strategy which are listed as follows:

- (1) The search would be limited to the previous 30-year timeframe and to studies from the UK. The period 1985 to 2015 spanned several changes of UK governing parties and associated health policies some of which addressed health inequalities in relation to diabetes care, the impact of which would be captured in literature published during this time.
- (2) The search would focus specifically on the UK population. Ethnic minorities and health systems are different in different countries and diabetes care is context related. Literature on ethnicity, access, and cultural competency from other countries such as the US, Canada, and Australia was drawn on where appropriate in the analysis and discussion of mechanisms.
- (3) The search would focus on the UKs' South Asian population rather than other or all ethnic minorities living in the UK. Previous research by members of the team provided insight into some of the inequalities that people with a South Asian background experience [14]. As these related to this particular population group's migration and settlement in the UK they are likely to be reflected in UK evidence from this timeframe. Despite a focus on one group we anticipated that some of the concepts and mechanisms emerging from this review would be applicable to other minority communities.
- (4) The search would use common age descriptors for older people as well as specific age categories from 55 years upwards. In the context of diabetes and care for minority groups age as a descriptor could be relative and variable depending on the population and phase of care (i.e., prevention, treatment, and palliation).
- (5) The search would use descriptors for diabetes that included the key complications: diabetic neuropathy, retinopathy, and nephropathy. Terms for the latter would be expanded as studies of diabetic nephropathy and end stage kidney disease would be likely to include the older South Asian population because of the links between ethnicity, diabetes, chronic kidney disease, and longevity [11, 15].
- (6) The search would be inclusive of research using qualitative and quantitative methods as well as grey literature in line with the realist methodology to prioritise relevance and contribution to theory building [16]. The quality standards applied in assessing potential publications were based on those appropriate for the type of publication, intervention, method, and design described [16, 17].

**2.2. Searching Methods.** A combination of hand searching and electronic searching of publication databases was carried out.

The following databases were searched: Academic Search Elite, CINAHL Plus with Full Text, MEDLINE, MEDLINE with Full Text, PsycARTICLES, PsycINFO, SocINDEX with Full Text, and Global Health. Publication abstracts were searched using keyword criteria as follows:

Diabetes OR diabetes mellitus OR type 1 diabetes OR T1DM OR type 2 diabetes OR T2DM OR hyperglycemia\* OR hypoglycemia\* OR non insulin dependent diabetes mellitus OR NIDDM OR insulin OR insulin resistance OR glucose level OR glucose regulation OR haemoglobin A1c OR HbA1C OR metabol\* OR foot problems OR amputation OR lower extremity OR lower limb OR complications OR nephropathy OR retinopathy OR kidney disease OR chronic kidney disease OR renal OR renal impairment OR kidney damage OR albuminuria OR proteinuria OR microalbuminuria OR renal replacement therapy OR CKD OR ESRD OR ESRF OR ESKD OR ESKF OR RRT OR end stage renal disease OR end stage kidney disease OR end stage kidney failure OR end stage renal failure OR dialysis OR primary care AND Older people OR older persons OR elder\* OR old age OR ageing OR aging OR late life OR frail\* OR non frail OR end of life OR geriatrics OR gerontology OR post menopausal OR over 55 years OR over 60 years OR over 65 years OR over 70 years OR over 75 years OR over 80 years OR over 85 years OR over 90 years OR over 95 years OR over 100 years OR end of life OR functional disability OR functional decline OR mortality AND Ethn\* OR race OR culture OR BAME OR BME OR minorit\* OR ethnic minority OR asia\* OR Indoasia\* OR south asia\* OR Indian OR Pakistani OR Bangladeshi OR Sri Lankan OR racial OR black\* OR culturally and linguistically diverse group OR CALD

Electronic search results were screened for duplication and relevance to the review area and question. Copies of the full publication were obtained for included abstracts which were screened and those considered relevant included in the analysis. This process was conducted by EW and MW jointly, with assistance from an information specialist and with input and oversight from the other members of the author team.

**2.3. Analysis and Synthesis.** The research question "What are the key mechanisms for reducing inequalities in diabetes care in the UK for older people with a South Asian background?" was the basis of capturing learning from the published literature. In realist terms it was conceptualised as a complex intervention comprising government policy, applied research, and evidence based practice from the UK which addressed inequalities in diabetes outcomes and care for older people with diabetes from ethnic minorities and spanned the diabetes care system as a whole. We drew on the RAMESES guidance [18] for reporting realist review to help make our review and its findings as clear as possible.

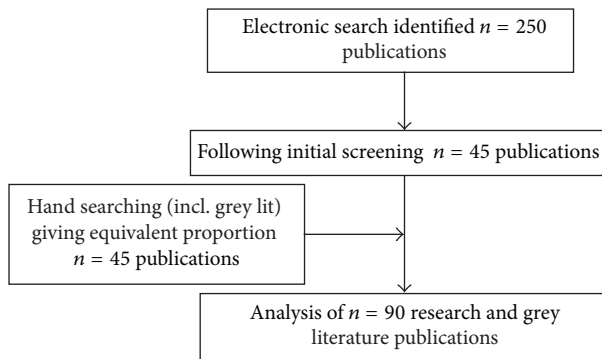


FIGURE 3: Search results.

The realist programme theory developed iteratively through the scoping, mapping, and theory building stages of the literature review and the findings are reported in two parts in Section 3:

Part 1: the overview and mapping of literature relevant to the research question and search criteria.

Included studies were analysed thematically into broad areas.

Part 2: the building of a theoretical framework for research in response to the question.

For each mapped area we considered the context, mechanisms, and outcomes and considered how these related to common concepts also emerging from the literature that could be explanatory in terms of observed inequalities in diabetes care and interventions to reduce them (see Table 1).

### 3. Results

The results of the literature search are summarised in Figure 3. The electronic search was most recently conducted on 27th July 2015.

**3.1. Results: Part 1 Mapping.** Following thematic analysis the included literature was following broad areas.

**3.1.1. Age and South Asian Ethnicity in Diabetes Research and Policy: Demography and Inequality.** There were very few studies which specifically investigated diabetes, older people, and ethnicity, and even fewer (none) which specifically addressed diabetes care for older South Asian people in the UK. Although studies which included South Asian people with diabetes often stated in their background that diabetes was a leading cause of mortality and morbidity and South Asians were the largest ethnic minority in the UK, the majority of studies identified by our literature search concerned prevalence and incidence of diabetes, diabetes related complications, and associated conditions particularly cardiovascular disease. Exceptions to this were the UK Asian Diabetes Study (UKADS) [19] and the Prevention of Diabetes and Obesity in South Asians (PODOSA) [20] which were

intervention studies of enhanced diabetes care and prevention respectively, within the UK South Asian population. We found however that the data and findings concerning age within included studies tended to be embedded within the results section of the publication, not detailed in the aims of the research nor discussed in more than a cursory way in relation to the timing of interventions in the population being studied.

In South Asians, the prevalence of type 2 diabetes is 4 times greater than that of White Europeans [21]. Most of the research papers which focussed on ethnicity included it as a demographic descriptor and independent variable of the outcome or outcomes being examined. Policy documents for diabetes, kidney care, and care of older people in contrast highlighted ethnicity as a key variable associated with inequality in access to quality care and in terms of interventions being culturally acceptable [22–24]. Recent guidelines for diabetes care for older people [25, 26] suggested that care should be individualised within an overarching theme of person centred diabetes care and that it should be tailored to individuals taking into consideration relevant factors. One such factor could be the person's ethnicity, but this was not explicitly stated within the guidelines.

Where ethnicity was discussed in relation to inequalities in the research literature it was mainly to explain variations in outcomes or patterns of distribution within a given population and there was a dearth of studies which analysed inequalities as it related to diabetes care specifically for older people with a South Asian ethnic background. There were very few studies about diabetes and diabetes care which explicitly included older South Asian people as participants and a similar number of papers which discussed the lack of participation of older people and ethnic minorities in studies as a research issue [27, 28].

**3.1.2. South Asians and Earlier Onset of Diabetes and Complications.** Studies of diabetes which include an analysis by ethnicity invariably noted the earlier onset of diabetes in South Asians compared to White Europeans as an important factor in understanding both aetiology and disease progression as well as indicating a timeframe for intervention and prevention which is different to the majority population. South Asians experience diabetes approximately 10 years before White Europeans and show signs of more rapid progression of complications [29, 30]. Research studies of diabetes complications in ethnicity minorities did not explicitly identify older people for inclusion, but because complications are related to time since diabetes diagnosis and age, they included a large proportion of older people within their study populations "by default" [31, 32].

Together, key UK government guidelines, the Quality Outcomes Framework and the National Service Frameworks for Diabetes and Kidney Disease, have encouraged GPs to consider ethnicity as a factor for earlier diagnosis and targeted care. These quality initiatives have gone some way to redress inequalities in diabetes care [33] but there are concerns that, as they stand, they may perpetuate the existing status quo and not reduce inequalities further [34].

TABLE 1: Proposed CMOs (context, mechanism, and outcomes) and explanatory concepts for theory building.

Mapped area of literature	Context	Mechanism	Explanatory concept cultural competency (CC), stratification (S), access (A)	Outcome
Age and South Asian ethnicity in diabetes research and policy: demography and inequality	(i) No specific focus on age and ethnicity in the research literature (ii) National frameworks and nonspecific guidelines (iii) Local level focus for interventions: community, family, primary care	(i) Cultural adaptation within services, for example, link workers (ii) Targeting cultural & social factors, for example, families, diet (iii) Ethnicity as risk factor for inequality in access	(i) CC (ii) CC, S (iii) CC, S, A	(i) Modest impacts to date, not cost effective: difficult to do & complex (ii) Cultural and social determinants can influence motivation & support for self-management (iii) Researching inequalities to include age dimension
South Asians and earlier onset of diabetes and complications	(i) Earlier onset of diabetes and complications (ii) Primary/secondary care interrelations (iii) National frameworks for quality diabetes & kidney care	(i) Quality initiatives for diabetes care in primary care (ii) Use of ethnicity data, referral patterns, progression rates (iii) System wide & pathway interventions	(i) CC, A (ii) CC, S (iii) CC, S, A	(i) Earlier diagnosis (ii) Improved diabetes care: monitoring & referral patterns (iii) Contested/better understanding quality improvements in relation to holistic diabetes care
South Asian ethnicity, heterogeneity, cardiovascular disease	(i) Heterogeneity within ethnicity (ii) Socioeconomic associations (iii) Diversity of outcomes as basis of individualised care	(i) Practice based research into stratification within diabetes populations (ii) Tailored approaches to diabetes & complications care	(i) S (ii) S, CC	(i) Targeted care (ii) Improved understanding of ethnicity influences (iii) Tackling the biological with the sociological
Diabetes and complications affecting older South Asian people	(i) Age and high prevalence of diabetes comorbidities & complications (ii) Early onset, increased risk, faster progression (iii) Extended timeframe of care	(i) System approaches: care pathway & disease trajectories (ii) Improved identification of comorbidities, for example, dementia & depression in older people with South Asian background	(i) S, A (ii) S	(i) Shift in the way we think about diabetes and ageing (ii) Prevention, identification, treatment & end of life care across different settings
Delivering quality diabetes care and prevention of complications in UK South Asian population	(i) Person centred care & assessment of need (ii) Quality care includes knowledge & information for patients (iii) Lack of evidence about cultural aspects of self-management (iv) More evidence which includes South Asian ethnicity required	(i) Cultural flexibility within care (ii) Improving access by better identification through screening (iii) Integrated care as part of a holistic and whole coordinated approach	(i) CC, A (ii) A, S (iii) S, A	(i) Better understanding of the different elements of diabetes care (ii) Access increased through combined and system wide approaches.
Researching the experience of older South Asian people with diabetes in and across different settings	(i) Lack of research involving South Asian patients (ii) Reliance on studies of ethnicity in kidney services (iii) Broader social and psychological contexts of care	(i) Culturally competent practice and research to redress inequalities in access & in research participation	(i) CC, A	(i) Improved understanding of patient experience so that care is effective and meaningful for all patients.



**3.1.3. South Asian Ethnicity, Heterogeneity, and Cardiovascular Disease.** Several of the studies which detail South Asian ethnicity describe the heterogeneity within the broad South Asian descriptor for the UK's diverse South Asian population and some, depending on the data source, were able to break down their results across the main South Asian groups (Indian, Pakistani, and Bangladeshi) in the UK [35]. Ethnicity was linked to socioeconomic status in some studies including use of income level as a proxy for age as an alternative explanatory variable to capture some of the social and cultural associations with age.

The complicating associations between diabetes and cardiovascular disease (CVD) were the subject of over half the studies identified through our electronic search. These were seeking to understand the aetiology of morbidity and mortality of CVD and included diabetes and ethnicity as established risk factors in the analysis [36]. Similarly, in relation to high blood pressure and atherogenic lipid profile, key risk factors for circulatory diseases, these have been found to have an association with South Asian ethnicity both in comparison with other ethnic groups and amongst the main UK South Asian groups [37].

Differences in diabetes related mortality and morbidity between different ethnic groups outlined in a small number of publications point to different mechanisms through which ethnicity exerts influence. For example, South Asian and Black groups both have increased risk of diabetes, CVD, and Stroke [38] compared to White Europeans but show differences in level of risk and type of stroke. This in turn suggests particular genetic differences in addition to social and behavioural factors all or some of which may be linked [39]. Furthermore these studies have shown that when diabetes and age are controlled for, ethnicity exerts an independent effect on cardiovascular outcomes [40, 41].

**3.1.4. Diabetes and Complications Affecting Older South Asian People.** Studies which focus on diabetic nephropathy show that South Asians also experience complications at an earlier age and their progression is faster than in White Europeans. South Asians' risk of diabetic nephropathy is 13 times that of the White European population [21]. As a group they are disproportionately represented in the population for renal replacement therapy, and because of this and the additional and independent risk of mortality from CVD that chronic kidney disease confers, together with a lack of ethnically compatible kidneys for transplantation, they are disproportionately represented in the group of people in need of end of life care [42].

Other diabetes complications, retinopathy and neuropathy, have a similar association with ethnicity; that is, they have been found to be associated with increased risk factors [43] and are indicators of microvascular damage. Furthermore South Asian populations are at increased risk of developing vascular dementia because of the increased incidence of diabetes, hypertension, and chronic kidney disease [44–46]. There is a higher rate of cognitive impairment in older people with CKD; it is largely unidentified and associated with severity of CKD [47–49].

As the South Asian population is ageing and as longevity is main risk factor for comorbidities in older people, the incidence of end stage renal failure and dementia are set to increase in South Asian ethnic group [50]. Both these complications are ultimately life limiting but have a disease trajectory which can last many years, and as retinopathy and neuropathy affect sight and pain symptoms, care provision of older people with diabetes and complications incorporates preventive activity, treatment of symptoms, and comorbidities and end of life care [22–24], which in the case of diabetic nephropathy may include renal replacement therapy.

Depression as a comorbid condition for people with diabetes is associated with both increased risk of developing cardiovascular problems as well as being secondary to cardiovascular complications and increasing risk of mortality [51]. It is also a prevalent and costly burden to end stage renal patients [52] and South Asian patients are disadvantaged if it is not identified [53] or they are unable to access services [54].

**3.1.5. Delivering Quality Diabetes Care and Prevention of Complications in UK South Asian Population.** Individualised assessment of need and cultural sensitivity are included within the national service frameworks for diabetes, kidney disease, and care of older people [22–24] as means of delivering person centred care. The equality impact assessment for the national dementia strategy however acknowledged that although South Asians together with Black Caribbeans represent the largest ethnic minority in the UK, evidence about dementia care in these communities is lacking [55].

Research into the extent of how well healthcare services are able to meet the needs of South Asian people who have diabetes has found that whilst services have implemented the organisational element of quality improvement policy such as the Quality Outcomes Framework and shifts of diabetes care from secondary to primary care they may not have resulted in quality of care from the patient perspective [56, 57] nor in reduction of inequalities [34]. This is attributed to lack of awareness about diabetes complications and services and communication barriers in healthcare encounters and research, although studies have not specifically addressed these in connection to age and ageing.

The small number of trials testing culturally appropriate self-management programmes [58] and structured education [59] has found some short term effects on diabetes control and increased knowledge; however they conclude that more research is needed to test different types and intensities of intervention and with different South Asian groups [60]. The patient experience research referred to, however, did not specifically include older people in their inclusion criteria.

Pilots of integrated diabetes care such as the North West London Integrated Care Pilot for people over 75 years of age considered ethnicity in their design and analysis [61, 62]. The attendance by South Asian people aged 40–75 in the first year of the health checks programme was higher than previous studies of screening programmes in diverse groups highlighting the role of primary care in access for South Asian patients compared to other parts of the NHS particularly in areas with high South Asian populations with GPs who have



the same ethnicity [63]. However whether the programme as a whole will achieve its target 75% uptake has been queried and the need for a combined population and high risk approach to prevention and targeting of care which considers age as the most powerful predictor of cardiovascular and diabetes risk [64] and takes into account the earlier onset of diabetes in people with South Asian ethnicity is a possible pragmatic solution [65].

*3.1.6. Researching the Experience of Older South Asian People with Diabetes in and across Different Settings.* Patient experience research with South Asian people with diabetes in primary care identified barriers one of which was a need for information and health education to be delivered in a culturally appropriate way that matches an individual's understanding of health and disease, as well as taking into account the broader social context for ethnic minority groups and common psychological responses [66–68]. Findings related to some dimensions of ageing and South Asian ethnicity, for example, age-related expectations of health and health related behaviours, but ageing was not a specific focus of these studies although they called for multidimensional approach to understanding the preventable diabetes related mortality and morbidity.

A care pathway approach to exploring patient experience of diabetes care across primary care and specialist renal care found that South Asian patients referred to renal care lacked awareness of kidney complications of diabetes despite familiarity with diabetes over more than 10 years. Furthermore reflecting back on diabetes care patients felt there had been missed opportunities for information and self-management support [57].

The small number of studies of South Asian patients' experiences of care in secondary care kidney services also tells us more about the care of older South Asian people with diabetes as nearly half the South Asian patients requiring renal replacement therapy also have T2DM [31]. Communication difficulties are a challenge in the day-to-day provision of renal care [69] as well as for end of life care services to South Asian patients who are often older and do not speak English as their first language [70, 71].

*3.2. Results: Part 2 Theory Building.* The exploratory mapping of the literature in this review created a context for the second part of our analysis. Explanatory concepts which emerged from the literature alongside the observational data were cultural stratification and comorbidities, cultural competency, and access. The relationship between these concepts and the CMO analyses in each mapped area is shown in Table 1. Together the mechanisms and explanatory concepts formed a theoretical framework (see Figure 4) for responding to the review question and identifying key areas for future enquiry which we articulated as broad research questions below.

*3.2.1. Comorbidities and Stratification.* As diabetes complications are associated with longevity and length of time with diabetes as well as South Asian ethnicity, it is common that older South Asian people with diabetes will have multiple comorbidities requiring some sort of prioritisation

and integration of treatment and care according to which conditions are of most concern or life limiting. Stratification of patients by risk, comorbidities, patient experience, and diagnosis is therefore a key part of informing effective care [72, 73] and determines the context for care.

The fact that South Asian people develop diabetes earlier and experience the complications younger means that in the context of diabetes care the descriptor “older” age needs to be brought forward relative to the White European population. The changing demographics of the UK mean that there will be more older South Asian people in the future and half will have developed diabetes by age 80 [74].

Studies which identified the cardiovascular risk and outcomes associated with diabetes and South Asian ethnicity and the small number breaking it down further into the predominant South Asian groups in the UK provide evidence for the high risk that South Asians with diabetes have for cardiovascular disease mortality and morbidity and persisting inequalities [35]. This finding is not new, but it points towards the importance of understanding the heterogeneity within ethnic categories as well as the specific genetic and social influences on health outcomes [75]. In the future it will be possible to draw more on the findings of biomarker and bariatric metabolic surgery research but at present accurate monitoring of ethnicity within the health system, the use of available data, targeting of screening programmes, and adaptability in day-to-day practice are ways of tailoring care towards individualised risk.

Detection of prediabetes, incident diabetes, and diabetes complications is important for prevention of the onset and progression of complications through the provision of appropriate and timely care which may need to be more aggressive for South Asians because of the greater risk for cardiovascular (including cognitive and renal) complications. Measures to detect complications which are culturally mediated, that is, dependent on language or ideas of dependency and quality of life, such as depression and cognitive impairment, need to be sensitive enough to identify complications in heterogeneous populations [53, 76].

The range of complications which are associated with older age and diabetes may contribute to frailty which results in vulnerability to sudden changes in health states and increased risk of falls, disability, long term care, and death [77]. A recognised frailty descriptor for the clustering of comorbidities and associated indicators has been suggested to be more meaningful in a clinical context [78, 79] than chronological age and particularly within a model for integrated care. If frailty is to be useful indicator for stratifying and tailoring diabetes care greater understanding of what it means for clinical care and prevention is required both across different ethnic groups and in relation to individual culture.

*Research Question. How can knowledge about diabetes comorbidities and associated impacts for older people with a South Asian background improve care that maximises quality of life and NHS resources?*

*3.2.2. Cultural Competency.* Whereas stratification on the basis of disease, comorbidities, and symptoms dictates the

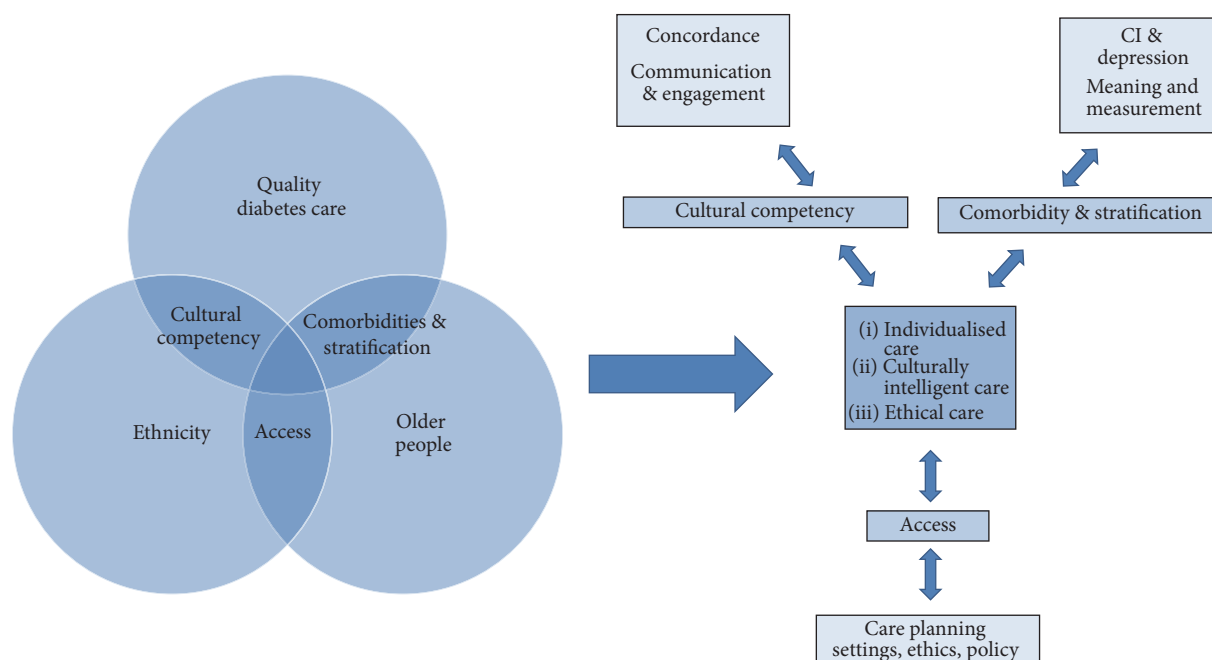


FIGURE 4: Theory building: concepts and mechanisms.

context for clinical care, the way that information is conveyed and discussed to people with diabetes is important for supporting self-management and decision making in patient care.

The opportunities for prevention of diabetes and complications are an important part improving outcomes for older South Asian people with diabetes because of the earlier and extended timeframe that they are living with diabetes. The focus on primary care and integrated care as a means of delivering patient centred outcomes, if supported by systemic knowledge and awareness of culture within the NHS, aligns with the concept of culturally competent care:

*Understanding the importance of social and cultural influences on patients' health beliefs, and behaviours; considering how these factors interact at multiple levels of the health care delivery system (e.g. at the level of structural processes of care or clinical decision making); and finally, devising interventions that take these issues into account to assure quality health care delivery to diverse patient populations. [80]*

Research which investigated ethnicity and quality of diabetes care in South Asian patients in primary and secondary care identified the importance of individualising care within a culturally competent approach to support concordance in the care process [33]. For individualised care to be supported practitioners therefore not only need culturally valid tools for assessing and diagnosing comorbid conditions, but also require a culturally adaptable approach which encourages concordance, that is, mutual agreement and involvement in their care.

To achieve this one on one with patients requires the resources within the system to be in place and a full understanding of the challenge. The evidence as it stands suggests that although it is possible to target diabetes interventions [81] and make cultural adaptations these have not been shown to be cost effective or to have fully addressed motivation as a key issue which requires a better understanding of culture and healthcare interactions at an individual and family as well as organisational level. Peer support interventions have been identified as a potentially effective way of achieving culturally competent care [82] but evidence is lacking from the UK of its usefulness with particular population groups [83, 84].

The concept of cultural intelligence takes the theory of cultural competency further [85, 86] by suggesting that care providers and the healthcare system as a whole are able to work effectively with all people of any culture. On an organisational level this concerns availability of sound data to inform decisions and at the level of the clinical encounter it involves open and adaptable communication skills.

*Research Question. What are the most effective communication methods for promoting concordance in diabetes care with older people with a South Asian background?*

**3.2.3. Access.** A person has access to quality care when the care they experience is meaningful and effective [87, 88]. As older people with diabetes and complications receive care in various settings: in general practice, acute departments of NHS hospitals, renal units, at home and in residential, and nursing care homes, commissioners require evidence of what constitutes quality care in these different contexts and in relation to inequalities within their local population.

Whilst the national quality improvement frameworks for diabetes and kidney services have improved diabetes care in terms of the infrastructure for monitoring in primary care with incentives for practices to do this, the evidence suggests that these do not support access to all aspects of diabetes care and that it can be fragmented and variable for all patients particularly for South Asian groups for whom there can be more barriers [89–91].

It has been estimated that a quarter of care home residents are likely to have diabetes [92] and whilst data on care home residency by ethnicity is sparse [93], it is reasonable to anticipate that numbers of South Asian older people requiring residential and social care services will grow in line with demographic changes. We also know there are growing numbers of South Asian people requiring palliative and end of life care [94] so that policy makers and commissioners must work with the range of care providers to ensure equitable access to care.

Our review of the literature highlights there is a dearth of research studies which have considered access as a collective function of providers within local systems and which include older patient and carer participation in diabetes care at local and individual levels. This is despite the growing awareness of the diabetes epidemic and observations that older age is when cultural differences and sensitivities can be most acutely experienced [95]; healthcare utilisation is at its greatest [8, 96]; and when the costs are directly felt by individuals and their carers through morbidities, disability, and reduced quality of life [97].

The prevention imperative to reduce levels of diabetes and complications requires intervention to raise public awareness of the issues of diabetes care for older people from ethnic minority groups and to shift attitudes of patients and clinicians towards a more empowered approach [98] to care planning. To enable access to holistic diabetes care for older people requires primary care commissioners to lead and facilitate an integrated approach with care providers, people with diabetes, and their carers [99].

Whilst evaluation of on-going programmes such as integrated care initiative, National Diabetes Audit with Patient Experience of Diabetes Services, and House of Care [100] will contribute to this process, primary research with patients, care providers, and formal and informal carers is necessary to understand the clinical and cultural contexts of ageing with diabetes better and to maximise ways to improve access and quality of care for older people and people with or at risk of diabetes and cardiovascular complications.

*Research Question.* What are patients and their informal and formal carers experience of involvement in care planning and how can these inform service improvement for older people living with diabetes who have a South Asian background?

## 4. Discussion

Current policy and interventions to reduce inequalities in diabetes care in older people with South Asian ethnicity have not resulted in a knowledge base of what works to reduce

complications and the poorer outcomes for this population. This exploratory synthesis of the literature is the first to put forward a theory based framework for doing so.

The lack of a body of research evidence which addresses inequality and quality of diabetes care for older South Asian people with diabetes reflects many and complex relationships between diabetes and macro- and microvascular complications; the different settings where care is provided; the lack of specific inclusion of older South Asian people in research; and the heterogeneity within ethnic and age descriptors. Studies which, by default, have included this group highlighted that the ethnic specific and ageing effects of diabetes require further enquiry.

Limitations of this review relate to complexity; diffuse literature; a broad research question; and the multidimensional influence of ethnicity and culture on health. We mitigated any shortfalls in capturing relevant literature via electronic databases by hand searching and including grey literature and including broad age descriptors which was in line with the exploratory nature of this study. The realist approach taken helped to expand the knowledge base by identifying common mechanisms across different contexts which together contributed to a theoretical framework for policy, research, and practice.

It is both a strength and a limitation that our review was conducted by a team with familiarity with particular areas of the literature, that is, diabetic nephropathy and end stage renal failure in South Asians, and frailty in relation to diabetes and older people. Whilst it helped inform the search strategy and theory building it could constitute bias as published research of inequalities in diabetic kidney disease and kidney care made an important contribution and the subsequent analysis applied some of the concepts from diabetic nephropathy research previously published by two of the authors [33]. To mitigate this risk the team rereviewed the analysis and synthesis at key stages during development and invited critical analysis of the review prior to finalising the work.

Team composition comprised public health researchers and senior academics who have been involved in guideline development, some of whom are practicing clinicians, strengthened our analysis and interpretation in policy and practice terms. Theory building from such a broad question and diverse literature base identified mechanisms which were “mid-level,” conceptual, and compatible with a systems viewpoint, and interpretation into practical questions for policy makers, clinicians, and researchers was a useful element of this review (see Table 2).

Although this piece of work was limited to a UK perspective and a focus on one (albeit broad and heterogeneous) ethnic grouping, the rationale, realist methodology used, and the resulting theoretical framework could equally well be applied to other groups and other diverse populations in other countries. The focus of the review was on understanding the mechanisms which could be useful for reducing inequalities in diabetes care and because the work was exploratory the theoretical ideas are at an early stage and conceptual so also relevant to other health systems.

TABLE 2: Issues to consider in improving access to diabetes care for older people with a South Asian background.

Policy makers	Providers	Researchers
<p>(1) There is a lack of research which has focussed on diabetes care of older people with a South Asian background.</p> <p>The growing numbers of older people from ethnic groups and burden of diabetes makes prevention and quality diabetes care a necessary priority for research and intervention.</p> <p>There is a lack participation, or access to participation, in health research studies for older people and people from ethnic minorities (including South Asian ethnicity).</p>	<p>Policy to be interpreted and care delivered with specific needs of older people and people from ethnic minorities in mind.</p> <p>Interventions need to be multilevel and system wide and promote engagement within diverse populations.</p> <p>NHS research and data systems to make it easier, and clinicians to be proactive to include more older people and people from ethnic minorities in research.</p>	<p>Researchers to develop research methodologies, methods, and skills which facilitate participation in research by older people and people from ethnic minorities.</p>
<p>(2) Earlier onset &amp; progression require earlier treatment for people with South Asian background.</p> <p>The definition of “older” and ageing in relation to diabetes care and ethnicity can vary and this has implications for the timing of interventions.</p>	<p>Providers have an educative as well as treatment role so they need to be aware of differences in disease progression within diverse populations.</p> <p>Provider organisations and practitioners to be aware of age in relation to diabetes care with proactive in targeting timely &amp; appropriate interventions.</p>	<p>Research knowledge required concerning attitudes of different providers towards prevention, older people, sociodemographics, and behaviour change.</p> <p>Researchers to further develop the concept of ageing in relation to diabetes care in diverse cultural groups.</p>
<p>(3) The complicating associations between diabetes and other chronic &amp; preventable diseases, for example, retinopathy, depression, and dementia to be considered in policy making for older patients with South Asian ethnicity.</p>	<p>Providers to be aware of the impact of complications on quality of life and quality of care. Also their role in prevention through integrated and cross disciplinary services.</p> <p>Targeting of interventions to be based on stratification, detection, and diagnosis.</p>	<p>Researchers to carry out more research about complicating associations, for example, diabetes &amp; dementia &amp; depression.</p> <p>Development of culturally relevant tools (and biomarker research to pick up risk earlier).</p>
<p>(4) Awareness of the heterogeneity with broad ethnic groups and the requirement for adaptable and culturally intelligent services to be promoted through policy.</p> <p>Care planning to promote access requires an ethical and culturally intelligent approach.</p>	<p>Services to be flexible and communicate well with people across a cultural spectrum and also at an organisational level.</p> <p>Care planning in different settings, for example, end of life, care homes to involve formal and informal care providers.</p>	<p>Researchers to engage and communicate and engage with culturally diverse people and services.</p> <p>Researchers to build capacity for cross cultural and organisational health services research.</p>



Figure 4 illustrates the review areas and emerging concepts and mechanisms described in the results. At the centre of this model, a theme which underpins UK diabetes policy is individualised, culturally intelligent, and ethical care for older people living and dying with diabetes. This review suggests that better understanding of how risk, disease trajectories, and comorbidities affect people differently (stratification); of how culture, and not just ethnicity, influences care (cultural competency); and of how services can be delivered so they are meaningful and effective for individuals in different settings (access) is all key mechanisms to achieve these objectives.

Our theory building went further to identify sub-mechanisms: concordance; the use of culturally meaningful measures for comorbidities affecting older people such as depression and cognitive impairment; and care planning, in particular understanding ways that older people with diabetes can be involved to ensure that it is as person centred as possible. These submechanisms, articulated as future research questions, were at the next level of abstraction from the evidence reviewed. Addressing these will enable us to revisit and refine this early theoretical framework to further improve understanding of how to ensure equitable care at the intersection represented with a “?” in Figure 2.

Underpinning individualised care and pertinent to understanding these mechanisms is the ability of the health-care system to work with the intersectionalities of individuals and groups within a population. The heterogeneity within broad ethnicity and age descriptors is lost in much of the research literature and a more nuanced approach to understanding individual identity and influences on health [101] will be needed to take forward the different research elements we have identified.

Research with diverse groups of older people and their care providers in different clinical and community settings requires a culturally intelligent approach by researchers [28, 102]. Conducting research with older people with diabetes also presents particular practical and ethical challenges particularly if the person has comorbidities such as cognitive impairment or is at end of life. However a focus on the lived experience and meaning of diabetes for older people with different comorbidities and cultural backgrounds is important to fill some of the evidence gaps in this area.

In practice terms too the awareness of multiple identities and individual experiences affecting diabetes care including, but not exclusive to ethnic group and age, requires closer involvement between patients and practitioners in negotiating care in order for it to be truly person centred [103]. Although this review focussed on South Asian ethnicity the mechanisms and recommendations made are transferrable and relevant to care delivery with other population groups.

In a similar way the relevance of this review in policy terms should be seen in the context of other influences on health inequalities, that is, the psychological, sociological, economic, and life course factors [104, 105]. Although we investigated inequalities and access to diabetes care in relation to ethnicity, the mechanisms identified are ways through which the diabetes care system can work with the individuals and the intersectionalities that influence diabetes risk, prevention, and management.

## 5. Conclusion

This review has found that there are very few studies which address care of older people with diabetes who have a South Asian background. As policy makers need evidence to help them respond to the changing demographic profile of the UK to commission effective services to prevent avoidable mortality and morbidity and maximise resources, this is an important limitation in the existing evidence base.

There is commissioning guidance for diabetes services and integrated care which by default covers care for chronic conditions and older people and points to earlier onset, need for services to consider ethnicity [106], but it seems that there has been limited organisational engagement, it has been low priority, and there are limited skills [107].

South Asian people experience diabetes earlier than White Europeans and have a greater risk of complications and faster progression so that care providers and patients would benefit from a better informed and targeted approach to intervention.

For policy, practice and research to make an impact on reducing inequalities in diabetes care for older people with diverse backgrounds we suggest attention is given to all three of the mid-level mechanisms: access, comorbidities, and stratification and cultural competency.

Research that specifically includes older people with a South Asian background would go some way to providing knowledge about the best way to do this.

The definition of “older” people needs to be redefined in the context of diabetes care and South Asian ethnicity and the influence of intersectionalities require more attention to understand and apply these mechanisms for reducing inequalities in diabetes care.

## Competing Interests

The authors have no interests to declare.

## Authors' Contributions

All authors contributed to design, conduct, drafting, and final approval of review paper.

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## Research Article

# The Relationship between Health Literacy and Health Behaviour in People with Diabetes: A Danish Population-Based Study

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**Background.** People with diabetes who have poor health behaviours are at greater risk for a range of adverse health outcomes. We aimed to investigate the relationship between health literacy and health behaviour (smoking, alcohol, physical activity, and diet) in people with diabetes. **Methods.** The study was based on respondents aged 25 years or older from a population-based survey in 2013 who reported having diabetes ( $n = 1685$ ). Two dimensions from the Health Literacy Questionnaire were used: “understand health information” and “actively engage with healthcare providers.” We used logistic regression to examine the association between health literacy and health behaviour. **Results.** After adjustment for sociodemographic factors, individuals with diabetes who found it difficult to understand information about health had higher odds of being physically inactive (OR: 3.43, 95% CI: 2.14–5.51) and having unhealthy dietary habits (OR: 3.01, 95% CI: 1.63–5.58). Similar results were observed for individuals who found it difficult to actively engage with healthcare providers. No associations were found between the two dimensions of health literacy and smoking and alcohol consumption. **Conclusion.** When developing health services and interventions to improve health behaviour among people with diabetes, our results suggest that they may benefit by including focus on health literacy.

## 1. Background

People with diabetes are at risk for a range of adverse health outcomes, including heart attacks, strokes, amputations, blindness, and end-stage renal disease [1]. Many of these adverse health outcomes can be prevented or delayed if people with diabetes maintain a healthy lifestyle in relation to diet, physical activity, alcohol, and smoking [2, 3]. Thus, it is important for health services and healthcare providers to develop strategies and interventions to help people with diabetes to improve and maintain their health behaviour.

Health literacy is defined as the cognitive and social skills that determine a person's motivation and ability to gain access to, understand, and use information in ways that promote and maintain good health [4]. Health literacy brings together

many concepts that relate to what people need in order to make effective decisions about health for themselves and their families. A recent Danish population-based study has shown that, even after adjusting for sociodemographic factors and comorbidities, people with diabetes find it more difficult to understand health information than the general population [5].

Diabetes is a chronic disease characterized by a high level of complexity that requires extensive self-care management including translation of guidelines into everyday life [6]. The demands for people with diabetes are complicated because self-care of a chronic disease often relies on information in printed educational materials, verbal instructions, and patient education courses [7]. People with low levels of health literacy may struggle to find and follow these instructions,



when they are to be integrated in everyday life. Furthermore, low levels of health literacy are associated with poor glycaemic control in diabetes patients [8], as well as with a number of diabetic complications [9]. Therefore, having adequate health literacy is critical for diabetes patients for managing their condition and navigating the healthcare environment.

Some studies have shown that inadequate health literacy is associated with unhealthy behaviours such as smoking, physical inactivity, and poor diet in the general population [10–14], while one study [15] shows that health literacy is not independently associated with some health behaviours. Few studies have investigated the relationship between health literacy and health behaviour such as smoking, alcohol consumption, physical activity, and diet in people with diabetes [16–20]. These studies showed no association between health literacy and these health behaviours. However, these studies were all conducted in small clinical settings and only measured health literacy in terms of cognitive and functional skills such as reading ability. To the best of our knowledge, no studies have investigated the association between health literacy and health behaviour in people with diabetes using a more comprehensive measure of health literacy including social and communication skills.

Using data from a large population-based survey, we aimed to investigate the association between health literacy and health behaviour (smoking, alcohol consumption, physical activity, and diet) in people with diabetes.

## 2. Methods

**2.1. Study Design and Data Collection.** The study is based on data from respondents aged 25 years or older from the 2013 Danish health and morbidity survey called “How Are You?” Geographically, Denmark is divided into five administrative regions and this study comprises data from one of these regions, the Central Denmark Region, where approximately 22% of the Danish population lives. Regarding sociodemographic and health related factors, the population of the Central Denmark Region is similar to the whole Danish population [21].

The survey consisted of a random sample of 46,354 people who were drawn from the Danish Civil Registration System. People were invited to complete a postal or a web-based questionnaire. Three reminders were issued. Data were collected by the Central Denmark Region between February and April 2013. In total, 29,473 people (63.6%) completed and returned the questionnaire. The questionnaire included an item on diabetes status; 1,685 individuals (5.7%) reported having diabetes.

### 2.2. Measures

**2.2.1. Health Literacy.** The Health Literacy Questionnaire (HLQ) is a widely used measure of health literacy that has been translated into many European and Asian languages [22]. The HLQ consists of nine dimensions and was developed using a validity-driven approach including in-depth grounded consultations, psychometric analyses, and cognitive interviews [22]. The translation and cultural adaptation of

the questions from English into Danish followed a rigorous forward-backward translation procedure and cognitive testing to ensure cross-cultural validity [23].

In the health and morbidity survey, two of the nine HLQ dimensions were included: “understand health information well enough to know what to do” to measure the functional dimension and “actively engage with healthcare providers” to measure the communicative dimension. Given that population surveys have limited space for survey questions, only these two scales were selected from the HLQ. The two scales cover two distinct elements of health literacy which we hypothesized would provide valuable insight into the health literacy challenges of individuals with chronic diseases. Each scale comprised five items where participants indicated their response on a four-point scale: 1 = very difficult, 2 = difficult, 3 = easy, and 4 = very easy. Scale scores were calculated as the mean of the five-item scores and then standardized to range between 1 (lowest ability) and 4 (highest ability) to ensure consistency with the response options. If responses to more than two items on a scale were missing for an individual, the scale score for that individual was regarded as missing. As a result of this, 137 observations (7.5%) were excluded from the “understand health information” scale and 131 observations (7.2%) from the “actively engage with healthcare providers” scale. Cronbach’s alpha coefficients indicated that the internal consistency of both scales was high: “understand health information”  $\alpha = 0.86$  and “actively engage with healthcare providers”  $\alpha = 0.90$ . The scales correlated positively with one another (Pearson’s coefficient = 0.78). We dichotomised the scale to identify individuals who found it very difficult or difficult (score  $\leq 2$ ) to understand health information or to actively engage with healthcare providers.

**2.2.2. Health Behaviour.** Four measures of health behaviour (smoking, alcohol consumption, physical inactivity, and unhealthy diet) were used. Respondents who indicated that they smoked on a daily basis were classified as smokers. Respondents were asked how many alcoholic drinks per week they normally drink. High-risk alcohol consumption was categorized in accordance with the Danish Health Authority’s recommendations, that is, more than 21 drinks weekly for men and 14 drinks for women. Respondents were classified as physically inactive if, during a typical week, they were not physically active at least one day for a minimum of 30 minutes. Dietary habits were assessed using the validated Diet Quality Score [24], which classifies diet quality in relation to cardiovascular risk. The scale consists of 25 items including questions about type of bread spread, fats used for cooking, and how often the participants consumed selected food items (including fish, meat, fruits, and vegetables). The diet score was calculated and categorized into two groups: unhealthy diet and very healthy/reasonably healthy diet. Unhealthy diet was defined as having low intake of fruit, vegetables, and fish and a high amount of saturated fat [24].

**2.2.3. Demographic and Socioeconomic Factors.** Data on age, gender, ethnic background, and marital status were collected from national registers to achieve complete data. Respondents were defined as Danish if they had Danish citizenship

or if at least one of their parents was a Danish citizen. Marital status refers to whether an individual is married or not. Information about educational attainment was derived from survey data. The participants were asked about their highest level of completed school education and any further higher-level education. We categorized educational attainment as low (1–10 years), medium (11–14 years), and high ( $\geq 15$  years).

**2.3. Ethics.** The study was approved by the Danish Data Protection Agency and was conducted in accordance with the Helsinki Declaration. Information about the survey was provided to potential participants in writing and via the web. The participants' voluntary completion and return of the survey questionnaires constituted implied consent.

**2.4. Statistical Analysis.** The unique personal identification number given to all Danish citizens was used to link both respondents and nonrespondents to Danish national registers. A weight was constructed using a model-based calibration approach based on register information from Statistics Denmark. The weight accounted for differences in selection probabilities and response rates between subgroups. Data was weighted to represent the population of the Central Denmark Region and was used in all the data analyses.

To examine the association between health literacy and health behaviour in people with diabetes, eight logistic regression models were conducted, one for each health literacy dimension with the four different health behaviour measures (daily smoking, high-risk alcohol consumption, physical inactivity, and unhealthy diet) as dependent variables. In each logistic regression model, the odds ratios were further adjusted for gender, age, ethnic background, educational attainment, and marital status.

Significance was set at  $p < 0.05$ . Statistical analyses were performed using STATA 13.

### 3. Results

Table 1 describes participant characteristics in relation to sociodemographic factors, the two health literacy dimensions, and health behaviour. Of the 1,685 individuals with diabetes, 34.1% had a low level of education. The majority of the participants were of Danish origin. In total, 9.3% of the participants found it difficult or very difficult to understand health information, and 9.3% found it difficult or very difficult to actively engage with healthcare providers. 11.8% of our sample had difficulties on at least one of the two scales (data not shown). The health behaviour characteristics of the participants show that 21.1% were daily smokers, 6.5% had high-risk alcohol consumption, 30.7% were physically inactive, and 12.3% had unhealthy dietary habits.

Nonresponse in the ten health literacy items was low and evenly distributed (between 5.3% and 8.2%) (Table 2), suggesting that the items were understood and had acceptable content. For all items, all response options were endorsed by some respondents although there were fewer in the extreme "very difficult" category and many in the "easy" category (Table 2).

TABLE 1: Characteristics of participants with diabetes from the "How Are You?" survey, Central Denmark Region (2013) ( $N = 1,685$ ).

	<i>N</i>	%
<i>Sociodemographic factors</i>		
Gender		
Male	954	54.9
Female	731	45.1
Age (years)		
25–44	115	9.5
45–64	652	39.5
65–84	866	47.1
85+	52	4.0
Educational attainment		
Low	529	34.1
Medium	790	48.9
High	282	17.1
Ethnic background		
Danish	1633	95.0
Non-Danish	52	5.0
Marital status		
Living alone	479	38.4
Married/cohabiting	1170	61.6
<i>Health literacy dimensions</i>		
Understand health information		
Difficult/very difficult	121	9.3
Easy/very easy	1446	90.7
Mean scale score (2.92, SD 0.61)		
Actively engage with healthcare providers		
Difficult/very difficult	133	9.3
Easy/very easy	1438	90.7
Mean scale score (3.00, SD 0.62)		
<i>Health behaviours</i>		
Daily smoker		
No	1319	78.9
Yes	330	21.1
High-risk alcohol consumption <sup>1</sup>		
No	1427	93.5
Yes	102	6.5
Physically inactive <sup>2</sup>		
No	1172	69.3
Yes	457	30.7
Unhealthy dietary habits <sup>3</sup>		
No	1390	87.7
Yes	168	12.3

<sup>1</sup>  $\geq 21$  drinks/week for men and  $\geq 14$  drinks/week for women.

<sup>2</sup> Max. 30 minutes of physical activity one day during a typical week.

<sup>3</sup> Low intake of fruit, vegetables, and fish, and a high amount of saturated fat.

Table 3 describes the association between health literacy and health behaviour in people with diabetes. After adjusting for gender, age, ethnic background, educational affiliation, and cohabitation status, people who found it difficult to understand information about health had higher odds of

TABLE 2: Response distribution and missing values for each item of the two health literacy scales.

	Very easy (%)	Easy (%)	Difficult (%)	Very difficult (%)	Item missing (%)
<i>Understanding health information well enough to know what to do</i>					
Confidently fill in medical forms in the correct way	19.9	50.6	16.3	5.8	7.4
Accurately follow the instructions from healthcare providers	17.0	51.8	20.2	2.9	8.2
Read and understand written health information	19.1	53.6	15.6	4.7	6.8
Read and understand all the information on medication labels	16.9	49.7	20.2	6.9	6.3
Understand what healthcare providers are asking you to do	19.8	59.8	11.0	2.5	7.0
<i>Ability to actively engage with healthcare providers</i>					
Make sure that healthcare providers understand your problems properly	20.2	49.1	19.5	3.4	7.9
Feel able to discuss your health concerns with a healthcare provider	23.3	53.8	14.6	2.0	6.4
Have good discussions about your health with doctors	25.0	53.6	13.5	2.5	5.3
Discuss things with healthcare providers until you understand all you need to	19.6	51.8	17.1	3.7	7.8
Ask healthcare providers questions to get the health information you need	20.5	54.0	14.9	3.4	7.6

being physically inactive (OR: 3.43, 95% CI: 2.14–5.51) and having unhealthy dietary habits (OR: 3.01, 95% CI: 1.63–5.58). Similarly, people who found it difficult to actively engage with healthcare providers had higher odds of being physically inactive (OR: 2.72, 95% CI: 1.76–4.20) and having unhealthy dietary habits (OR: 2.73, 95% CI: 1.51–4.94). No significant results were found for the association between the two dimensions of health literacy and cigarette smoking and alcohol consumption.

#### 4. Discussion

Results from this large population-based survey suggest that 9% of the participants found it difficult or very difficult to understand health information, and 9% found it difficult or very difficult to actively engage with healthcare providers. Respondents who found it difficult to understand information about health had higher odds of being physically inactive and having unhealthy dietary habits. Similar results were seen for people who found it difficult to actively engage with healthcare providers.

For diabetes patients with low health literacy levels, it may be difficult to navigate the large number of recommendations on diet and physical activity behaviour. These are complex behaviours that everyone uses on a daily basis and are subject to a number of individual and societal pressures that may be difficult to change. On the contrary, recommendations about smoking and alcohol consumption are generally more straightforward and have been promoted for several decades now. For example, the Danish Health Authority has run several antismoking campaigns and Denmark has continually undergone legislative changes with regard to smoking during the last decade, for example, tax on cigarettes and smoking bans at restaurants and public areas [25]. This attention to smoking may have led to high awareness about the risk of smoking in the Danish population and also among people with diabetes, and therefore information on smoking risk might be easier to understand, regardless of health literacy level compared with other health behaviours.

In contrast with our results, most research in individuals with diabetes does not support an association between health literacy and health behaviour such as physical activity and dietary habits [16–20]. However, research on health literacy in people with diabetes has focused on a one-dimensional concept of health literacy, that is, verbal ability. Furthermore, research has been conducted in clinical settings making it difficult directly to compare our results with other studies. For example, Bains and Egede showed no association between health literacy and physical activity and diet [16]. However, their study only included 125 adults recruited from a primary care clinic in the United States. Additionally, they assessed health literacy by asking patients to pronounce medical words, thus having a more narrow measure of health literacy than in our study. Kim et al. also found no association between health literacy and health behaviour, but they too had a small clinical sample consisting of 92 patients and the researchers only measured reading abilities [17]. In another study, smoking, physical activity, and diet were not significantly associated with health literacy [18]. These results on smoking are similar to our study. However, only 50 African Americans participated in the study, and health literacy was measured in terms of pronunciation and reading ability.

**4.1. Implications.** People with diabetes often have an ongoing interaction with the healthcare system and meet many healthcare practitioners throughout the life course. The challenges of adhering to public health recommendations concerning diet and physical activity are well known, particularly among patients with long-term conditions such as diabetes. Patients with long-term conditions such as diabetes need support to develop and maintain their health literacy skills. Our study suggests that it is difficult for patients with diabetes and low health literacy levels to adhere to recommended treatment guidelines. Adequate health literacy is crucial for patients to make optimal choices for their health. Healthcare providers therefore need to be aware of health literacy oriented strategies to support patients in making such choices. One strategy is to educate healthcare providers to communicate

TABLE 3: Association between health literacy dimensions and health behaviour among individuals with diabetes from the “How Are You?” survey, Central Denmark Region (2013) (N = 1,685).

	Daily smoking		High-risk alcohol consumption		Physically inactive		Unhealthy dietary habits	
	Unadjusted OR (95% CI)	Adjusted OR <sup>a</sup> (95% CI)	Unadjusted OR (95% CI)	Adjusted OR <sup>a</sup> (95% CI)	Unadjusted OR (95% CI)	Adjusted OR <sup>a</sup> (95% CI)	Unadjusted OR (95% CI)	Adjusted OR <sup>a</sup> (95% CI)
<i>Understand health information</i>								
Difficult/very difficult	0.94 (0.55–1.60)	0.87 (0.47–1.59)	1.56 (0.76–3.19)	2.09 (0.90–4.81)	4.50* (2.85–7.11)	3.43* (2.14–5.51)	3.11* (1.79–5.40)	3.01* (1.63–5.58)
Easy/very easy	1	1	1	1	1	1	1	1
<i>Actively engage with healthcare providers</i>								
Difficult/very difficult	1.07 (0.64–1.80)	1.03 (0.59–1.79)	1.18 (0.54–2.58)	1.45 (0.63–3.34)	2.83* (1.85–4.34)	2.72* (1.76–4.20)	2.59* (1.48–4.52)	2.73* (1.51–4.94)
Easy/very easy	1	1	1	1	1	1	1	1

<sup>a</sup>OR adjusted for gender, age, ethnic background, educational attainment, and marital status.

\* p < 0.05.

CI: confidence interval.



health information so that it is tailored to develop patients' understanding of their health condition and how to manage it. Exploring health literacy levels in more detail among individuals with diabetes with newly developed and validated tools is also a promising avenue of research [26].

**4.2. Strengths and Limitations.** We used data from a large population-based survey with a high response rate. As the survey was not focussed on individuals with diabetes, this may have lowered the risk of social desirability bias when responding to questions on health behaviour and health literacy level. An advantage of using a population-based sample for this study was that we included diabetes patients in the long maintenance phase of living with the disease. Many clinical studies only include individuals at the time of diagnosis or when adverse health outcomes cause them to use the healthcare services. The self-reported prevalence of diabetes was 5.7% in our study sample. This agrees well with data from the Danish National Diabetes Register [27], which shows that 6% of the Danish population above the age of 16 has diabetes. Another strength of this study was that we had the opportunity to control for a wide range of sociodemographic factors. Furthermore, to date, most health literacy research has focused on reading ability and numeracy based on data collected through direct testing procedures [28–30]. We used two different self-reported dimensions of health literacy that capture a dynamic state depending on how the individual person perceives his or her current situation.

Our findings are based on cross-sectional data, and therefore no conclusions about the temporality or causation can be made. Also, we were unable to differentiate between individuals with type 1 and type 2 diabetes. Health literacy and health behaviours might be different in these two groups. Also, it should be noted that there may be some imprecision and bias associated with using self-report measures of behaviour. Furthermore, the ability and motivation to fill out a health survey may be viewed as a health literacy competency in itself; thus, the most vulnerable groups may have been excluded from our study. As the questionnaire was not translated into other languages, people who had limited Danish language skills may not have participated in the survey. The study is also limited by including only two of the nine defined dimensions of the HLQ. Thus, it suffers from construct underrepresentation [31]. We can therefore draw conclusions only about the two dimensions we measured and not about health literacy overall. Application of the complete tool was not possible for practical reasons in this large population survey. We dichotomised the health literacy dimensions to be able to differentiate between respondents who found it “difficult” and “easy” to understand health information. This may have reduced the power to explore potential associations. However, using the exposure variable as a continuous measure did not change the overall results.

## 5. Conclusion

Even after adjusting for sociodemographic factors, people with diabetes who find dimensions of health literacy difficult have higher odds of being physically inactive and having

unhealthy dietary habits compared to people who do not have these difficulties. Strategies for improving physical activity and diet among people with diabetes may benefit by having focus on health literacy within prevention, patient education, and other public health interventions.

## Competing Interests

The authors declare that there are no competing interests regarding the publication of this paper.

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## Research Article

# Developing a Conceptually Equivalent Type 2 Diabetes Risk Score for Indian Gujaratis in the UK

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**Aims.** To apply and assess the suitability of a model consisting of commonly used cross-cultural translation methods to achieve a conceptually equivalent Gujarati language version of the Leicester self-assessment type 2 diabetes risk score. **Methods.** Implementation of the model involved multiple stages, including pretesting of the translated risk score by conducting semistructured interviews with a purposive sample of volunteers. Interviews were conducted on an iterative basis to enable findings to inform translation revisions and to elicit volunteers' ability to self-complete and understand the risk score. **Results.** The pretest stage was an essential component involving recruitment of a diverse sample of 18 Gujarati volunteers, many of whom gave detailed suggestions for improving the instructions for the calculation of the risk score and BMI table. Volunteers found the standard and level of Gujarati accessible and helpful in understanding the concept of risk, although many of the volunteers struggled to calculate their BMI. **Conclusions.** This is the first time that a multicomponent translation model has been applied to the translation of a type 2 diabetes risk score into another language. This project provides an invaluable opportunity to share learning about the transferability of this model for translation of self-completed risk scores in other health conditions.

## 1. Introduction

The prevalence of type 2 diabetes (T2DM) and the number of people at high risk of T2DM in the UK have been rising at an increasing rate in recent decades and both are predicted to continue to rise over the next decade [1]. Up to 7 million people in the UK are currently undiagnosed with this condition [2].

Earlier identification and treatment of T2DM can reduce the risk of complications [3, 4]. National consensus guidelines [5–7] relating to the identification of people at high risk of T2DM reflect this evidence.

Guidance recommends a two-staged approach to screening [8] involving the use of a validated risk assessment tool followed by a confirmatory blood test. This can be followed by appropriate referral to evidence based structured lifestyle intervention programmes [5]. In the UK, this approach forms the basis of an innovative national diabetes prevention

programme (NHS DPP) currently being piloted, to be implemented nationally in 2016 [9].

Earlier identification of T2DM and those at high T2DM risk is particularly salient for South Asian (SA) populations as their risk of T2DM and associated mortality and morbidity is significantly higher than white Europeans [10]. Due to the increased risk in this population, NICE recommend offering screening at an earlier age of 25 rather than 40 years as for the general population. Although the benefits of NICE recommendations have been acknowledged, concerns have been raised about the capacity of the National Health Service (NHS) to implement these recommendations, particularly in communities characterised by high numbers of people from diverse ethnic groups. This has led to NICE suggesting that non-NHS organisations (faith, voluntary, and community centres) can facilitate access and support for lay people to self-assess their own risk using a validated risk score [5].

The Leicester Self-Assessment Risk Score (LSAS) [11] is an example of a validated risk score that has been developed for use in a multiethnic population for detecting undiagnosed T2DM and those at high risk. It is noninvasive and simple to calculate based on seven demographic variables. The LSAS gives an estimate of T2DM risk and provides advice on what further action should be taken (see Appendix 1 in Supplementary Material available online at <http://dx.doi.org/10.1155/2016/8107108>).

Language and health literacy levels are significant barriers to the completion of such risk scores in SA populations. These issues were emphasised during early testing of Gujarati and Punjabi forward translated versions of the LSAS. This evaluation was originally undertaken by conducting two separate focus groups with Punjabi Sikhs and Gujarati Hindus. The focus group findings demonstrated a low level of conceptual understanding about the purpose of the LSAS. Participants suggested that accuracy and readability level were low, with some parts being incomprehensible. Additionally, participants advocated that a translated version of the LSAS should be understood by people with a reading and comprehension age of  $\geq 12$  years. It was felt that those with a lower reading age would be unable to adequately comprehend and complete the task and would require assistance.

This preliminary work demonstrated the need for further translation and development of the LSAS for completion by non-English speaking individuals. In this paper, we describe how commonly used methods for cross-cultural translation of research instruments [12–14] were used to develop a model that aimed to achieve conceptual and linguistic equivalence [15] for Gujarati speakers with a reading and comprehension age of 12 and above [14]. Due to the demographics of the local population, we initially selected Gujarati as the first language to translate into; this process served as the process through which we developed the translational model.

## 2. Participants and Methods

**2.1. Methods for Translation of the English LSAS.** We received ethical approval for this project from the College Ethics Committee, University of Leicester, UK (ref. 0373), and Local Research Governance approval.

We developed a translation model (Figure 1) based on methods described in cross-cultural translation literature [12–14], including forward and backward translation, clinician review, and pretest interviews with the target population. Below, we provide a description of each stage and the issues that arose.

**2.2. Recruitment and Selection of Translators.** We recruited four experienced translators with a diploma in public service interpreting. This qualification formed part of our selection criteria to ensure a high standard of translation. Two of the translators were already known to the researchers having provided translation for other studies focusing on T2DM. The other two translators were diabetes “naïve” [14]. We assigned two of the translators to stage 3 (one with previous experience and one who was diabetes naïve) and two to stage 4 of the process (Figure 1). Before commencing translation,

all translators received project information to help them to contextualise their specific role within the overall project.

**2.3. Stage One: Revision and Refinement of the English LSAS.** The research team made revisions to the LSAS to help clarify the messages in the text using plain English (see Appendix 1). This stage produced a revised version of the English LSAS and it was the source document from which translations were undertaken.

**2.4. Stage Two: Development of Conceptual Guidance Document for Translators.** A conceptual guidance document was developed to specify the intended meaning of each section of text from the LSAS, in order to promote accuracy of translation and conceptual meaning. For example, terms such as BMI have no Gujarati language equivalent; translators were advised to use phonetic translations; they were also advised to retain the use of English words such as diabetes and stroke which are commonly used by UK Gujarati speakers.

**2.5. Stage Three: Forward Translation.** In August 2013, translators 1 and 2 received copies of the source document and conceptual guidance. Once the translations were complete, both translators attended a meeting with the project team to discuss and resolve differences. Examples of issues highlighted during this stage included the use of “everyday spoken language” that was unsuitable for a written document, technical and spelling errors. During the meeting, an agreement was reached about the forward translation using a phonetic translation of the word for “risk,” with its Gujarati equivalent, in English script, in brackets (*jokhem*). The word sugar was phonetically translated with glucose in Gujarati in brackets.

**2.6. Stage Four: Backward Translation.** The reconciled translation was sent to translators 3 and 4 for back translation without the aid of the conceptual guidance. During review by the research team, it was apparent that both translations had captured the meaning of the forward translation, but comparison with the original English highlighted important differences, particularly relating to the complexity of language used and the use of modal verbs (e.g., can and could). Some examples included the use of “age” instead of “getting older,” “consult their GP” instead of “talking to their GP,” and “you can” develop T2DM instead of “could you” have T2DM?

**2.7. Stage Five: Reconciliation of Forward and Backward Translations.** This additional stage was not in the original project plan but was included to address differences highlighted in the backward translations. It involved three meetings with all the four translators working with the project team. The meetings involved focused discussions about each paragraph of the source document and the forward and backward translations. The discussions were guided by a schedule produced by the research team that detailed differences.

**2.8. Stage Six: Clinician Review.** Two local general practitioners (GPs) who spoke and read Gujarati and used the language in consultations with patients were asked to give their consent and recruited to the study. Both GPs were asked

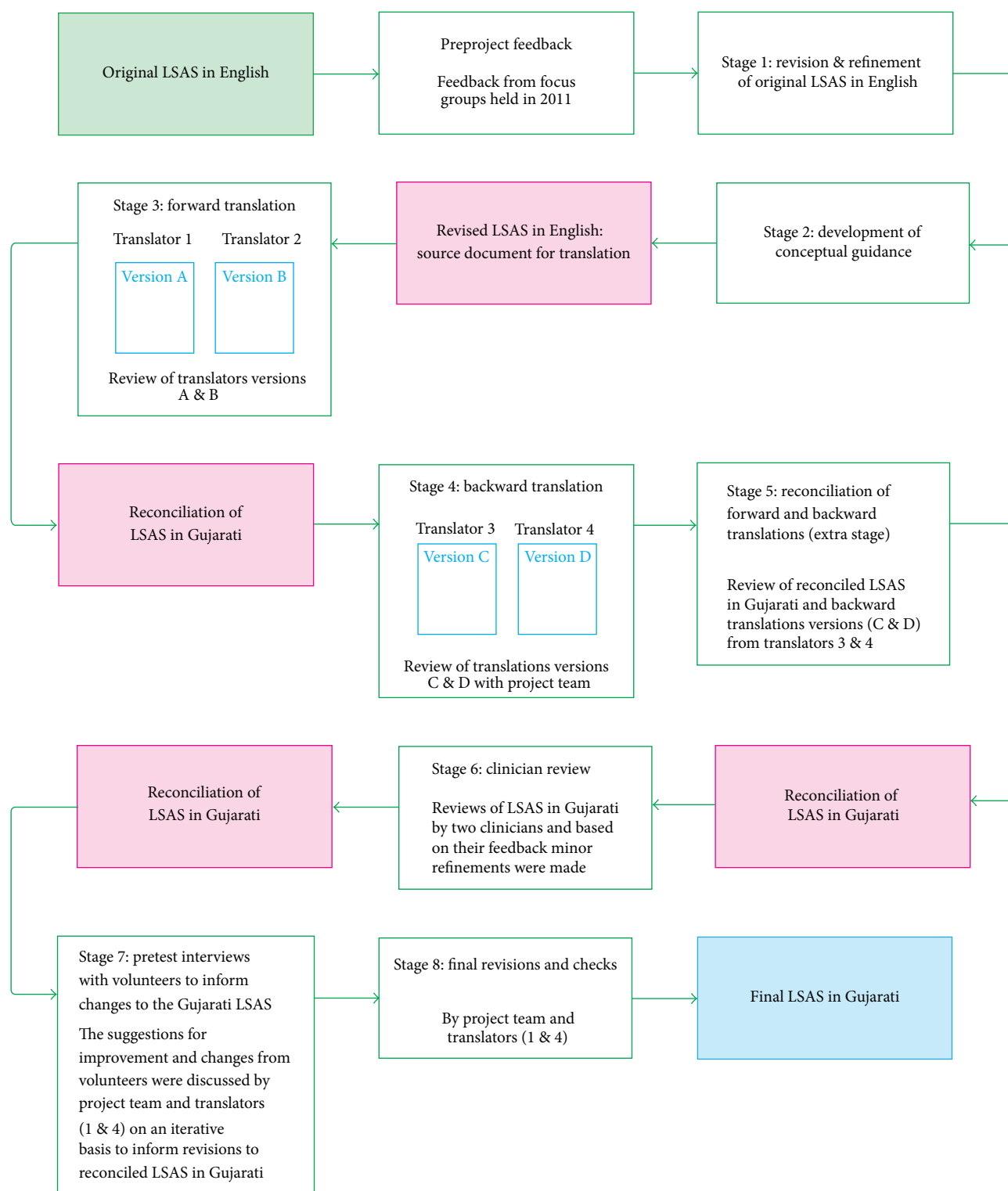


FIGURE 1

to independently complete a clinical review of the LSAS. This involved use of their knowledge to assess the clinical accuracy of the terms used, as well the appropriateness and accuracy of the content and level of the language used.

**2.9. Stage 7: Pretest Interviews with Volunteers to Inform Changes to the Gujarati LSAS.** Recruitment of Gujarati volunteers took place with the aid of an adult learning organisation. Assistance with recruitment was also given by



an Indian Muslim community volunteer who took part in the project as a participant and subsequently helped recruit four additional Indian Muslim participants. The organisation and volunteer were provided with guidance about the eligibility criteria for the project and the purposive sampling strategy, which aimed to recruit a varied group of up to 20 people whose main language was Gujarati. The sample variation was based on factors including age, gender, education level, country of birth, and length of residency in the UK.

A total of 18 Gujarati volunteers who reflected the diversity of the local population in terms of people who were born and educated in India as well as those that migrated from Africa to the UK were recruited to take part.

Before commencing interviews, the researcher (NP) gave each volunteer the participant information sheet (available in English and Gujarati) to read and gave a verbal explanation of the project. Informed consent was recorded for their permission to audio-record the interview, store anonymised interview transcripts electronically, and publish quotations from the transcripts in an anonymised form. Four volunteers arrived in pairs for the interviews; the researcher (NP) checked whether they had any concerns about confidentiality and they were happy to go ahead with taking part in the study. Both pairs completed their LSAS individually but gave feedback together.

During the interviews, participants were asked to self-complete the LSAS, with assistance from the researcher if required. After self-completion, participants were asked to share with the researcher (NP) what they understood from each section of the LSAS and to suggest improvements and changes. Finally, NP facilitated discussions with the aid of a topic guide about volunteers' perception of their risk and views about the LSAS. Qualitative data collection was undertaken on an iterative basis to ensure that volunteers' suggestions could be used to refine and revise the Gujarati LSAS and to document changes suggested for the English LSAS.

Data were collected during 18 interviews, at which point no further suggestions for revising the translation were forthcoming. Volunteers were given a £20 store voucher as a token of appreciation for their contributions.

NP transcribed the interviews, simultaneously translating those conducted wholly or partially in Gujarati. The data were organised thematically using framework charts [16] broadly reflecting topic guide themes. Detailed notes were made of volunteers' suggested changes to the text and graphics of the LSAS; these notes informed subsequent discussion between the project team and translators (one from each of the following stages: 3 and 4).

**2.10. Stage 8: Production of Final Version of the Gujarati LSAS.** In response to volunteers' suggestions from stage 7, the project and translators made some additional minor changes to the Gujarati LSAS.

**2.11. Refining the English Version of the LSAS.** Over the course of the project, minor changes to the English LSAS were also made.

### 3. Results

During the translation process, a number of challenges were encountered; examples are provided in Table 1. These challenges were linked to achieving different forms of equivalence (conceptual and linguistic), with some being linked to more than one form. Difficulties with providing satisfactory translations for the terms "risk" and "risk factors," for example, were linked to conceptual equivalence [15, 17] and also to cultural equivalence, which recognises differences in cultural understandings [15, 17]. Features of the language, including complexity and levels of abstraction [17], were considered during discussions about the education level of the language used, whilst translation and modification of the BMI table involved consideration of operational equivalence [18], related to the need to provide a format which produces equivalent translations. The latter challenge, relating to self-estimation of BMI, proved to be the most challenging to address.

Both GPs felt that the standard of the LSAS translation was very good and was pitched at the appropriate level. They suggested only minor changes, which were noted for further during volunteer interviews. Minor amendments to the Gujarati LSAS were made, but one GP's suggestion for replacement of the phonetic translation of the word "diabetes" with the Gujarati term was not followed as it was felt that this might confuse people not familiar with the term.

Key aspects of the feedback were linked to perceptions of the purpose and usefulness of the LSAS and methods of encouraging its use. This qualitative feedback was received during pretest interviews with volunteers (stage 7); supporting quotations are provided as follows:

#### *Comprehension, Impact of the Risk Score, and Family History*

*It was easy.* (Volunteer 13, male 35–60 yrs & Volunteer 14, male 35–60 yrs)

*Whether you say risk or jokem it's the same thing.* (Volunteer 10, male, aged over 60 yrs)

*I need to work on my weight. It is a surprise, it is a surprise. Because I don't think that I would be on yellow level. I thought I was on green but I am on yellow so I need to work out for myself how to reduce my weight. I need to do some exercise to get my weight but I need less weight to come to the right group. Surprise yeah. I did not think I had any risk at all as no-one has diabetes in my family. My dad is 83 and he does not have anything. So surprise.* (Volunteer 06, male, aged between 35–60 yrs)

*It's helpful and very good. More than 75%, 80% is very good. The way in which people have explained, it will be helpful to Asians. Because it's about knowing what is going on within my body and I was able to think about it and that was helpful.* (Volunteer 07, male, aged over 60 yrs)



TABLE 1: An illustration of the challenges addressed in the translation with Gujarati words.

Terms and concepts	Challenge	How addressed
Risk and risk factors	<p>A Gujarati equivalent that would convey the idea of risk in relation to diabetes was felt to be lacking;</p> <p>an appropriate Gujarati equivalent to the term risk factors was also felt to be lacking: initially, a phonetic translation of the English term was used, but some interview participants did not fully understand this</p>	<p>Initially, it was considered that a phonetic translation of the English word “risk” would be best, but many of the interview participants preferred the Gujarati word; in the final version, the initial paragraph used the phonetically spelt term “risk” with “jokhem” in brackets to help familiarise the reader; thereafter, throughout the document the Gujarati word for risk was used; an explanation of what risk factors are was provided, spelling “factors” phonetically and using the translated word for “reasons” rather than factors; this was tested on participants in the later interviews and it helped to aid comprehension</p>
Ethnicity	<p>Lack of equivalent Gujarati term to convey meaning</p>	<p>Rather than using a single word, a detailed explanation was given to aid conceptual and linguistic understanding and examples were given to aid comprehension- તમારી વંશીયતા (તમે ભલે ગમે ત્યાં જન્મ્યા હોવ પરંતુ સામાન્ય રીતે તમારા બાપ- દાદા/બુઝર્ગો જે દેશનાં મૂળ વતની હોય તે તમારી વંશીયતા ગણાય-દા.ત.ઈન્ડીયાના હોય તો ઈન્ડીયન, પાકિસ્તાનના હોય તો પાકિસ્તાની વિગેરે.)</p>
Lifestyle	<p>Difficulty of conveying the intended meaning; some of the terms suggested by a minority of the interview participants had multiple meanings or were too general and did not capture the full meaning of the word <i>lifestyle</i>, as opposed to <i>life</i></p>	<p>We retained the translators’ use of the Gujarati term for lifestyle (જીવનશૈલી) as participants understood the meaning</p>
Questionnaire	<p>Translation of the word questionnaire as <i>prashnavali</i> was perceived as being pitched at too high educational level by a minority of interview participants</p> <p>A minority of interview participants</p>	<p>A simple term used (<i>savalo ne yadi-savali ni yadi</i>)</p>
Term for diagnosis	<p>suggested that the Gujarati word (નિદાન) might be too technical, although they understood it themselves; discussion with the translators about other possible Gujarati equivalents suggested that these would give rise to ambiguity</p>	<p>It was decided to retain the original translation as this had been understood by interview participants and the translated version was aimed at people with a reading age of 12 or over</p>
Terms used for “waist size group” (in the questionnaire) and “waist measurement” (in “how to measure your waist” instructions)	<p>Some participants suggested using the Gujarati word for measurement (<i>map</i>) instead of waist size, acknowledging that it was not technically correct but commonly used and understood</p>	<p>After discussion, the word <i>map</i> (માપ) was used in the risk score and how to measure your waist instructions</p>

TABLE 1: Continued.

Terms and concepts	Challenge	How addressed
The LSA states that...the good news is being diagnosed sooner rather than later...	The majority of interview participants found use of “good news” to be inappropriate and insensitive	This was revised to “it’s good to know” (ભવિષ્ય માટે એ સારું છે કે એનું નિદાન જલ્દી થયું) because you have been diagnosed early
Thrush (as a symptom of diabetes)	A detailed explanation of this term was deemed by the project team to be too technical, overly descriptive, and potentially distressing; the Gujarati word for thrush suggested by a few participants (નળબીજ) can also mean weakness and had the potential to create misunderstanding	The word for thrush (થ્રશ) was phonetically translated in English
BMI table (the LSA includes a table for self-estimation of BMI)	The table was felt to be conceptually and practically challenging to use; the language used was not entirely the cause of the problem; providing examples did not appear to help with self-completion	This table was changed 3 times in response to feedback; what helped was simplifying the explanation and using systematic instructions similar to those used in for waist measurement; towards the end of the pretesting stage, it could be self-completed by some interview participants

*It is helpful uh just to care if it's going to happen in the future I've got to be careful from the very beginning and take the precaution.* (Volunteer 08, male, aged over 60 yrs)

*I was shocked at the results um (pause) (Interviewer explored why)...mainly for myself by working out the tables and what they made me feel that I should do something for myself so it's that personal risk yeah. ...* (Volunteer 18, female, aged between 35–60 yrs)

#### *Using the Gujarati LSA in Different Settings*

*If it was in supermarkets it would be helpful to help people know where they stand.* (Volunteer 11, male, aged over 60 yrs)

*Online is really good but the people who are risk, the age range I believe, mainly 45+ or 50+ so majority of adults at that age. I must say I don't have a ratio of how many are IT literate and you know, so online is really good but there are certain issues whether they know how to operate computer whether they will be able to do it online.* (Volunteer 02, female, aged between 35–60 yrs)

*I think those that are interested in their health, and if it's in the mandir, then people may feel it's important because it's there. If we want to improve our life or take care of our body, if there is family history.* (Volunteer 05, female, aged between 35–60 yrs)

*Just giving out a leaflet like this would not work because these days people are lazy and do not want to read. [...] but what you can do is give a lecture on this and then give this out would be more helpful than just distributing all these things.* (Volunteer 07, male aged over 60 yrs)

It was evident from volunteers' responses that completion of the LSAS had impacted on a number of different levels, including awareness of preventative action and risk factors for T2DM such as weight. For a minority of volunteers, completion of the LSAS had also challenged beliefs that they were at low risk of developing T2DM because of a lack of family history of diabetes.

The suggestion of having the LSAS available online and in supermarkets and temples was discussed with most volunteers and a variation in views was apparent; some supported this idea and others doubted whether some people who are likely to be "at risk" due to age would be computer literate. A minority felt that only health conscious people would be interested in completing the LSAS in temples and supermarkets, but greater effectiveness might be achieved by providing a talk to accompany its distribution.

## 4. Discussion

In this paper, our findings have made a useful contribution to existing research by illustrating real world challenges to self-assessment of T2DM risk by non-English literate populations in the UK. We have shown that overall the translation model (Figure 1) was effective in achieving the study aims. The majority of the volunteers stated that they found the standard of Gujarati easy to read and understand. The model that we have developed is of significant relevance to healthcare researchers and commissioners internationally who wish to develop translated risk scores or other health assessment tools to meet the needs of populations speaking different languages.

Some aspects of the model used for developing the Gujarati version of the LSAS played key roles. Firstly, the pre-project stage was not part of the formal development process but provided evidence of the need to undertake the project. In addition, this preliminary phase, involving feedback from focus groups with Gujarati and Punjabi participants, helped to inform a focused approach to the refinement of the original LSAS in English as the source document (Appendix 1). Secondly, additional stage 5 (Figure 1) was included, which shared some features associated with the committee approach [19] described in the literature. This entailed all four translators and project team working together to consider assumptions about terms, particularly those that had secondary meanings and dialectical differences. On reflection, this stage may have assisted in producing a better standard of translation and possibly reduced the time spent making changes in response to feedback from volunteers. It was noted, however, that this extra stage added to the duration and costs of the project.

Thirdly, the diversity of the translators' backgrounds and varied experience [14], knowledge of diabetes, and education (e.g., in terms of education within or outside of the UK) [19, 20] helped to produce a LSAS translation which was acceptable to a wide audience [15]. The need for such an approach was salient given the variation in the community of bilingual and monolingual readers of the target language. Additionally, aspects such as regional Indian dialects, mixing of Gujarati and English language in everyday use, "borrowing" of terms from other languages (such as East African languages) due to migration [15], and variations in educational levels further compound this variation. The sampling strategy for the pretest stage of the project enabled the project team to capture and take account of this variation in the level and standard of Gujarati used.

Lastly, eliciting responses and exploring volunteers' rational for these responses were possible through undertaking qualitative interviews for pretesting of the translated LSAS. The iterative process of making revisions and then conducting further interviews to test these changes allowed the project team to identify potential challenges to comprehension and respond rapidly and to test whether, for example, changes to the BMI table using systematic instructions were successful. This iterative approach also helped to identify the point at which no new major changes were required to the LSAS translation.

A frequently advocated approach to translation of research tools involves a process of decentring, when both the English and target language translations are developed concurrently [21]. Whilst this approach is resource intensive, its strength is the avoidance of translations situated in one culture [22]. Such an approach could be considered relevant; however, it was beyond the scope of this project as the English version of the LSAS is already widely used. Therefore, the project team were tasked with balancing the need to achieve conceptual equivalence of the English LSAS in Gujarati, without changing its construct [14]. Although revalidation of translated versions of instruments such as questionnaires is optimal, it was considered that our approach to obtaining equivalence in developing the Gujarati version of the LSAS would minimise any impact on the instrument's content validity and reliability, both of which had already been validated in the target population using the English version of the LSAS.

Outside the formal remit of the project, the Gujarati LSAS has been used at health fairs and informal feedback obtained has indicated that the language used is well understood. Completion of the LSAS and estimation of BMI were, however, still found to be challenging, suggesting the need for exploration of alternative means of calculation.

## 5. Conclusion

Our experiences have drawn attention to challenges that are likely to be encountered in adapting a document of this type, as well as highlighting the overall usefulness of the model used. It is acknowledged that the translated version of the LSAS may require additional testing in other Gujarati speaking populations in the UK. The version developed was however found to be useful in facilitating wider access to the LSAS and promoting understanding of factors beyond family history when estimating personal risk of developing T2DM. Despite positive feedback regarding the translation, some operational problems still exist. Further development is required to allow calculation of BMI. In some cases support may need to be provided by people trained to use the LSAS. Providing this type of support as part of a risk self-assessment facilitated by community, faith, and voluntary organisations could ease the burden on the NHS and enhance the impact and reach of the NHS DPP in 2016.

## Additional Points

**Novelty Statement.** (i) The paper addresses a gap in published research evidence relating to perceptions and implications of using a diabetes risk score in people from black and minority ethnic backgrounds using the Gujarati language as an exemplar. (ii) We also describe and comment on the application of a cross-cultural translation model, based on methods commonly used to undertake cross-cultural translation of research instruments, to the translation of a diabetes risk score. (iii) The work described makes a timely contribution to understanding how the burden of risk assessment can potentially be eased in the national prevention programme for type 2 diabetes in the UK in 2016.

## Disclosure

The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health or Diabetes, UK.

## Competing Interests

Professor Melanie Davies has acted as Consultant, Advisory Board Member, and Speaker for Novartis, Novo Nordisk, Sanofi-Aventis, Lilly, Merck Sharp & Dohme, Boehringer Ingelheim, and Roche. She has received grants in support of investigator initiated trials from Novartis, Novo Nordisk, Sanofi-Aventis, Lilly, Pfizer, Merck Sharp & Dohme, and GlaxoSmithKline. Professor Kamlesh Khunti has acted as a Consultant and Speaker for Novartis, Novo Nordisk, Sanofi-Aventis, Lilly, and Merck Sharp & Dohme. He has received grants in support of investigator and investigator initiated trials from Novartis, Novo Nordisk, Sanofi-Aventis, Lilly, Pfizer, Boehringer Ingelheim, and Merck Sharp & Dohme. Professor Khunti has received funds for research and honoraria for speaking at meetings and has served on Advisory Boards for Lilly, Sanofi-Aventis, Merck Sharp & Dohme, and Novo Nordisk. All other authors have no conflict of interest to declare.

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## Research Article

# Optimising Health Literacy and Access of Service Provision to Community Dwelling Older People with Diabetes Receiving Home Nursing Support

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**Background.** Health literacy is the ability to access, understand, and use information and services for good health. Among people with chronic conditions, health literacy requirements for effective self-management are high. The Optimising Health Literacy and Access (Ophelia) study engaged diverse organisations in the codesign of interventions involving the Health Literacy Questionnaire (HLQ) needs assessment, followed by development and evaluation of interventions addressing identified needs. This study reports the process and outcomes of one of the nine organisations, the Royal District Nursing Service (RDNS). **Methods.** Participants were home nursing clients with diabetes. The intervention included tailored diabetes self-management education according to preferred learning style, a standardised diabetes education tool, resources, and teach-back method. **Results.** Needs analysis of 113 quota-sampled clients showed difficulties managing health and finding and appraising health information. The service-wide diabetes education intervention was applied to 24 clients. The intervention was well received by clients and nurses. Positive impacts on clients' diabetes knowledge and behaviour were seen and nurses reported clear benefits to their practice. **Conclusion.** A structured method that supports healthcare services to codesign interventions that respond to the health literacy needs of their clients can lead to evidence-informed, sustainable practice changes that support clients to better understand effective diabetes self-management.

## 1. Introduction

Health literacy has been described as “the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health” [1]. Health literacy goes beyond the individual, however, as the skills, preferences, and expectations of healthcare providers (doctors, nurses, and home health workers) also play a critical role in creating environments that enable people with low

health literacy to get access and to use services equitably [2]. It is therefore essential that health professionals and healthcare services are active in identifying and responding to the needs of their clients. This is particularly relevant for people with chronic conditions such as diabetes in whom the health literacy requirements for effective self-management are high [3]. Given the increasing prevalence of diabetes and other chronic conditions in the community [4, 5], new approaches that focus on health literacy as an integrated component of care are important to consider. One such approach is the

Optimising Health Literacy and Access (Ophelia) process, a structured method that supports healthcare services and providers to codesign interventions that respond to the health literacy needs of their clients [6]. An underlying principle of the Ophelia approach is that interventions are locally relevant. This is important because health literacy is context-specific [7], and interventions that are developed in one population or setting may not be relevant in other settings. Approaches such as Ophelia can be used on a small scale to codesign interventions that are appropriate for and specific to the needs of particular client groups or communities.

The Ophelia process was developed and tested in a proof-of-concept study across nine diverse healthcare services in Victoria, Australia (hereafter referred to as Ophelia Victoria) [6, 8]. This paper describes the process as undertaken in one healthcare service, RDNS, a large home nursing service provider delivering care across metropolitan Melbourne [8]. On commencement of the project, each participating healthcare service was asked to identify a priority group in whom health literacy was thought to be a contributing factor to incomplete access to services or poorer health outcomes. The home nursing service identified that many clients with diabetes struggled with independent self-management of their condition and that education of these clients was not consistent throughout the service.

The overall aim of the project was therefore to improve the service's approach to diabetes education so that clients were better supported to self-manage their condition. In line with the Ophelia process, the subaims were to (i) conduct an assessment of health literacy among clients with diabetes, (ii) develop an intervention to address any identified needs, and (iii) evaluate the outcome of the intervention. This paper reports on the Ophelia process as undertaken within the service, including clients' health literacy-related outcomes and the perceptions of staff about barriers to delivery of the intervention and any impact upon their clinical practice or client outcomes.

## 2. Methods

**2.1. Study Design.** A three-phase codesign study was used to achieve the aims of the study. Phase one, a needs assessment, involved undertaking a health literacy survey in a cohort of community-based clients with diabetes who were receiving home nursing services [8]. Clinicians from the service then generated a range of potential intervention ideas in response to the issues identified by the survey. Phase two of the study involved selection of a set of intervention ideas considered to be most likely to achieve the study aim, then combining these ideas to form one overall intervention which was further refined through small quality improvement cycles. In Phase three, the selected intervention was implemented and evaluated more broadly within the service, measured by client outcomes and staff experiences.

**2.2. Setting.** Seven RDNS sites across the Melbourne metropolitan area participated in a health literacy survey of their clients and implementation of the intervention. Health literacy data were collected for the period July 2013 to

December 2014 and the intervention was implemented and evaluated between September 2014 and February 2015.

### 2.2.1. Phase One: Needs Assessment

**Participants for Phase One.** All home nursing clients with diabetes, from the seven study sites, were considered suitable for participation on the basis of belonging to the priority group identified at study commencement. Inclusion criteria were being aged 18 years or over, cognitively able to participate, and able to provide informed consent. Participants and data collection are described in detail elsewhere [8].

**Data Collection for Phase One.** Eligible clients were approached by their attending generalist nurse to undertake the survey. To maximise the participation rate of people with low health literacy, consenting clients were invited to either complete the Health Literacy Questionnaire (HLQ) by themselves or to have assistance from family members, carers, or nursing staff. The HLQ is a widely used and well-validated 44-item measure that captures the concept of health literacy across nine distinct domains [8]. The nine scales of the HLQ can be used as a needs diagnostic tool and an outcomes measure. Importantly, the scales allow for the development of health literacy "profiles" describing an individual's health literacy needs and strengths [9]. The nine HLQ scales are (1) feeling understood and supported by healthcare providers; (2) having sufficient information to manage my health; (3) actively managing my health; (4) social support for health; (5) appraisal of health information; (6) ability to actively engage with healthcare providers; (7) navigating the healthcare system; (8) ability to find good health information; and (9) understanding health information enough to know what to do. In combination, these scales provide a profile of a person's health literacy strengths and limitations. Data were also collected on demographic and health status [8].

**Data Analysis for Phase One.** As described elsewhere [6], cluster analysis of the HLQ alongside demographic data was then undertaken using SPSS [10]. This statistical technique allows identification of groups of clients placed into clusters on the basis of having similar health literacy profiles across the nine HLQ dimensions. The pattern of health literacy scores within each cluster then informs the development of short narratives (vignettes). These vignettes describe an archetypal individual with a specific health literacy profile of strengths and weaknesses. Each vignette details how that person's health literacy profile might impact upon their ability to manage their health and interact with the services around them. Demographic data were analysed using STATA [11].

**2.2.2. Phase Two: Cocreation of the Intervention.** In a workshop setting, highly experienced Clinical Diabetes Educators and a Senior Research Fellow from the home nursing service discussed the clinical vignettes and developed potential intervention ideas in response to the health literacy needs identified within. Following the workshop, a set of these intervention ideas was selected as being likely to meet the

aims of the study. Program Logic models [12] were developed to describe how the intervention ideas could lead to the desired outcome, with selection of the final set of interventions based on further consensus meetings, including a cross-site meeting with the other eight organisations participating in the Ophelia study from across Victoria [6] in which project teams shared their intervention ideas and provided peer feedback to each other. Following this cross-site meeting, a single site from the home nursing service undertook pilot testing and refinement of their intervention processes and materials using Plan, Do, Study, Act (PDSA) cycles.

*2.2.3. Phase Three: Implementation and Evaluation.* From Phase two, the final selected intervention set included three components (described in more detail in the results section):

- (1) Use of guidelines and checklist for education of clients with diabetes.
- (2) The services' generalist nurses trained in using the teach-back method of patient education.
- (3) Development of an online library of resource material for generalist nurses to use when providing education to clients with diabetes.

Phase three involved broader dissemination of the intervention within seven sites of the home nursing service as follows.

#### *Participants for Phase Three*

*Clients.* Over a five-month period, across the seven home nursing sites from Phase one (including from the site used for pilot testing), convenience sampling was used to identify all eligible clients with diabetes who required education for self-management of their diabetes. Exclusion criteria included being cognitively impaired and having difficulty understanding and retaining information (likely to be the clients who were not routinely provided with detailed education but where others manage most of the care for the client). Clients not speaking or reading English were also excluded. Of note, the intervention was delivered as "usual care" by participating nurses to all clients receiving diabetes education. Only those clients who consented to be involved in evaluation were included as study participants for this phase.

*Nurses.* All generalist nurses at the seven participating sites were invited to a training session and introduced to the use of teach-back and the diabetes education guidelines and checklist. These sessions were facilitated by the Clinical Diabetes Educators who had been involved in the study from the start.

*Data Collection for Phase Three.* Data collection activities were undertaken by generalist nurses from the seven home nursing sites, with this phase of the project managed by the Clinical Diabetes Educators. Generalist nurses who had attended the training sessions were asked to invite eligible clients to participate in evaluation of the intervention. As noted above, clients who did not wish to participate were still provided with education about their diabetes using all

components of the intervention but did not complete the pre- and postevaluation measures. Clients who agreed to participate were invited by the nurse to provide written consent. The generalist nurse then administered baseline questionnaires. Educational activities were undertaken as outlined above, according to each individual client's educational needs. Each client's involvement with the intervention varied from between one to three months depending on their educational requirements and length of episode of care with the service. Participating clients were then asked to complete the posteducation assessments. Data were collected before and after intervention using three scales of the HLQ [13] and the Diabetes Knowledge Questionnaire (DKQ) [14]. The DKQ is a 12-item multiple choice questionnaire that aims to measure knowledge change following a diabetes education intervention. There are two additional questions for people taking diabetes medication, and one for people with Type I diabetes. The questionnaire also asks for medication type and frequency, plus whether people have seen a diabetes educator or dietitian. The DKQ has been validated in Australian clinical settings [14].

All participating nurses were invited to take part in a postintervention semistructured interview to identify barriers to delivery of the intervention and any impact or changes in their clinical practice.

*Outcome Measures for Phase Three.* Outcome measures included changes to clients' knowledge about diabetes and changes in their ability to understand and use information about their diabetes. Evaluation consisted of completion of the DKQ and three scales of the HLQ prior to the intervention and completion of these same two questionnaires during an interview 8 weeks after the intervention. The three selected HLQ scales were as follows: (2) having sufficient information to manage my health; (5) appraisal of health information; and (9) understand health information enough to know what to do. Scale (5) was chosen as the comparison scale under the assumption that this aspect of health literacy was unlikely to be impacted upon by the intervention. We postulated that if there were no changes in the comparison scale, then this would suggest that any changes in the remaining two scales were more likely to be due to the intervention than not. The selection of scales (2) and (9) was based upon the program logic model, in which we identified that the intervention could be expected to impact on clients feeling they have sufficient information to manage their health and their ability to understand health information well enough to know what to do. A third scale identified by the program logic model, feeling understood and supported by healthcare providers, was not included to minimise respondent burden given that the Diabetes Knowledge Questionnaire and a comparison HLQ scale was also administered.

*Statistical Analysis for Phase Three.* Pre- and postintervention HLQ scale scores were analysed using effect sizes to estimate the change in scores. Interpretation of effect size was "small" >0.20–0.50, "medium" approximately 0.50–0.80, and "large" >0.80 [15]. DKQ scores were standardised to a possible score of 100 (as possible scores varied according to whether people

were taking medication or whether they had Type I or Type 2 diabetes). DKQ were not normally distributed and are presented as medians and interquartile ranges (IQR). Data were analysed using STATA [11].

*Qualitative Analysis for Phase Three.* Interviews with nursing staff aimed to identify barriers to delivery of the intervention and any impact or changes in their clinical practice or for their clients. These data were analysed using NVivo Qualitative Software [16]. All transcripts were imported into NVivo in the initial stage. Themes were created deductively, guided by the stages of analysis as outlined by Colaizzi [17]. Any statement which was considered useful to the analysis was highlighted and coded as a node within NVivo. All transcripts were read in this manner, and the extracted significant statements were reread to gauge the embedded meanings. Thereafter a number of “mother” nodes reflecting these meanings were created, and related statements were grouped together and collapsed under the related mother node. A process of continual checking and rechecking between the transcripts and the nodes was undertaken to ensure the statements were being coded in the context they were spoken. The remaining transcripts were analysed and coded using the same process. NVivo’s hierarchical tree structure for coding allowed the nodes to be classified, reclassified, and organised into main (mother) nodes and subnodes as required during this process.

**2.3. Ethics.** The study was approved by the Human Research Ethics Committees of the Royal District Nursing Service (project 138) and Deakin University (project 2012-295). Informed consent was obtained from all participants.

### 3. Results

**3.1. Phase One: Health Literacy Assessment.** One hundred and thirteen clients were recruited into the first phase of the study. The majority were female with a mean age of 75 years of age. The most commonly reported comorbidities were heart disease and arthritis (see Table 1).

Mean HLQ scores are shown in Table 2. Overall scores demonstrated that clients experienced difficulties in Scale (3), actively managing my health (mean 2.99, SD 0.42), and Scale (8), ability to find good health information (mean 3.55, SD 0.77). Many clients also reported difficulty with Scale (5), appraisal of health information (mean 2.78, SD 0.42). Higher HLQ scores were seen for Scale (1), feeling understood and supported by healthcare providers and Scale (6), ability to actively engage with healthcare providers (mean 3.23, SD 0.44 and 3.99 SD 0.57, resp.).

Cluster analysis produced thirteen clusters, each displaying a distinct pattern of responses to the HLQ. Cluster profiles ranged from lower to higher health literacy, and summary descriptors for each were developed, such as that who *has quite high health literacy but may be overwhelmed with information from too many sources; can understand health information when it is provided but is not active in health and feels unsupported by healthcare providers and others; and trusts healthcare providers but is not proactive or engaged with their own health.*

TABLE 1: Demographic and health profile of participants who completed initial health literacy needs assessment ( $n = 113$ ).

Variable name	$n$ (%)
Age (mean, standard deviation)	75 $\pm$ 10.0
Female	61 (55%)
Lives alone	58 (53.2%)
Australian born	73 (65.2%)
Main language	103 (92.0%)
Part secondary education or less	78 (69.7%)
Private health insurance	37 (33.9%)
Healthcare card	99 (88.4%)
Assisted with questionnaire	73 (65.7%)
Arthritis	55 (49.6%)
Back pain	41 (36.6%)
Heart problems	60 (53.6%)
Respiratory	16 (14.3%)
Cancer	15 (13.4%)
Depression and/or anxiety	35 (31.3%)
Diabetes	107 (95.5%)
Stroke	17 (15.2%)
Other conditions	34 (30.1%)
Reported no health condition	1 (0.3%)

The workshop to develop potential intervention ideas was attended by six staff from the service including five Clinical Diabetes Educators and one Senior Research Fellow. During the workshop, a raft of factors that clinicians regarded as contributing to clients having such health literacy profiles were reported. Among the key issues identified were inconsistencies in the way diabetes education was delivered across the service, and the amount of information many clients accumulate (but do not necessarily engage with) from a range of sources. In total, 35 potential client-level and organisation-level responses to these needs were generated during the workshop, including educational focused strategies such as *not inundating patients with information; ensuring that education is provided in different ways; providing contextualised information; using teach-back to deliver information in small steps; and formal diabetes education for everyone.*

**3.2. Phase Two: Codesign of the Intervention.** The intervention ideas from the workshop were organised by the Clinical Diabetes Educators into a set of interventions suitable for use by generalist nurses that could be used to improve the quality and consistency of diabetes education within the nursing service provider. The researchers and Diabetes Educators then codeveloped a program logic model to identify how the intervention could achieve the project aims (Figure 1). The initial components of the program identified by the Clinical Diabetes Educators were then refined at a combined-site workshop in March 2014 (see Figure 2).

As shown in Figure 2, pilot testing of all processes and materials using PDSA cycles was conducted at one home nursing site where generalist nurses were trained in the use of the teach-back method of client education and



TABLE 2: Health literacy questionnaire (HLQ) scale scores.

	HLQ scale	Mean (standard deviation)
Possible scores for these scales range between 1 & 4	(1) Feeling understood and supported by healthcare providers	3.23 (0.44)
	(2) Having sufficient information to manage my health	3.02 (0.43)
	(3) Actively managing my health	2.99 (0.42)
	(4) Social support for health	3.07 (0.48)
	(5) Appraisal of health information	2.78 (0.42)
Possible scores for these scales range between 1 & 5	(6) Ability to actively engage with healthcare providers	3.99 (0.57)
	(7) Navigating the healthcare system	3.79 (0.60)
	(8) Ability to find good health information	3.55 (0.77)
	(9) Understanding health information well enough to know what to do	3.72 (0.72)

For scales (1) to (5): a score of 1: strongly disagree; 2: disagree; 3: agree; 4: strongly agree.  
For scales (6) to (9): a score of 1: cannot do or always difficult; 2: usually difficult; 3: sometimes difficult; 4: usually easy; 5: always easy.

Situation/need:  
Clients with diabetes experience difficulties actively managing their health and have limited capacity to find and appraise health information  
Diabetes education is delivered inconsistently across the service and clients often receive information they do not understand how to use

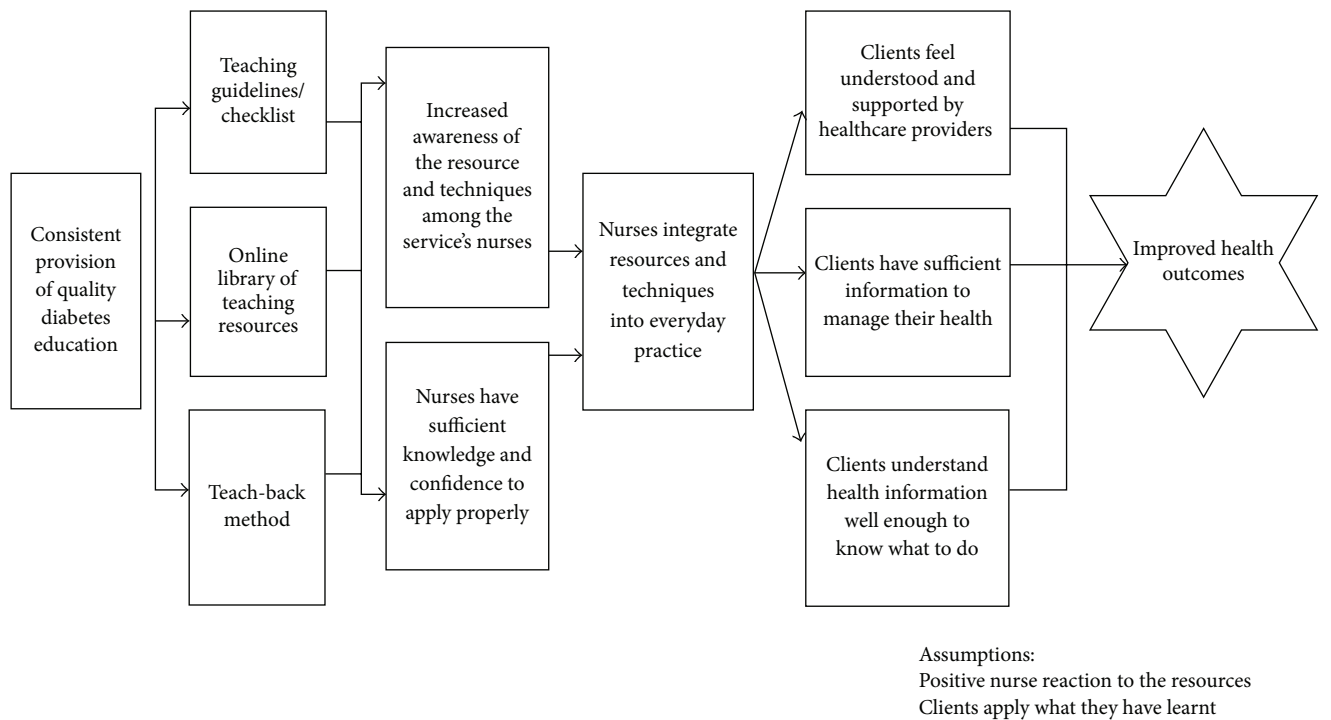


FIGURE 1: Program logic model for intervention.

orientated to use of the diabetes education checklist and online library resources. Nurses were asked to use the teach-back method with at least one client and to evaluate the checklist and resources. Two PDSA cycles were undertaken, with refinements made to materials, processes, and logistical arrangements as follows: (i) inconsistencies in the way teach-back was being applied led to longer training sessions, (ii) a learning styles assessment tool was introduced, and (iii) clearer guidelines for use of the online library were developed.

The final intervention consisted of three components:

- (i) Guidelines and educational checklist are to be used by the home service nurses for education of clients with diabetes. Both resources were developed by the diabetes nurse specialist team.
- (ii) Home nursing staff participating in the project were trained in use of the teach-back method [18]. This is a 4-step process in which clients are asked to repeat



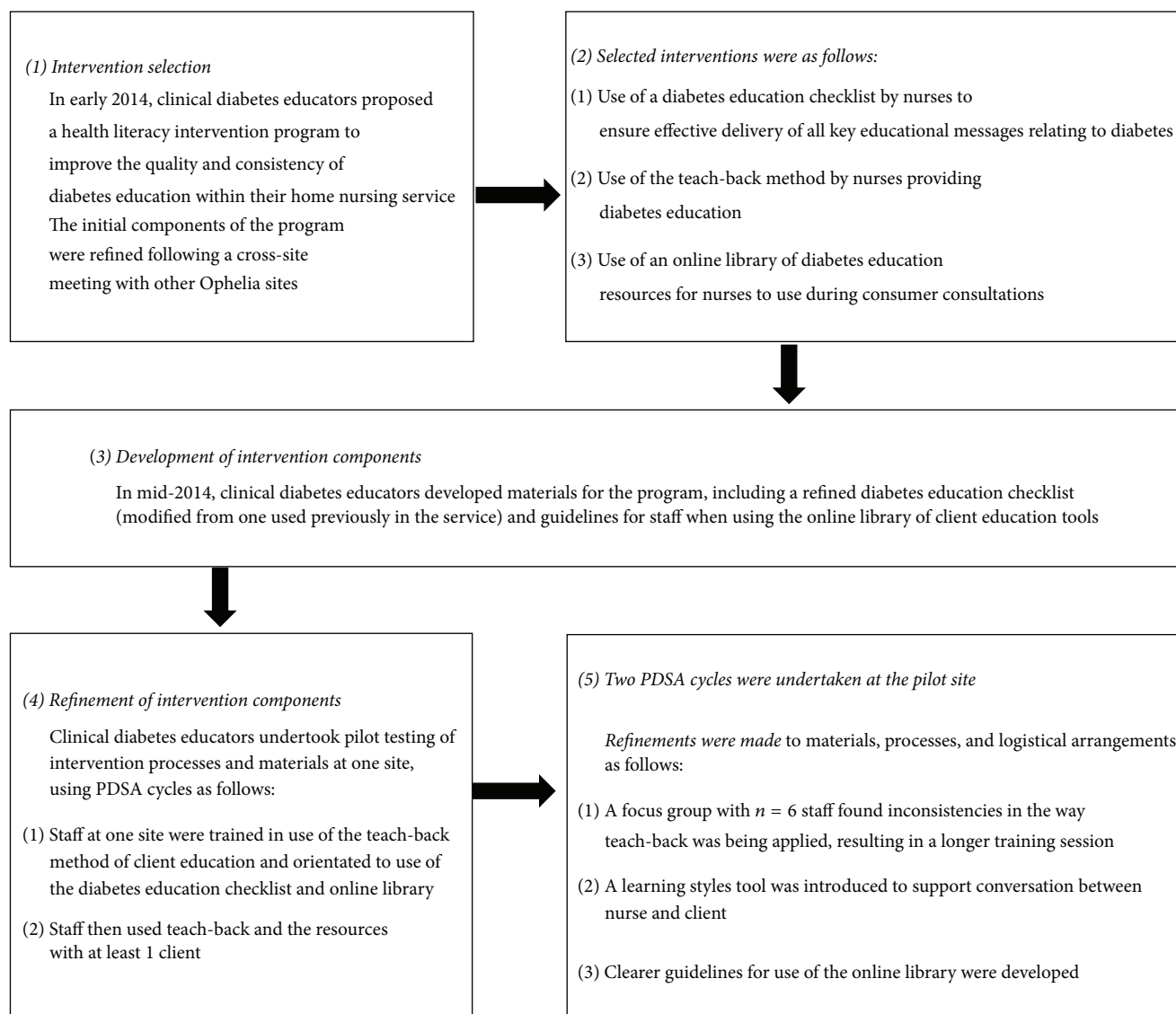


FIGURE 2: Intervention selection and development (Phase two).

back information provided by the clinician in their own words to demonstrate understanding. Teach-back provided the opportunity for nurses to identify and clarify misunderstandings in relation to the client's ability to undertake diabetes self-management activities. The training session on teach-back provided nurses with the skills to adapt this method of education according to each client's personal context.

- (iii) An online library of best-practice educational material was developed as a resource for nurses providing education to clients with diabetes.

Tailored diabetes self-management education was delivered in accordance with the client's preferred learning style. This was assessed using a learning styles assessment tool developed by another organisation participating in the larger Ophelia Victoria study and shared with RDNS to use as part of their intervention. The tool, which has not yet been

validated, consists of a single page of pictures each depicting a method of learning. Clients were asked which of the methods they tended to use most when learning new information or tasks.

**3.3. Phase Three: Intervention and Evaluation of the Final Intervention.** A total of 79 clients were eligible to participate. Of these, 24 clients (16 females, 8 males) with a mean age of  $75.3 \pm 13$  years (range, 51 to 98 years) agreed to participate in evaluation of the educational intervention (see Figure 3 and Table 3). While participants resided in a range of areas of according to the Australian Bureau of Statistics Socioeconomic Index for Areas (SEIFA) classifications [19] the majority (seventy-one percent) lived in areas categorised as disadvantaged.

Twenty-two of the 24 clients recruited to the intervention study completed the pre-HLQ questions, with 15 of these completing both pre- and post-HLQ questions (Figure 4).

TABLE 3: Intervention participant demographics.

Age	Mean (SD) = 75.3 ± 13.2, range 51 to 98
Gender	Female: <i>n</i> = 16 (66.7%); male: <i>n</i> = 8 (33.3%)
Years with diabetes	Mean (SD) = 9.78 ± 9.5, range 0.1 to 35 <i>n</i> = 23 of 24 clients had type 2 diabetes ( <i>n</i> = 1 missing data)
Medication type	Oral medication only ( <i>n</i> = 9, 37.5%); insulin only ( <i>n</i> = 5, 20.8%); both ( <i>n</i> = 9, 33%); none ( <i>n</i> = 1, 4%); missing ( <i>n</i> = 1, 4%)
Ever seen diabetes educator	Yes = 18 (75%); no = 6 (25%)
Ever seen dietitian	Yes = 14 (58.3%); no = 10 (41.7%)
SEIFA index of relative disadvantage*	SEIFA < 1000, <i>n</i> = 17 (71%) SEIFA ≥ 1000, <i>n</i> = 7 (29%)

\* ABS: socioeconomic indexes for areas (SEIFA) index of relative disadvantage [19]. Note: a lower score indicates that an area is relatively disadvantaged compared to an area with a higher score. Index scores have been standardised to have a mean of 1,000.

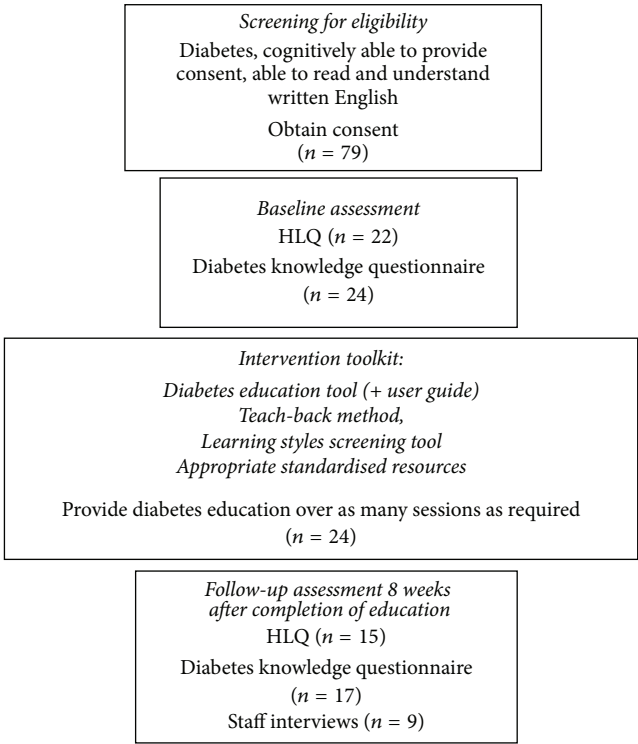


FIGURE 3: Flow diagram of Phase 3 of the Ophelia health literacy intervention showing client selection, intervention, and evaluation tasks.

As expected, no difference was seen in the comparison scale (Scale (5), appraisal of health information; mean prescore 2.93 (SD 0.51), postscore 2.91 (0.74). Effect size (ES) 0.04, 95% CI −0.67, 0.76). Minimal positive increases were seen in the remaining two scales (Scale (2), having sufficient information to manage health; mean prescore = 2.88 (0.59), postscore = 2.98 (0.72). ES = 0.15, 95% CI −0.57, 0.87), and (Scale (9), understanding health information well enough to know what to do; mean prescore = 4.04 (0.49), postscore = 4.08 (0.57). ES = 0.08, 95% CI −0.64, 0.79).

All 24 clients completed the preintervention Diabetes Knowledge Questionnaire and 17 completed both pre- and

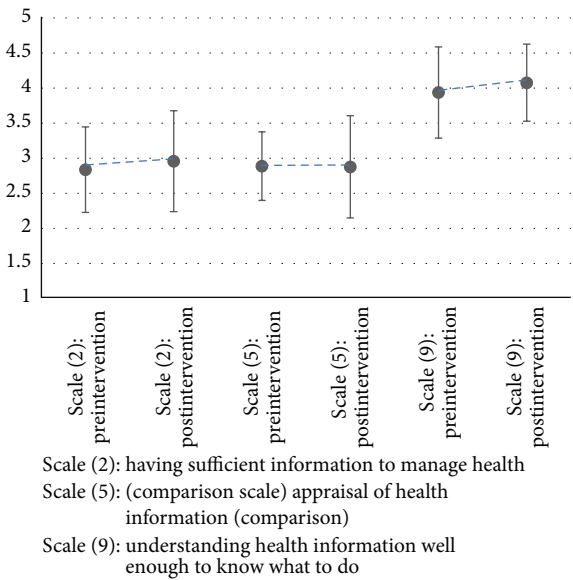


FIGURE 4: Changes in three HLQ scores before and after intervention (*n* = 15).

postintervention (see Table 4). Trends suggested an overall increase in median DKQ scores but this difference was not statistically significant.

**3.4. Nurses' Perceptions of Barriers to Implementation and the Utility of the Intervention and Its Impact on Their Clinical Practice and Client Outcomes.** Twenty-four nurses attended training sessions of which 13 recruited clients and delivered education. Nine of the 13 nurses participated in interviews to report on their perceptions in relation to barriers and utility of the intervention and any impacts for themselves or their clients.

A total of six themes were identified in the NVivo analysis. There were five strong themes and a sixth weaker theme relevant to the use of the learning styles tool (see Table 5). Strong themes encompassed those where a minimum of five participant responses supported key trends, while the weaker theme involved responses by only two participants.

TABLE 4: Changes in diabetes knowledge questionnaire score (DKQ).

	Median (interquartile range)
<i>Participants only completing preintervention DKQ (n = 24)</i>	
Pre-DKQ score	75 (62, 89)
<i>Participants completing pre- &amp; postintervention DKQ (n = 17)</i>	
Pre-DKQ score	77 (65, 88)*
Post-DKQ score	89 (77, 96)

Possible score range for the DKQ = 0 to 100.

\*No significant difference between median scores using Wilcoxon signed rank sum test.

#### 4. Discussion

This study describes a systematic process that enabled a home nursing service to identify and respond to the health literacy strengths and challenges of their clients with diabetes. The Ophelia process allowed the service to lead the collection of health literacy data, participate in codesign workshops, codevelop their own program logic models, apply quality improvement cycles, and then lead the implementation and evaluation of an effective intervention. In this setting, the Ophelia process is shown to be a feasible approach by which an organisation can understand and respond to the health literacy needs of their clients and build health literacy capacity of staff and the organisation itself.

Overall findings suggested small improvements in outcomes. There were slight, but not significant, increases in the two HLQ scale scores used for evaluation and in the Diabetes Knowledge Questionnaire scores. In addition, the generalist nurses indicated positive behaviour changes for some clients and a greater rapport between nurse and client. There were also clear benefits for generalist nursing staff to using a consistent approach and expected standard for diabetes education delivery, with a dedicated resource hub and the diabetes education checklist now embedded into usual practice for assessment of client education needs. The “teach-back” education method has been identified as a skill for staff development and has been advocated for use across the home nursing service training/education programs as part of the effort to educate generalist nurses on health literacy and practical intervention and support. The intervention is thus becoming part of routine clinical practice and will become embedded within the organisation over time. Due to a new remote working environment of the home nursing service, teach-back training may need to be delivered using online learning modules, supported by regional Clinical Diabetes Educators. In addition, the Diabetes Clinical Educators and Senior Clinical Nurse Advisor for dementia will collaborate to ensure the intervention is suitable for the needs of clients with dementia. In this way, the intervention is tailored to meet the changing needs of the organisation and its clients.

The intervention was derived from a detailed needs assessment of the client group, and the use of teach-back

and assessment of learning styles allowed further tailoring of education to client’s individual needs. Similar findings were seen in a US community clinic, where the use of educational materials targeted to health literacy levels and learning styles was found to increase clients’ diabetes knowledge compared to those not receiving the tailored intervention [20]. A systematic review of the efficacy of tailored interventions for self-management in chronic disease found that among clients with diabetes, the provision of tailored information was associated with improved self-care behaviours and knowledge [21]. The author also found that development of a personal rapport or relationship with the person providing the information was an important component of the intervention [21]. Personal rapport and empathy have been shown to be related to health outcomes [22] and may have been a contributing factor to the success of our intervention in which education was generally provided by the same nurse over a period of time, allowing for a positive relationship to develop. Similarly, a systematic review of the effectiveness of diabetes self-care interventions found that healthcare provider support and health literacy influenced people’s self-care ability, with findings from this review also suggesting that using approaches that are tailored to the needs of different groups of people with diabetes are effective [23].

Other studies examining the effectiveness of teach-back for clients with diabetes have shown similar findings, even where patients have lower health literacy. A frequently reported study from North America found that physicians’ use of teach-back was associated with improved glycaemic control among patients with diabetes mellitus and low functional health literacy [24]. A study from Iran found that among patients with type 2 diabetes and low health literacy attending a diabetes outpatient clinic use of teach-back was associated with improved knowledge about diabetes and improved adherence to medication, maintained at 6 weeks after intervention [25]. Use of teach-back was also associated with knowledge recall among community-based patients with type-2 diabetes in the USA; however, knowledge retention was not maintained at 2 weeks [26].

Involvement of the nurse Clinical Diabetes Educators in all stages of the process (from data collection to evaluation of the intervention) ensured ownership of the intervention and empowered the Diabetes Educators. It also meant that the Educators were able to support the service’s generalist nurses to understand and apply the intervention, by explaining the project in words that their colleagues understand, and using practical and relevant examples. Further, the close involvement of the Educators meant that the organisational context, structure, and culture were considered when designing the intervention. Understanding the context of a person’s daily life and knowledge of the healthcare service is an important factor in the design of health literacy interventions. Health literacy is very context-specific [7], and so interventions delivered in one context or to one group of patients may not be as effective in another, even if people have similar health literacy abilities. The Ophelia process applies a codesign approach that takes into account the knowledge of clinicians who are not only very experienced clinically but who have also worked with the client target group for some time and

TABLE 5: Key themes and illustrative quotes.

Themes	Findings	Illustrative quotes
Benefits experienced during the use of diabetes education checklist	Six nurses reported that the checklist helped them keep on track with client education by focusing only on areas the client thought were necessary. Overall, the checklist appeared to be well accepted and utilised and was termed “user-friendly”	I think it was useful – in her situation I was the only one giving her the education, when lots of different nurses – where it’s good to have different ideas you sometimes end up guessing what has been covered, often re-hashing and going over time that has already been spent, making sure that you haven’t missed, whereas if doing all education, . . . in that conversation you realise that oh they didn’t know that, useful conversation around what do you know/ not know. (RDNS 7) I tend to use the checklist now for all my diabetes clients - this is much easier for me to tick off what they need to learn (RDNS 4)
Benefits and barriers experienced during the use of teach-back	The method was praised by most nurses ( $n = 7$ ) who felt that while it had been part of their routine clinical practice for some time, participating in this intervention led to consistent and conscious use of the method during client education. Using the method more formally was seen to reinforce the importance of the teaching and learning trajectory to both clinicians and clients. The nurses ( $n = 7$ ) reported that using teach-back raised their awareness of the needs of clients in relation to learning such as the need to provide information in stages, use of simple terms, and being specific about actions that clients needed to undertake. The method was seen as contributing to a greater rapport with clients ( $n = 4$ ). Using the method with dementia patients and other cognitively impaired patients was a challenge identified by two clinicians	I felt confident straight away to practice – was already using techniques, but the project made me more aware and made me use it more consciously and consistently (RDNS 1) I spend a lot more time asking patients what was the main thing they understood from that and encouraging them to talk back to me. Before I was more “you’ve heard the information now go and do it”. It was reinforcing to me about my teaching, she and I both enjoyed it (RDNS 2) With teach-back, I think it’s a great way to communicate with people – we say “this is what we are going to do”, not “this is what you need to do”. We work with them and get a better response all round. (RDNS 5)
Benefits and barriers experienced during the use of online library of resources	Five clinicians noted that these resources were “useful for quick answers,” “user-friendly,” and “easy to use.” However, two clinicians felt the topics were limited, and sharing the resources with clients was challenging when large/multiple documents needed to be downloaded, printed, and mailed out to clients	I use the diabetes education checklist and online resources all the time with other clients. They are good, they help keep me on track and remember what I’ve covered (RDNS 5) I used all online resources – they are written in simple language, a couple I got from the National Diabetes site, plus shopping list off the diabetes website – a very useful tool (has product names on it, much more practical) (RDNS 2) Then there is still same problem with accessing resources – large documents that have to be downloaded – we need to print them as that’s the only way I can give to people to read – not enough time in our meeting to read over again in our session, screens too small, especially if lots of sections – do people really bother to read them all? (RDNS 7)
Benefits and barriers experienced during the use of the learning styles tool	Only two nurses specifically reported using this tool; one nurse felt it made educating staff easier and was a user-friendly tool to use, while the second reported that using the tool with older clients, who had set habits, was a challenge	I used the learning styles tool initially, thought that was useful but I do that anyway (RDNS 2) The learning styles – I think that’s important, but with our kind of clients, we don’t really have the ability to do things differently. We’ll go in and talk about things – if they need resources we’ll do what we can. With the age of our clients, what they’re used to is us sitting down with them – it’s not practical to know about their learning styles (RDNS 5)



TABLE 5: Continued.

Themes	Findings	Illustrative quotes
<i>Experiences and outcomes</i>	Two strong subthemes here were the “opportunities” and “challenges” which arose during utilisation of the intervention’s tools. There were positive reports by three nurses of clients becoming more proactive, asking more questions and showing improvements in self-management of their condition. Nurses ( $n = 5$ ) felt this was a result of increased knowledge, understanding, and opportunity for clients to refresh their memory on certain vital topics. In terms of changes to their own knowledge and practice, two nurses reported no changes, while five reported that the intervention provided opportunity to reflect on how education was delivered to clients and taught them to look for cues to ascertain client understanding of the content. Nurses ( $n = 5$ ) felt the intervention either formalised the process of information delivery, and/or provided an opportunity to check on a client’s existing knowledge, refresh knowledge, and build rapport with a client. In relation to challenges, five nurses reported that recruiting suitable clients to participate in the intervention was difficult given the large proportion from non-English speaking backgrounds. The second biggest challenge was client cognitive decline or impairment as noted by two nurses	She’s more confident to ask questions. She has had a foot wound which she has stopped looking after, so she has asked me if anything else, and I said well let’s do foot care, so we’ve done more about this and got her to a podiatrist, so definitely more proactive than previously. I’ve known her for 3 years, and this is different. (RDNS 2) Has given me an opportunity to reflect on how I deliver education and reflect back and look at what I’ve done more analytically and see that nodding the head doesn’t mean they get it. . .looking for objective and subjective cues about how they have learnt (RDNS 6) I found only one suitable person, because limited criteria I have many patients with non-English speaking background or cognitive decline (RDNS 3)
<i>Critical facts and lessons learnt</i>	Cultural and linguistic diversity was predominant amongst the target population and therefore translation and use of simple language were suggested to make the intervention more relevant ( $n = 5$ ). The continuous promotion of the intervention within the organisation was advised to maintain its momentum. In terms of client behaviours, staff ( $n = 3$ ) felt some clients/carers may dislike being assessed/questioned on topics they had limited knowledge about. Allowing clients to learn at their own pace, educating them without impeding their confidence, and encouraging clients to be independent were suggested as vital points by clinicians ( $n = 3$ ). One nurse reported that using the tools with some clients revealed cognitive issues which had not been previously identified, due to a lack of formal assessment. Finally, nurses praised the Clinical Diabetes Educators who led the project from within the home nursing service for their supportiveness, availability, and responsiveness	CNCs will need to keep promoting it. If there is no one driving it, it won’t be successful (RDNS 1) If we are going to take education seriously, we should use this method- each site in RDNS is doing something different. Not to say it’s bad but to be consistent, we need consistent methods. . .incorporating teach back is the first tool (RDNS 6) We don’t encourage our patients to be independent (RDNS 3) Think it is a good idea, but can see that many people would benefit from education, but not all are English speaking, so some translation required (RDNS 3) It comes with practice and being aware that everyone is at different stages, some will take longer, and need to go over and over, some people take it in quickly. Need to be really patient with people (RDNS 8)

so are familiar with many of their day to day health literacy challenges and abilities.

**4.1. Study Strengths and Limitations.** This is the first time this process has been used in a large home nursing service and was a proof-of-concept study with limited outcome data; however, our findings demonstrate that a health literacy intervention can be generated and applied in this setting using the Ophelia approach.

A major restructure of the home nursing service occurred during this project, including the introduction of remote service delivery. These changes led to a delayed start to Phase three of the project, impacting upon the numbers of study participants recruited and reducing the available time for intervention implementation and evaluation. Further, participants who completed both the pre- and posthealth literacy and diabetes knowledge questionnaires are likely to be those who have greater self-management skills and

possibly higher health literacy and therefore results are not likely representative of the wider client population. Many people with low health literacy are not likely to have taken part and therefore there are limits to the transferability of the results to this group in particular. Strategies for ensuring that clients who are appropriate for engaging with the interventions, that is, including those with a range of substantial health literacy challenges, will need to be explored further and a stratified approach used for those who are unable to engage with the planned intervention to ensure maximal independence and safety is maintained. In addition, the learning styles assessment tool was not validated prior to its use and so cannot be said to accurately assess preferred learning styles. In order to provide a strong evidence base we recommend that our model requires further testing and a wider scale evaluation.

## 5. Conclusion

The organisation will continue to evaluate and develop a consistent and deliverable diabetes education program that responds to the needs of a diverse client population with varying health literacy strengths and limitations. From participating in this process, staff and management now have a greater understanding of the relevance of health literacy for their clients and increased knowledge of how to develop interventions based on these needs. In this setting, the Ophelia process has contributed to evidence-informed practices changes that, to date, have been maintained.

## Competing Interests

The authors declare no competing interests.

## Authors' Contributions

Richard H. Osborne led the initial conceptualisation and design of the Ophelia approach. Alison Beauchamp, Dianne Goeman, and Richard H. Osborne led the design on the RDNS component. Dianne Goeman, Sue Conway, Ralph Norman, and Jo Morley undertook the data collection. Alison Beauchamp performed the data analysis. Dianne Goeman prepared the initial draft of the manuscript, and all authors contributed to the final version. All authors have read and approved the final manuscript.

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## Clinical Study

# Effects of a Patient-Provider, Collaborative, Medication-Planning Tool: A Randomized, Controlled Trial

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Among patients with various levels of health literacy, the effects of collaborative, patient-provider, medication-planning tools on outcomes relevant to self-management are uncertain. *Objective.* Among adult patients with type II diabetes mellitus, we tested the effectiveness of a medication-planning tool (Medtable™) implemented via an electronic medical record to improve patients' medication knowledge, adherence, and glycemic control compared to usual care. *Design.* A multicenter, randomized controlled trial in outpatient primary care clinics. 674 patients received either the Medtable tool or usual care and were followed up for up to 12 months. *Results.* Patients who received Medtable had greater knowledge about indications for medications in their regimens and were more satisfied with the information about their medications. Patients' knowledge of drug indication improved with Medtable regardless of their literacy status. However, Medtable did not improve patients' demonstrated medication use, regimen adherence, or glycemic control (HbA1c). *Conclusion.* The Medtable tool supported provider/patient collaboration related to medication use, as reflected in patient satisfaction with communication, but had limited impact on patient medication knowledge, adherence, and HbA1c outcomes. This trial is registered with ClinicalTrials.gov NCT01296633.

## 1. Introduction

Medication is central to treating and managing type II diabetes mellitus, a prevalent age-related chronic illness [1]. Effective treatment is often undermined by nonadherence, with as many as half of patients not taking medications as prescribed [2, 3].

Nonadherence is traced to many causes but often involves a gap between the cognitive demands of adherence and inadequate cognitive resources that patients bring to the task,

a problem that is compounded by limited healthcare system support [4]. For example, to manage complex medication regimens, patients with type II diabetes must create plans for taking multiple medications that meet constraints such as avoiding medication interactions and timing with respect to meals or other daily events. Planning requires cognitive resources related to health literacy [5–7], such as processing capacity (e.g., working memory) and health knowledge [8]. Nonadherence increases with regimen complexity [9], in part because of inadequate planning [5]. Older adults are

especially likely to demonstrate nonadherence because they tend to have more complex medication regimens, yet experience declines in literacy and cognitive resources needed for self-care [8].

Healthcare system support for adherence is often inadequate [2]. For example, patient-provider collaboration is crucial for adherence [10, 11]. Education by providers can increase patient knowledge and self-care skills, and simplifying regimens and coordinating treatment across providers reduce adherence demands on patient cognitive resources. However, effective collaboration requires patients and providers to work together to ensure information is mutually understood [12], and providers do not always collaborate with patients effectively. While providers do most of the talking during consultations [13], they may skip key information [14], use non-patient-centered language [15], or fail to check patients' comprehension of the information that they present [16]. Medication review with patients is sporadic and fragmented [17] and reconciliation, the process of ensuring accurate, complete, and current patient medication lists, is often inadequate [2]. As a consequence, patients leave consultations with deficits in memory for important information and inadequate plans for self-care [18].

Adults with lower health literacy and cognitive resources are especially vulnerable to inadequate collaboration with providers. Patients with diabetes and lower health literacy report worse communication with providers [19] and have worse outcomes than do patients with adequate literacy [20, 21]. Adults with complex regimens and multiple self-care needs are candidates for system support because they are less likely to develop shared adherence plans with their providers, leading to nonadherence [2, 22].

Inadequate collaboration reflects barriers such as limited contact time and lack of support for consistent use of patient-centered communication strategies [2]. A promising approach is multimedia support for patient/provider collaboration. Patient memory for self-care information is improved when information is provided visually (text and graphics) as well as verbally during clinic visits, especially when the presented information is consistent, standardized, and embedded in structured processes that activate patients [13, 23]. Well-designed information technology can support multimedia approaches to patient-centered communication [4], but this potential has yet to be realized. For example, comprehensive medication lists printed on cards are recommended for medication review and reconciliation with patients, but studies evaluating such cards in pharmacy [24], hospital discharge [25], and specialized clinic [26] environments produced inconsistent evidence. This finding may reflect the fact that the cards were not specifically designed to support patient-provider collaboration nor were they linked with health information technology, thus not integrated with clinical practice.

We developed a patient education tool called the Medtable that is integrated with the electronic medical record (EMR) in primary care clinics [27]. The purpose of the Medtable is to improve patient self-management via patient-provider collaboration. Guided by distributed cognition theory, which suggests that cognitive activity can be effectively

distributed across individuals (such as nurses and patients) and external artifacts (tools such as computers or paper) to support collaboration [28], the Medtable was designed to accomplish three goals: (1) to promote patient knowledge by clearly conveying accurate and relevant medication information; (2) to support collaborative planning wherein a patient, guided by a nurse, could efficiently organize medications tailored to his or her daily schedule to support use; (3) to embed the tool into clinical practice by integrating it with EMR systems so that it is easily updated, reliable, and shareable with providers.

Our use of EMR-integrated technology to support collaborative planning for medication use is unique in the literature on medication adherence among patients with diabetes. Few previous studies focus on patient/provider consultation (for review, see [29]). For example, one study assesses the use of paper-based tools to support patient/provider planning about medication taking [30]. Other studies evaluate problem solving protocols to address barriers to adherence during face-to-face [30–32] or telephone-based [33] communication. These studies do not involve the use of EMR-integrated tools designed to support specific cognitive processes underlying patient/provider collaboration and learning.

This EMR-enabled Medtable strategy was evaluated to determine its impact on medication use and health outcomes among patients with type II diabetes mellitus. The intervention involved nurses using the tool to support patients' medication planning. We hypothesized that, compared to usual care, patients randomized to this intervention will have greater medication knowledge, adherence, and better outcomes (as measured by glycosylated hemoglobin HbA1c levels), as well as being more satisfied with provider communication about medications. A secondary hypothesis was that intervention benefits would be greater for patients with lower health literacy than for those with adequate literacy, because the intervention was designed to address literacy-related barriers.

## 2. Methods

The study design was a two-arm, patient-randomized, controlled trial. Details about the trial design have been published [27]. The trial settings were outpatient primary care clinics in Chicago and Peoria, Illinois. All the research sites used the same electronic medical record and version (Epic, Verona, Wisconsin). The institutional review boards of Northwestern University and the University of Illinois approved the research. A group of experts comprised the Data Safety and Monitoring Board that monitored the trial and reviewed protocol changes.

**2.1. Inclusion and Exclusion Criteria.** Criteria for enrollment were (a) age 40 years and older; (b) native speaker of English; (c) no physical or cognitive impairments that could limit participation (e.g., stroke in the last 3 years, current cancer treatment involving radiation or chemotherapy); (d) score of 4 or higher on the short screen for dementia [34]; (e) no severe visual impairment (less than 20/50 corrected vision)



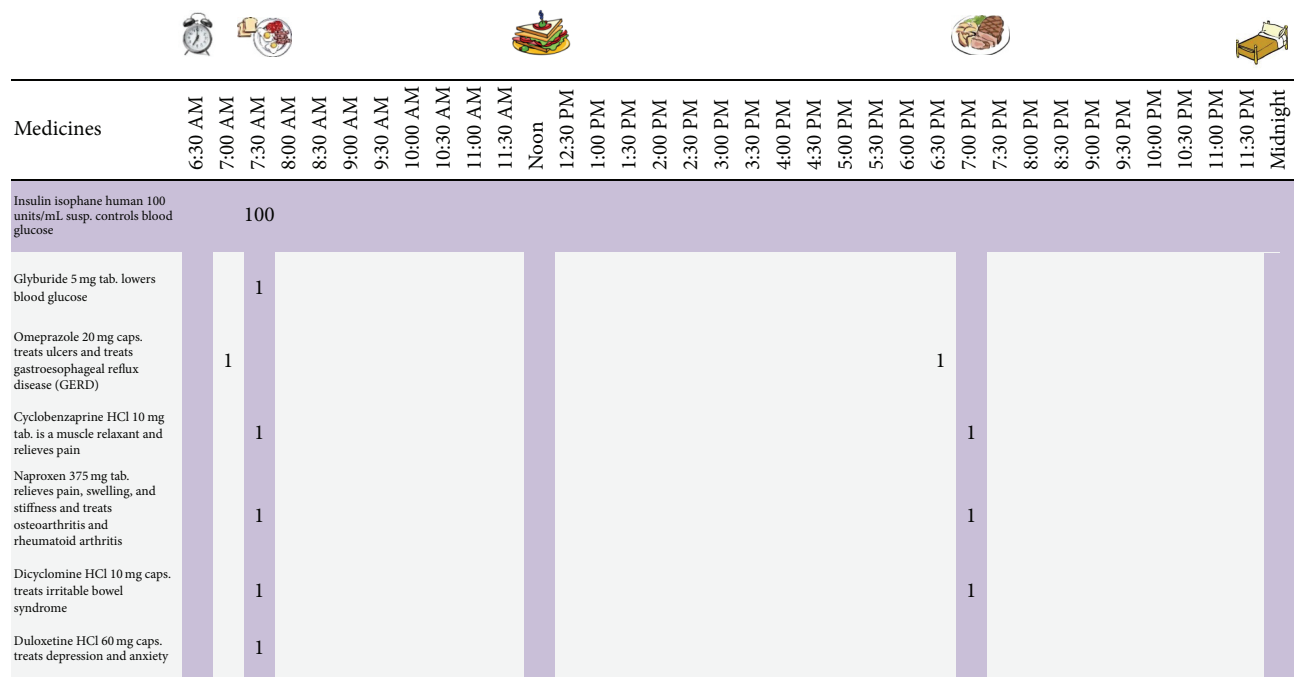


FIGURE 1: Example of Medtable. The patient and provider collaborate to choose times for each medication in the regimen. Modified and reprinted from [27] with permission from Elsevier.

or auditory impairment that would limit participation; (f) diagnosis of type II diabetes mellitus; (g) taking at least 5 prescribed medications; and (h) glycosylated hemoglobin (HbA1c) level of 7.0% or higher. The inclusion/exclusion criteria related to language proficiency and physical, sensory, and cognitive impairment were designed to minimize factors that might reduce response to the intervention and confound interpretation of the findings.

**2.2. Participant Recruitment.** Recruitment occurred from ambulatory care general internal medicine clinics in Chicago and Peoria, Illinois, which served as the performance sites for this study. Primary care physicians gave permission to screen their patient panels for potential participants who had the appropriate age, HbA1c, and number of medications. Then, potential participants received a letter via mail that described the research and said the patient would be contacted via telephone. Shortly before a scheduled clinic visit with the primary care clinician, clinical research coordinators contacted potential participants via phone to provide a questionnaire for inclusion/exclusion criteria, determine eligibility, and initiate the informed consent process. Participants who provided informed consent via telephone were scheduled for the baseline research visit that coincided with the next clinic visit with the primary care clinician. Participants completed the informed consent process at the baseline research visit and then immediately received the randomized intervention. Because of slow recruitment, the Data Safety and Monitoring Board authorized a change in the inclusion criteria to enroll participants with HbA1c of 6 or more.

**2.3. Intervention: Medtable.** Patients who were allocated to the experimental condition received the Medtable-based intervention (see Figure 1). A complete description of the Medtable has been published [27]. In summary, the Medtable is a structured tool that was implemented within the electronic medical record (EMR) at the outpatient clinics. The goal of the Medtable was to organize collaborative, patient/provider interactions for medication review, reconciliation, and education. Features of the Medtable included searchable libraries of medication administration instructions in direct, actionable language, timelines that support text, and familiar icons that represent key daily events. Implementation of the tool occurred during routine clinic visits, and this occurred in three stages. During the setup stage and prior to the patient visit, the nurse loaded the patient medication list from the EMR into the Medtable. At this stage, the nurse used the Medtable to customize the technical language from the EMR to provide language appropriate for patients with low health literacy. The second stage occurred with the patient during the clinic visit. The patient reviewed the EMR-based medication list, and then the nurse and patient collaboratively reconciled the list. The nurse added or deleted information in the EMR in response to the reconciliation stage. The goal of the second stage was an accurate and current medication list.

In the final stage, the patient and nurse jointly created a medication schedule while using the Medtable tool. Patients described their daily routine so the nurse could set up the tool around the routine. The Medtable displayed icons and highlighted columns to which the patient and nurse could refer while developing the schedule. The nurse and patient

scheduled each medication by clicking on the cell in the table corresponding to the medicine (row) and the time slot (column). In this way, the tool scaffolded collaborative planning for taking the patient's medications. The nurses also discussed how to take each medication with the patients and used teach-back techniques to ensure patient comprehension. At the end of the third stage, the patient received a paper copy of the Medtable-based summary of their daily medication schedule to take home.

The intervention nurses were trained to use the Medtable as part of patient-centered care. Education for intervention nurses involved several components. Nurses received a multimedia manual with project overview, rationale for the intervention, overview of the Medtable tool and how it is used, and specific information about Medtable procedures. The education emphasized teach-back and teach-to-goal strategies to ensure patients understand how to take their medicines. While training, nurses interacted with the Medtable as patients as well as providers to optimize understanding from multiple perspectives. Nurses participated in simulated patient encounters to set up the tool and work with patients to develop schedules for medication regimens of varying complexity. To ensure fidelity of the intervention to the research protocol, the research personnel observed intervention nurses while working with several actual patients at both research sites. Feedback was provided to the nurses to reinforce initial training and ensure consistent delivery of the intervention across sites [27].

**2.4. Usual Care.** Patients allocated to usual care received medication counseling and communication from clinic nurses according to the standard of care at the research sites. Usual care included reconciliation of the patient's list of medications. The medication instructions on the list were comparable to the text commonly found on prescription labels. Usual care recipients and their providers did not receive prompts to organize the medication list around the patient's daily activities.

**2.5. Measurement of Knowledge.** The primary prespecified outcomes were verbal and demonstrated knowledge of the medication regimen [5, 35]. Research personnel assessed medication knowledge at baseline, immediately following the research intervention, and then 3 and 6 months later. Patients received a reminder to bring current prescription medication bottles or containers to each study visit. Clinical trial coordinators recorded all medications and dose directions from the label. To assess verbal knowledge of directions for use of injectable medications like insulin, clinical trial coordinators recorded the patient's responses to two questions: "On a usual day, how many times a day do you take this medicine?" and "How many units of this medicine do you usually take each time?" We scored correct verbal knowledge per injectable medication if the patient answered both questions correctly when compared to directions on the label. To assess verbal medication knowledge of directions for use of noninjectable, prescribed medications, clinical trial coordinators recorded the patient's responses to three questions for each medication: "On a usual day, how many times a day do you take this

medicine?" and "How many pills of this medicine do you take each time?" and "How many pills of this medicine do you take each day in total?" For noninjectable medications, we scored correct verbal knowledge per medication if the patient answered all three questions correctly when compared to directions on the label. For purposes of analysis, we calculated combined verbal knowledge of the regimen for all questions: the number of medications scored as correct verbal knowledge divided by the total number of medications in the regimen.

Another verbal medication knowledge item was indication for each medicine in the patient's regimen. Older and less educated adults are less likely to know the purpose of their medications [36]. Clinical trial coordinators recorded the verbatim response to the following question: "What is the medicine for?" For purposes of analysis, we calculated combined knowledge of the indication for drugs in the regimen: the number of medications scored as correct indication knowledge divided by the total number of medications in the regimen.

We also assessed demonstrated medication knowledge for each noninjectable drug in the regimen. Clinical trial coordinators asked patients to show how they would take each of their medicines by placing beads (representing pills) into a pillbox that was partitioned into 24 slots, each slot representing an hour of the day [5]. We scored correct demonstrated knowledge per medication if the patient correctly demonstrated all 4 of the following: number of pills per dose, number of doses per day, number of pills each day in total, and amount of time (spacing) between doses. Combined demonstration knowledge of the regimen was the number of medications scored as correct demonstrated knowledge divided by the total number of medications in the regimen.

Scoring of the primary outcome was a blinded process. We employed board-certified internal medicine physicians who adjudicated the verbal and demonstrated knowledge items. The adjudicators had no contact with research participants, clinical trial coordinators, intervention nurses, or clinical site nurses. Two adjudicators who were blind to intervention allocation independently scored each patient response as correct or incorrect when compared to the prescription label on the medication container. The initial scores by each adjudicator were compared and revealed moderate to very good agreement. For example, Cohen's Kappa was 0.87 for two adjudicators who scored patient responses to the question, "How many pills of this medicine do you take each day in total?" The Kappa was 0.43 for two adjudicators who scored responses to the question, "How many pills of this medicine do you take each time?" The other verbal and demonstrated knowledge questions had Kappa values between 0.54 and 0.95. When initial adjudications were discordant, the adjudicators met and they successfully resolved all discrepancies.

**2.6. Measurement of Adherence.** A secondary prespecified outcome was adherence. We assessed patient-reported adherence with the Patient Medication Adherence Questionnaire (PMAQ) [37]. Clinical trial coordinators recorded adherence

at baseline and then three and six months after randomized allocation. For each daily prescribed medication, clinical trial coordinators asked patients if they missed taking a dose yesterday, the day before yesterday, 3 days ago, or over the past weekend. Participants were scored as being adherent to the medication if they answered “no” to all of the four questions. For purposes of analysis, we constructed a regimen adherence score for each patient: the total number of medicines for which the patient was adherent divided by the total number of medications in the patient’s regimen.

**2.7. Measurement of Satisfaction.** Satisfaction with information about medicines was another secondary, prespecified, patient-reported outcome. Clinical trial coordinators asked patients in both intervention groups to rate satisfaction with the information received from the doctor or nurse about medicines during the visits immediately after intervention, at month 3, and at month 6. The response options were “too much,” “about right,” “too little,” “none received,” or “none needed.” The five satisfaction items were a subset of the Satisfaction with Information about Medicines Scales (SIMS) [38]: “what your medicine is called,” “what your medicine is for,” “how to use your medicine,” “whether the medicine has any unwanted effects (side effects),” and “whether the medicine interferes with other medicines.” Responses of “about right” or “none needed” were interpreted as satisfaction. We scored dissatisfaction if the patient reported “too much,” “too little,” or “none received” or if the value was missing.

**2.8. Measurement of Glycemic Control.** HbA1c, a common measure for glycemic control, was another secondary, prespecified outcome. HbA1c was collected from a glycosylated hemoglobin blood test. The blood tests were analyzed at certified clinical laboratories from patient samples drawn at baseline and then during subsequent visit windows that were 3, 6, 9, and 12 months after random allocation. Clinical trial coordinators abstracted HbA1c results from the patient record.

**2.9. Sample Size.** The sample size estimate for the clinical trial was made with the following assumptions. We assumed 45% of patients in the usual care arm would have correct knowledge of their multidrug regimens at six months. The anticipated retention rate at six months was 80%. There were no planned interim analyses. We needed to recruit a sufficient number of patients to have 600 evaluable participants at six months. Under these assumptions, the sample size of 600 (300 per arm) at six months had 82% power to detect a difference of 12% between study arms with a 5% type I error rate.

**2.10. Randomization Scheme.** Research personnel at the clinical trial coordination center generated the random allocation sequence with computer-generated random numbers. The allocation ratio was 1:1 with stratification by site, Chicago versus Peoria, and random permuted blocks within site. The coordination center personnel in Champaign, Illinois, transferred the allocation sequence to sequentially numbered, opaque envelopes and then distributed the sealed envelopes to the clinical sites in Chicago and Peoria. Clinical trial

coordinators in Chicago and Peoria performed telephone interviews to screen potential participants, confirm eligibility, and obtain verbal consent. Next, the clinical trial coordinators obtained the concealed allocation to Medtable or usual care by opening the sealed envelope. After random allocation, the participant, the clinical trial coordinator, and the clinic personnel were not blind to the study intervention.

**2.11. Measurement of Covariates.** Health literacy was measured by the Rapid Estimate of Adult Literacy in Medicine (REALM), a health word recognition test that involves pronouncing 66 medical terms [39]. Performance on REALM is associated with patient age, medication adherence, and health outcomes [6, 40]. A patient with limited health literacy was defined as having a REALM score of less than 61. We measured fluid mental ability (speed of mental processing) with the Letter and Pattern Comparison tests. Fluid mental ability is vulnerable to aging and is associated with differences in health literacy [41, 42]. We measured patient knowledge about diabetes mellitus with the 24-item Diabetes Knowledge Questionnaire [43]. To adjust for patient self-activation, we assessed the Summary of Diabetes Self-Care Activities (SDSCA) [44]. We assessed illness experience in years when we asked the question, “How long have you had diabetes?” To adjust for health status, we measured comorbidity with the Charlson method and general health status via Short Form-36 [45, 46]. We measured the Medication Regimen Complexity Index (MRCI), a 65-item tool with three domains: medication dosage form, dosing frequency, and additional medication directions [47]. The variables for patient age, gender, race, education, employment, and income were measured by a modified version of the Older Americans Resources and Services (OARS) instrument [48].

**2.12. Analysis Plan.** We analyzed all outcome measures under the principle of intention to treat. To address missing glycosylated hemoglobin (HbA1c) scores, we used the last observation carried forward [49]. Missing satisfaction values were replaced with dissatisfaction values. All other missing outcome measures and missing baseline covariates were replaced using the method of maximum likelihood estimation. Generalized Estimating Equations were used for correlated response data when testing the intervention effects over time with logit link and identity link functions for binary outcomes and continuous outcomes, respectively. When examining the intervention effects within each time visit, we used logistic regression or linear regression models for binary and continuous responses, respectively. All analyses were performed with SAS 9.4 (SAS Institute Inc., Cary, NC). Two-tailed  $p$  values were calculated for all tests and  $p < 0.05$  was the threshold for significance.

The primary analyses evaluated whether the Medtable intervention improved patient outcomes relative to the usual care group. Generalized Estimating Equations included group (Medtable versus usual care), time, group  $\times$  time, and appropriate covariates. The group  $\times$  time interaction term evaluated intervention-related benefits that varied with the amount of time exposure to the Medtable collaborative tool. The assumption was that patients might need time to learn

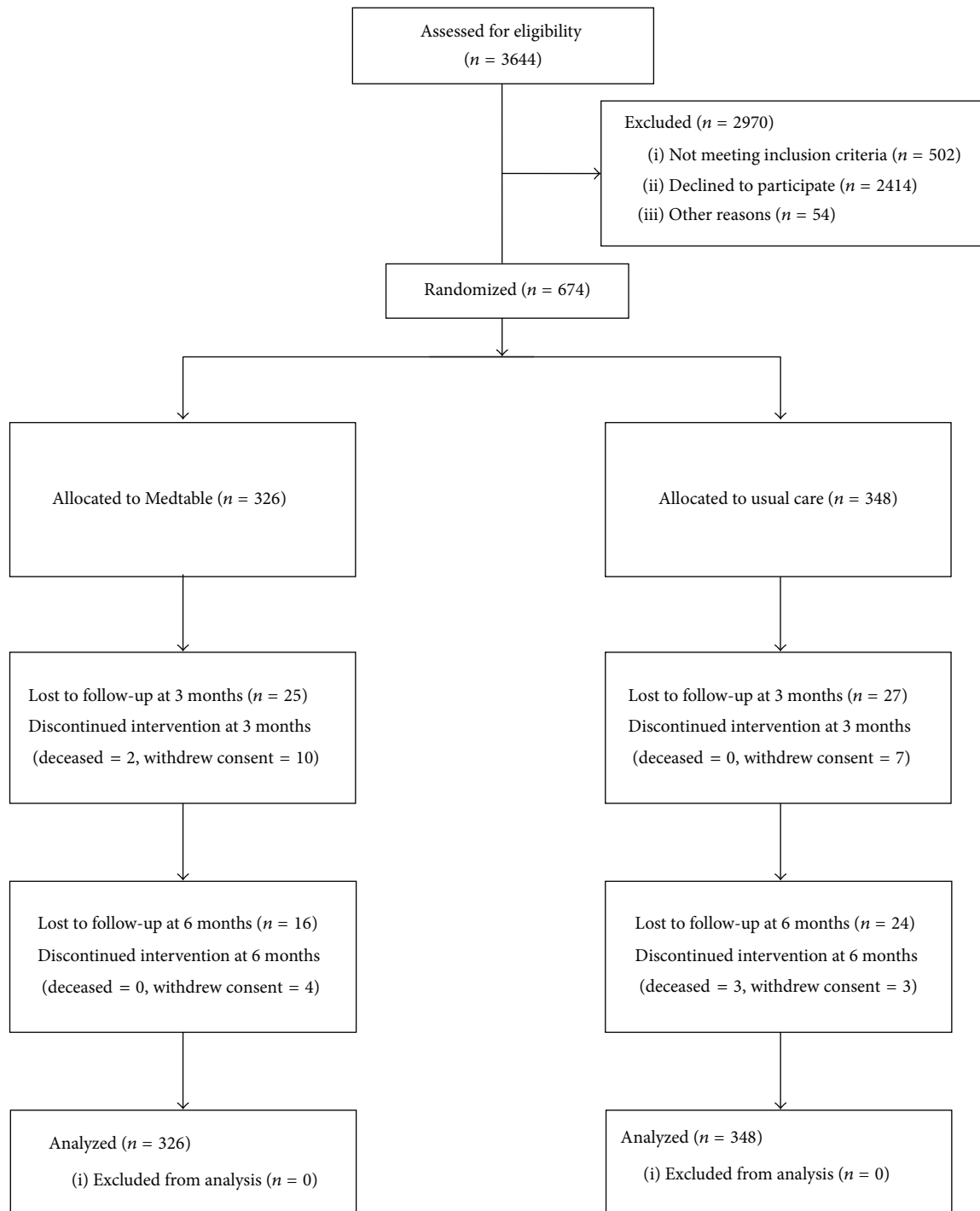


FIGURE 2: Trial flow diagram.

to use the tool to structure medication-taking strategies at home and to communicate with providers during office visits. Research site was included in all analyses.

### 3. Results

The researchers performed a clinical trial and screened 3644 outpatients. Clinical trial coordinators recruited participants

between September 2011 and October 2013. The trial flow diagram (Figure 2) shows the numbers of patients screened, excluded, randomized, and followed up. The patient-participants who received the randomized intervention, Medtable versus usual care, were comparable at baseline (Table 1) except for years with diabetes mellitus. The characteristics of the participants included age greater than 65 years for 43.3% (292/674), high school or less education



for 30.1% (203/674), and limited literacy (as measured by the REALM) for 22.3% (150/674).

One of the primary outcomes of the clinical trial was the effect of the intervention, Medtable versus usual care, on the patients' verbal knowledge of their medication regimen. To score the verbal knowledge, we used adjudicators who were blind to intervention allocation. Adjudicated results in Table 2 are for noninjectable medications. There was no difference between the intervention and control group for "combined verbal knowledge of the regimen for all questions" (Generalized Estimating Equation parameter group, adjusted  $p = 0.3035$ ; parameter group  $\times$  time, adjusted  $p = 0.6280$ ). Separate analyses for each question within the verbal knowledge score also revealed no consistent effect of the intervention. The only significant effect was for the following: "On a usual day, how many times a day do you take this medicine?" (Generalized Estimating Equation parameter group, adjusted  $p = 0.0373$ ; parameter group  $\times$  time, adjusted  $p = 0.5294$ ). The analysis of verbal knowledge of the regimen for injectable drugs showed similar results to noninjectable drugs (data available upon request).

The other primary outcome of the trial was the patient's demonstrated knowledge of their medication regimen. The adjudicators who scored the demonstrated knowledge were blind to intervention allocation. The results in Table 3 reveal no difference between the intervention and control group for "combined demonstration knowledge of the regimen for all 4 questions" (Generalized Estimating Equation parameter group, adjusted  $p = 0.3916$ ; parameter group  $\times$  time, adjusted  $p = 0.8227$ ). Separate analyses for each question within the demonstrated knowledge score exposed no consistent effect of the intervention.

Some evidence for the impact of the intervention on medication knowledge was provided by the measure of medication indication. Adjudicators who were blind to intervention allocation scored the patients' responses to the question, "What is the medicine for?" The results in Table 4 reveal significant increases in correct patient knowledge about indication in the Medtable intervention versus usual care group immediately after the beginning of the intervention that persisted for 6 months (Generalized Estimating Equation parameter group, adjusted  $p$  less than 0.0001).

Satisfaction with information about medicines was a prespecified secondary outcome. Patient-reported responses to five satisfaction questions were recorded by research personnel who were not blind to the intervention allocation. The results of the intention-to-treat analysis in Table 5 reveal that patients reported greater satisfaction with Medtable versus usual care at all times. The Generalized Estimating Equation for each satisfaction question included all time points and confirmed the significant increase with Medtable: all adjusted  $p$  values for group were less than 0.0161.

Medication adherence was a prespecified secondary outcome. Patient-reported adherence was recorded by research personnel who were not blind to the intervention allocation. The results for medication adherence appear in Table 6 and Figure 3. Adherence was greater at baseline in the usual care group and then adherence decreased monotonically over the next 6 months. In contrast, adherence in the Medtable group

TABLE 1: Baseline characteristics of 674 outpatients allocated to Medtable or usual care.

	Medtable N = 326	Usual care N = 348
Age, years, mean (SD)	63.8 (10.3)	63.5 (10.0)
Gender, n (%)		
Female	170 (52.1)	202 (58.1)
Male	156 (47.9)	146 (41.9)
Race, n (%)		
White	228 (69.9)	214 (61.9)
Black	79 (24.2)	118 (33.9)
Other	19 (5.8)	16 (4.6)
Education, n (%)		
High school or less	89 (27.3)	114 (33.0)
Some college or college graduate	237 (72.7)	231 (67.0)
Annual income, n (%)		
Less than \$20,000	63 (20.0)	79 (24.4)
\$20,000–\$50,000	109 (34.6)	114 (35.2)
Greater than \$50,000	143 (45.4)	131 (40.4)
Employed status, n (%)		
Full-time	82 (25.4)	73 (21.1)
Part-time	31 (9.6)	44 (12.7)
Not employed	210 (65.0)	229 (66.2)
REALM, mean (SD)	61.1 (8.8)	61.2 (8.9)
Health literacy, n (%)		
Limited, REALM less than 61	77 (23.6)	73 (21.0)
Adequate, REALM 61 and above	249 (76.4)	275 (79.0)
Pattern Comparison test, mean (SD)	27.2 (7.1)	26.5 (7.0)
Letter Comparison test, mean (SD)	17.4 (5.1)	16.9 (4.8)
Years with diabetes mellitus, mean (SD)	13.4 (9.7)	11.7 (9.2)
Diabetes mellitus knowledge, mean (SD)	18.8 (2.9)	18.6 (2.9)
Diabetes self-care activities		
Diet, mean (SD)	4.1 (2.1)	4.3 (2.1)
Exercise, mean (SD)	2.5 (2.1)	2.5 (2.0)
Glucose testing, mean (SD)	4.6 (2.7)	4.6 (2.7)
Comorbidity Index, mean (SD)	2.2 (1.8)	2.3 (1.7)
General health from SF-36, mean (SD)	51.3 (21.1)	50.4 (22.4)
Number of medications per patient, mean (SD)	7.3 (2.8)	7.2 (2.9)
Medication Regimen Complexity Index, mean (SD)	17.7 (7.6)	17.2 (7.7)
Dosage forms, mean (SD)	3.3 (2.5)	3.2 (2.8)
Dosage frequency, mean (SD)	10.9 (4.9)	10.7 (4.7)
Additional directions, mean (SD)	3.5 (2.3)	3.3 (2.4)

REALM: Rapid Estimate of Adult Literacy in Medicine.

remained flat and did not deteriorate over time. Figure 3 shows the difference in slopes for the Medtable group and usual care group. The Generalized Estimating Equation for



TABLE 2: Patient-reported verbal knowledge of the noninjectable medication regimen before and after intervention: Medtable versus usual care.

	Time	Medtable Mean (SD)	Usual care Mean (SD)	Unadjusted intervention effect (ITT)		Adjusted intervention effect (ITT)	
				OR (95% CI)	p value	OR (95% CI)	p value
Combined verbal knowledge of the regimen for all questions	Baseline, preintervention	0.808 (0.175)	0.802 (0.180)	1.03 (0.89, 1.18)	0.7059	1.05 (0.91, 1.21)	0.5470
	Immediate, postintervention	0.812 (0.172)	0.80 (0.176)	1.08 (0.94, 1.25)	0.2598	1.10 (0.96, 1.27)	0.1819
	Month 3	0.808 (0.180)	0.801 (0.168)	1.07 (0.93, 1.23)	0.3641	1.06 (0.92, 1.23)	0.4153
	Month 6	0.806 (0.184)	0.795 (0.179)	1.10 (0.95, 1.26)	0.1968	1.09 (0.94, 1.26)	0.2487
“On a usual day, how many times a day do you take this medicine?”	Baseline, preintervention	0.916 (0.113)	0.906 (0.131)	1.09 (0.89, 1.32)	0.4104	1.09 (0.89, 1.33)	0.4092
	Immediate, postintervention	0.923 (0.104)	0.910 (0.129)	1.12 (0.92, 1.37)	0.2556	1.13 (0.92, 1.38)	0.2576
	Month 3	0.924 (0.113)	0.904 (0.125)	1.31 (1.07, 1.60)	0.0092	1.29 (1.05, 1.59)	0.0142
	Month 6	0.925 (0.103)	0.912 (0.119)	1.26 (1.03, 1.54)	0.0273	1.23 (1.00, 1.52)	0.0492
“How many pills of this medicine do you take each time?”	Baseline, preintervention	0.877 (0.150)	0.881 (0.145)	1.01 (0.85, 1.20)	0.9125	1.04 (0.87, 1.23)	0.6930
	Immediate, postintervention	0.882 (0.147)	0.880 (0.143)	1.06 (0.89, 1.25)	0.5312	1.09 (0.92, 1.30)	0.3175
	Month 3	0.869 (0.161)	0.875 (0.140)	0.99 (0.83, 1.17)	0.8694	1.00 (0.84, 1.19)	0.9826
	Month 6	0.875 (0.153)	0.868 (0.142)	1.05 (0.88, 1.24)	0.5996	1.06 (0.90, 1.26)	0.4807
“How many pills of this medicine do you take each day in total?”	Baseline, preintervention	0.862 (0.147)	0.859 (0.154)	1.01 (0.86, 1.19)	0.8924	1.02 (0.87, 1.20)	0.7857
	Immediate, postintervention	0.866 (0.148)	0.852 (0.152)	1.10 (0.94, 1.29)	0.2376	1.12 (0.95, 1.32)	0.1810
	Month 3	0.867 (0.145)	0.858 (0.146)	1.09 (0.92, 1.28)	0.3222	1.08 (0.92, 1.28)	0.3435
	Month 6	0.870 (0.147)	0.862 (0.152)	1.14 (0.97, 1.34)	0.1201	1.12 (0.95, 1.33)	0.1874

ITT: intention-to-treat analysis. Covariates used for adjustment were health literacy (REALM), Letter Comparison test, Pattern Comparison test, diabetes mellitus knowledge, diabetes self-care: diet, diabetes self-care: exercise, diabetes self-care: glucose testing, years with diabetes mellitus, Comorbidity Index, general health, age, gender, race, patient education, research site, and Medication Regimen Complexity Index.

TABLE 3: Patient-demonstrated knowledge of the medication regimen before and after intervention: Medtable versus usual care.

	Time	Medtable Mean (SD)	Usual care Mean (SD)	Unadjusted intervention effect (ITT)		Adjusted intervention effect (ITT)	
				OR (95% CI)	p value	OR (95% CI)	p value
Combined demonstration knowledge of the regimen for all 4 questions	Baseline, preintervention	0.86 (0.15)	0.85 (0.16)	1.03 (0.88, 1.20)	0.7320	1.03 (0.88, 1.21)	0.7402
	Immediate, postintervention	0.86 (0.15)	0.85 (0.15)	1.08 (0.92, 1.26)	0.3560	1.09 (0.93, 1.29)	0.2799
	Month 3	0.86 (0.15)	0.85 (0.15)	1.07 (0.91, 1.26)	0.3916	1.06 (0.90, 1.25)	0.4814
	Month 6	0.86 (0.14)	0.86 (0.14)	1.08 (0.92, 1.27)	0.3676	1.06 (0.90, 1.26)	0.4763
When compared to the label, the patient demonstrates correct number of pills per dose	Baseline, preintervention	0.895 (0.131)	0.90 (0.13)	0.97 (0.81, 1.17)	0.7728	0.99 (0.82, 1.19)	0.8971
	Immediate, postintervention	0.9 (0.131)	0.90 (0.13)	1.05 (0.87, 1.26)	0.6274	1.09 (0.90, 1.31)	0.3880
	Month 3	0.90 (0.134)	0.89 (0.13)	0.95 (0.79, 1.14)	0.5549	0.95 (0.79, 1.14)	0.5925
	Month 6	0.902 (0.128)	0.91 (0.119)	0.99 (0.82, 1.20)	0.9553	1.00 (0.83, 1.22)	0.9839
When compared to the label, the patient demonstrates correct number of doses per day	Baseline, preintervention	0.89 (0.13)	0.88 (0.14)	1.03 (0.87, 1.23)	0.7262	1.03 (0.86, 1.24)	0.7093
	Immediate, postintervention	0.89 (0.126)	0.88 (0.14)	1.10 (0.92, 1.32)	0.2823	1.12 (0.93, 1.34)	0.2448
	Month 3	0.90 (0.129)	0.88 (0.139)	1.19 (0.99, 1.42)	0.0622	1.18 (0.98, 1.42)	0.0758
	Month 6	0.901 (0.127)	0.90 (0.126)	1.12 (0.93, 1.35)	0.2243	1.10 (0.91, 1.33)	0.3228
The patient demonstrates correct number of pills each day in total	Baseline, preintervention	0.87 (0.143)	0.87 (0.147)	1.04 (0.88, 1.23)	0.6258	1.04 (0.88, 1.23)	0.6504
	Immediate, postintervention	0.878 (0.140)	0.87 (0.14)	1.06 (0.90, 1.25)	0.5046	1.07 (0.90, 1.27)	0.4345
	Month 3	0.875 (0.136)	0.87 (0.14)	1.07 (0.91, 1.27)	0.4020	1.06 (0.90, 1.26)	0.4883
	Month 6	0.880 (0.134)	0.88 (0.135)	1.07 (0.90, 1.26)	0.4623	1.05 (0.88, 1.25)	0.5656
The patient demonstrates correct amount of time (spacing) between doses	Baseline, preintervention	0.89 (0.130)	0.88 (0.147)	1.02 (0.86, 1.21)	0.8340	1.02 (0.85, 1.22)	0.8082
	Immediate, postintervention	0.90 (0.126)	0.88 (0.14)	1.09 (0.91, 1.30)	0.3301	1.11 (0.93, 1.33)	0.2611
	Month 3	0.90 (0.130)	0.88 (0.14)	1.17 (0.98, 1.40)	0.0855	1.17 (0.97, 1.40)	0.1104
	Month 6	0.9 (0.127)	0.89 (0.126)	1.12 (0.93, 1.34)	0.2457	1.09 (0.91, 1.32)	0.3525

ITT: intention-to-treat analysis. Covariates used for adjustment were health literacy (REALM), Letter Comparison test, diabetes mellitus knowledge, diabetes self-care: diet, diabetes self-care: exercise, diabetes self-care: glucose testing, years with diabetes mellitus, Comorbidity Index, general health, age, gender, race, patient education, research site, and Medication Regimen Complexity Index.

TABLE 4: Patients-reported knowledge about the indications for medicines in their regimen before and after intervention: Medtable versus usual care.

	Time	Medtable Mean (SD)	Usual care Mean (SD)	Unadjusted intervention effect (ITT)		Adjusted intervention effect (ITT)	
				OR (95% CI)	p value	OR (95% CI)	p value
Combined knowledge of the indication for drugs in the regimen, “what is the medicine for?”	Baseline, preintervention	0.87 (0.21)	0.87 (0.20)	1.04 (0.88, 1.23)	0.6815	1.06 (0.89, 1.27)	0.4977
	Immediate, postintervention	0.94 (0.12)	0.88 (0.19)	2.22 (1.80, 2.74)	<0.0001	2.32 (1.86, 2.88)	<0.0001
	Month 3	0.95 (0.12)	0.88 (0.19)	2.34 (1.88, 2.91)	<0.0001	2.45 (1.95, 3.09)	<0.0001
	Month 6	0.96 (0.09)	0.91 (0.17)	2.35 (1.86, 2.98)	<0.0001	2.53 (1.97, 3.25)	<0.0001

ITT: intention-to-treat analysis. Covariates used for adjustment were health literacy (REALM), Letter Comparison test, diabetes mellitus knowledge, diabetes self-care: diet, diabetes self-care: exercise, diabetes self-care: glucose testing, years with diabetes mellitus, Comorbidity Index, general health, age, gender, race, patient education, and Medication Regimen Complexity Index.

TABLE 5: Patient-reported satisfaction with information about medicines after intervention: Medtable versus usual care.

Satisfaction question	Time	Medtable N = 326 n (%)	Usual care N = 348 n (%)	Unadjusted intervention effect (ITT) OR (95% CI)	p value	Adjusted intervention effect (ITT) OR (95% CI)	p value
“What your medicine is called”	Immediate, postintervention	314 (96.3%)	289 (83.0%)	5.34 (2.81, 10.14)	<0.0001	5.84 (3.00, 11.38)	<0.0001
	Month 3	281 (86.2%)	246 (70.7%)	2.60 (1.75, 3.83)	<0.0001	2.85 (1.88, 4.31)	<0.0001
	Month 6	253 (77.6%)	237 (68.1%)	1.62 (1.15, 2.29)	0.0058	1.57 (1.09, 2.25)	0.0146
“What your medicine is for”	Immediate, postintervention	319 (97.9%)	298 (85.6%)	7.65 (3.41, 17.13)	<0.0001	8.91 (3.87, 20.53)	0.0001
	Month 3	285 (87.4%)	247 (71.0%)	2.84 (1.90, 4.24)	<0.0001	3.10 (2.02, 4.74)	<0.0001
	Month 6	261 (80.1%)	238 (68.4%)	1.86 (1.30, 2.64)	0.0006	1.82 (1.26, 2.63)	0.0014
“How to use your medicine”	Immediate, postintervention	315 (96.6%)	279 (80.2%)	7.08 (3.67, 13.65)	<0.0001	8.03 (4.07, 15.85)	<0.0001
	Month 3	285 (87.4%)	233 (67.0%)	3.43 (2.31, 5.10)	<0.0001	3.83 (2.52, 5.84)	<0.0001
	Month 6	254 (77.9%)	225 (64.7%)	1.93 (1.37, 2.71)	0.0002	1.19 (1.32, 2.70)	0.0005
“Whether the medicine has any unwanted effects (side effects)”	Immediate, postintervention	225 (69.0%)	229 (65.8%)	1.16 (0.84, 1.60)	0.3740	1.18 (0.84, 1.66)	0.3495
	Month 3	207 (63.5%)	188 (54.0%)	1.48 (1.09, 2.02)	0.0127	1.61 (1.16, 2.25)	0.0048
	Month 6	194 (59.5%)	190 (54.6%)	1.22 (0.90, 1.70)	0.1983	1.20 (0.87, 1.65)	0.2622
“Whether the medicine interferes with other medicines”	Immediate, postintervention	212 (65.0%)	216 (62.1%)	1.14 (0.83, 1.56)	0.4249	1.10 (0.78, 1.55)	0.5803
	Month 3	189 (58.0%)	171 (49.1%)	1.43 (1.05, 1.94)	0.0217	1.55 (1.11, 2.16)	0.0096
	Month 6	187 (57.4%)	167 (48.0%)	1.46 (1.08, 1.98)	0.0150	1.50 (1.08, 2.08)	0.0147

ITT: intention-to-treat analysis. Covariates used for adjustment were health literacy (REALM), Letter Comparison test, diabetes mellitus knowledge, diabetes self-care: diet, diabetes self-care: exercise, diabetes self-care: glucose testing, years with diabetes mellitus, Comorbidity Index, general health, age, gender, race, patient education, research site, and Medication Regimen Complexity Index.

TABLE 6: Patients-reported adherence to their medication regimen before and after intervention: Medtable versus usual care.

	Time	Medtable	Usual care	Unadjusted intervention effect (ITT)		Adjusted intervention effect (ITT)	
		Mean (SD)	Mean (SD)	OR (95% CI)	<i>p</i> value	OR (95% CI)	<i>p</i> value
Regimen adherence score	Baseline, preintervention	0.80 (0.26)	0.84 (0.23)	0.83 (0.72, 0.96)	0.0115	0.78 (0.68, 0.91)	0.001
	Month 3	0.82 (0.19)	0.81 (0.20)	1.09 (0.95, 1.25)	0.2028	1.05 (0.92, 1.21)	0.4636
	Month 6	0.80 (0.20)	0.75 (0.21)	1.17 (1.03, 1.32)	0.0156	1.13 (0.999, 1.29)	0.0526

ITT: intention-to-treat analysis. Covariates used for adjustment were health literacy (REALM), Letter Comparison test, Pattern Comparison test, diabetes mellitus knowledge, diabetes self-care: diet, diabetes self-care: exercise, diabetes self-care: glucose testing, years with diabetes mellitus, Comorbidity Index, general health, age, gender, race, patient education, research site, and Medication Regimen Complexity Index.

TABLE 7: Glycosylated hemoglobin (HbA1c) before and after intervention: Medtable versus usual care.

Time	Medtable	Usual care	Unadjusted intervention effect (ITT)		Adjusted intervention effect (ITT)	
	Mean (SD)	Mean (SD)	Coefficient (95% CI)	<i>p</i> value	Coefficient (95% CI)	<i>p</i> value
Baseline, preintervention	8.06 (1.55)	8.05 (1.63)	0.01 (−0.23, 0.25)	0.9506	0.04 (−0.19, 0.27)	0.7164
Month 3	7.80 (1.37)	7.92 (1.61)	−0.09 (−0.33, 0.14)	0.4508	−0.09 (−0.32, 0.13)	0.4090
Month 6	7.75 (1.41)	7.91 (1.61)	−0.14 (−0.37, 0.10)	0.2535	−0.15 (−0.38, 0.07)	0.1823
Month 9	7.82 (1.46)	8.0 (1.69)	−0.14 (−0.40, 0.11)	0.2680	−0.16 (−0.39, 0.07)	0.1811
Month 12	7.75 (1.33)	7.93 (1.64)	−0.12 (−0.35, 0.11)	0.3130	−0.15 (−0.37, 0.07)	0.1904

ITT: intention-to-treat analysis. Covariates used for adjustment were health literacy (REALM), Letter Comparison test, Pattern Comparison test, diabetes mellitus knowledge, diabetes self-care: diet, diabetes self-care: exercise, diabetes self-care: glucose testing, years with diabetes mellitus, Comorbidity Index, general health, age, gender, race, patient education, research site, and Medication Regimen Complexity Index.

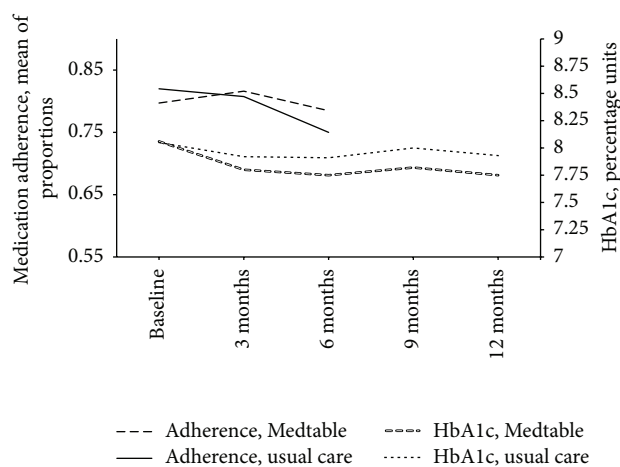


FIGURE 3: Medication adherence and glycosylated hemoglobin (HbA1c) before and after intervention: Medtable versus usual care.

adherence reflects the difference in slopes in the group  $\times$  time interaction: adjusted  $p = 0.0268$ . However, the GEE for adherence did not reveal a significant overall effect of Medtable: group adjusted  $p$  value = 0.7423.

Glycosylated hemoglobin (HbA1c) was a prespecified secondary outcome that was abstracted from the patient record. HbA1c results are in Table 7 and Figure 3. Regardless of the intervention group, patients had significant decreases (improvements) in their HbA1c during their time in the trial: the adjusted parameter estimate for time in the Generalized Estimating Equation had  $p$  less than 0.0001. There were no significant differences in HbA1c between the intervention

groups. In the Generalized Estimating Equation for HbA1c, the parameter for group had adjusted  $p = 0.3639$  and the parameter for group  $\times$  time had adjusted  $p = 0.6079$ .

Table 8 has knowledge and adherence outcomes within strata defined by limited or adequate literacy. For verbal and demonstrated knowledge of the regimen, there was no apparent effect of Medtable in either stratum. Patients' knowledge of drug indication improved with Medtable regardless of their literacy status. For regimen adherence, the improvements caused by Medtable were seen in patients with adequate literacy and were only demonstrable at the sixth month.

#### 4. Discussion

The Medtable intervention increased patient satisfaction with communication about medications during clinic visits. However, there was only mixed evidence that the intervention also improved patients' knowledge about their medications. Knowledge about medication indication improved in the Medtable group. In contrast, the Medtable did not improve verbal or demonstration measures of knowledge about directions for use. The intervention also sustained adherence to medications during the trial while adherence declined in the control group, but the overall difference with the usual care control group was not significant. Finally, the intervention did not influence HbA1c levels, which declined (better glycemic control) equally for the two groups during the trial.

The study results are partially consistent with the process-knowledge model of health literacy [8]. According to this model, improving health knowledge (medication knowledge in our study) should improve self-care behaviors (adherence



TABLE 8: Stratified analysis by patients' literacy status for knowledge of and adherence to the noninjectable medication regimen before and after intervention: Medtable versus usual care.

	Time	Health literacy	Medtable Mean (SD)	Usual care Mean (SD)	Unadjusted intervention effect (ITT) OR (95% CI)	<i>p</i> value
Combined verbal knowledge of the regimen for all questions	Baseline, preintervention	Limited	0.81 (0.17)	0.82 (0.17)	0.89 (0.66, 1.20)	0.4457
		Adequate	0.81 (0.18)	0.80 (0.18)	1.07 (0.91, 1.25)	0.4332
	Immediate, postintervention	Limited	0.82 (0.15)	0.82 (0.16)	0.92 (0.68, 1.24)	0.5775
		Adequate	0.81 (0.18)	0.79 (0.18)	1.13 (0.96, 1.32)	0.1341
	Month 3	Limited	0.82 (0.16)	0.81 (0.17)	1.06 (0.78, 1.44)	0.6997
		Adequate	0.80 (0.19)	0.80 (0.17)	1.06 (0.90, 1.25)	0.4644
	Month 6	Limited	0.80 (0.17)	0.83 (0.19)	0.94 (0.69, 1.28)	0.6845
		Adequate	0.81 (0.19)	0.79 (0.18)	1.14 (0.97, 1.34)	0.1061
Combined demonstration knowledge of the regimen for all 4 questions	Baseline, preintervention	Limited	0.86 (0.15)	0.87 (0.16)	0.83 (0.59, 1.17)	0.2828
		Adequate	0.85 (0.15)	0.84 (0.16)	1.08 (0.91, 1.29)	0.3790
	Immediate, postintervention	Limited	0.87 (0.14)	0.88 (0.14)	0.77 (0.54, 1.09)	0.1399
		Adequate	0.86 (0.15)	0.84 (0.16)	1.17 (0.98, 1.40)	0.0838
	Month 3	Limited	0.86 (0.15)	0.86 (0.16)	1.01 (0.72, 1.43)	0.9444
		Adequate	0.86 (0.15)	0.85 (0.14)	1.09 (0.91, 1.30)	0.3630
	Month 6	Limited	0.86 (0.15)	0.89 (0.13)	0.88 (0.62, 1.25)	0.4740
		Adequate	0.87 (0.14)	0.86 (0.14)	1.14 (0.95, 1.37)	0.1711
Combined knowledge of the indication for drugs in the regimen, "what is the medicine for?"	Baseline, preintervention	Limited	0.83 (0.26)	0.83 (0.24)	1.09 (0.79, 1.50)	0.6025
		Adequate	0.89 (0.19)	0.88 (0.19)	1.04 (0.85, 1.27)	0.6921
	Immediate, postintervention	Limited	0.93 (0.14)	0.84 (0.23)	2.44 (1.66, 3.59)	<0.0001
		Adequate	0.95 (0.12)	0.89 (0.18)	2.20 (1.72, 2.82)	<0.0001
	Month 3	Limited	0.94 (0.13)	0.83 (0.24)	2.56 (1.73, 3.80)	<0.0001
		Adequate	0.96 (0.11)	0.90 (0.17)	2.33 (1.79, 3.04)	<0.0001
	Month 6	Limited	0.94 (0.11)	0.85 (0.23)	2.29 (1.53, 3.44)	<0.0001
		Adequate	0.97 (0.09)	0.92 (0.16)	2.51 (1.87, 3.37)	<0.0001
Regimen adherence score	Baseline, preintervention	Limited	0.76 (0.28)	0.80 (0.24)	0.68 (0.51, 0.90)	0.0077
		Adequate	0.81 (0.25)	0.83 (0.22)	0.91 (0.77, 1.07)	0.2438
	Month 3	Limited	0.80 (0.21)	0.80 (0.19)	0.97 (0.74, 1.27)	0.8269
		Adequate	0.83 (0.19)	0.81 (0.20)	1.15 (0.98, 1.34)	0.0858
	Month 6	Limited	0.78 (0.22)	0.76 (0.18)	0.99 (0.77, 1.28)	0.9656
		Adequate	0.81 (0.19)	0.75 (0.21)	1.23 (1.07, 1.42)	0.0040

REALM: Rapid Estimate of Adult Literacy in Medicine. Patients with limited literacy had REALM scores less than 61. Adequate literacy was a REALM score of 61 and above. ITT: intention-to-treat analysis.

in this case), which in turn should influence outcomes such as HbA1c. While use of the Medtable by nurses and patients in the clinics influenced collaboration (reflected by improved patient satisfaction) and improved some aspects of patients' medication knowledge (knowledge about indication but not directions for use), the intervention had only limited impact on adherence. Moreover, the intervention did not improve health outcomes as measured by HbA1c. Our results are similar to a recent trial in which a computer-based decision aid designed to support self-care planning among patients with diabetes improved patient perceptions of information clarity and helpfulness, but not health knowledge or outcomes [31].

The finding that the Medtable intervention improved patient satisfaction with provider communication might be important because patient satisfaction is linked to quality and reimbursement [50]. The Medicare Shared Savings

Program and other Pay-for-Performance Programs rely on patient satisfaction measures, specifically the Clinician and Group Survey, Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) [51]. A limitation of our study is the unknown correlation between Satisfaction with Information about Medicines Scales (SIMS) and broader measures of satisfaction, like CG-CAHPS, which are used for value-based purchasing. Future studies should include measures like CG-CAHPS to assess patient satisfaction with the Medtable.

The intervention may have had an attenuated impact on medication knowledge for several reasons. First, performance on both the verbal and the demonstration measures approached ceiling, perhaps reducing the ability of the measures to detect differences between conditions. Second, taking the results at face value, they suggest that usual care practices

related to patient education and medication reconciliation at the research site clinics were effective in supporting patients' knowledge about medication.

The limited impact of the intervention on medication adherence may reflect the fact that adherence was self-reported in this study, which can overestimate adherence [52]. More objective measures of adherence might have been more sensitive to potential intervention effects. The intervention may also have had a limited effect on adherence because of its selective effect on participants' medication knowledge. While it is important for patients to know what medications are used for, it is equally if not more important to know how to take the medication, and both groups of participants in the study demonstrated good knowledge about directions for use. In addition, adherence is a complex behavior that is influenced by many factors in addition to medication knowledge, such as patient self-efficacy and cost of the medication. It is also possible that the intervention improved planning for taking medication when working with providers at the clinics, but patients had difficulty implementing these plans at home due to either cost, health, unmeasured socioeconomic factors, or prioritization.

The intervention did not improve HbA1c, which tended to improve equally in both groups. This may well reflect the limited impact of the intervention on medication knowledge and adherence. Also, like medication adherence, HbA1c is influenced by a range of patient factors [53]. Therefore, an intervention designed to improve knowledge and planning for how to take medication might have a limited impact on this outcome, even if it had had a large impact on knowledge. For example, only four of 15 studies investigating impact of communication interventions on patients with cardiovascular disease showed improved clinical outcomes [54]. It is also possible that 6 months was too short for the intervention to produce detectable effects on health outcomes.

One of the limitations of our trial design was the unmasked intervention. For participants assigned to usual care, their clinic nurses may have changed communication and collaborative planning after observation of colleagues who used the Medtable. This phenomenon is encountered in unmasked trials and is called contamination. We attempted to minimize contamination when we blocked the Medtable display in the electronic medical records of participants assigned to usual care. However, some contamination was inevitable. When contamination occurred, there was bias toward the null (increased type II error).

Another limitation of the study is the generalizability of the results. Only 18% (674/3644) of the patients in the screening population provided consent to participate in our trial. The results of our study are most applicable to ambulatory clinic populations that resemble the characteristics reported in Table 1.

The Medtable tool supported provider/patient collaboration related to medication use, as reflected in patient satisfaction with communication, but had limited impact on patient medication knowledge, adherence, and outcomes. A possible reason for this pattern is that the tool as implemented in this study was designed to support collaboration in the

clinic but did not support patients at home when taking their medication. Integrating the tool into smartphones or other patient-centered technologies used at home, especially if integrated with provider information technology (e.g., electronic health record patient portal), may support distributed collaboration between providers and patients at home, so that patients can more easily implement plans and update them as medication regimens change.

## Disclosure

Any opinions, findings, and conclusions or recommendations expressed in this publication are those of the authors and do not necessarily reflect the views of the NIH.

## Competing Interests

The authors declare that there are no competing interests regarding the publication of this paper.

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## Research Article

# Patient Activation in Type 2 Diabetes: Does It Differ between Men and Women?

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**Background.** Aim was to investigate whether the degree of patient activation of patients with type 2 diabetes (T2D) is different between men and women. Furthermore, we investigated which factors are associated with patient activation in men and women. **Methods.** This cross-sectional study included 1615 patients with T2D from general practices. Patient activation was measured with the Patient Activation Measure (PAM) questionnaire. Multivariate linear regression analyses were used to investigate the association between gender and patient activation. Stratified analyses according to gender were performed to investigate which factors are associated with patient activation. **Results.** No association between gender and PAM score was found after adjustment for all selected confounders ( $p = 0.094$ ). In men, lower age ( $p = 0.001$ ), a higher WHO-5 score ( $p < 0.001$ ), and a lower BMI ( $p = 0.013$ ) were associated with a higher PAM score. In women, a higher WHO-5 score ( $p < 0.017$ ) and the absence of macrovascular complications ( $p < 0.031$ ) were associated with a higher PAM score. **Conclusion.** There is no difference in the degree of patient activation of men and women with T2D. Age, well-being, and BMI were found to be associated with patient activation in men, whereas well-being and macrovascular complications were found to be associated with patient activation in women.

## 1. Introduction

Patient participation is essential to achieve and maintain good overall and diabetes control. The Association of American Diabetes Educators (AADE) has defined 7 self-care behaviours, which are essential for successful and effective diabetes self-management. These are healthy eating, being active, taking medication, monitoring, problem solving, healthy coping, and reducing risks of diabetes-related complications [1].

Not all subjects with type 2 diabetes (T2D) are equally capable of performing these self-care tasks as performing

these tasks requires knowledge, discipline, and perseverance. To measure someone's ability to take control of his or her own health, Hibbard et al. developed the Patient Activation Measure (PAM) questionnaire [2, 3]. They have defined patient activation as someone's knowledge, skills, and confidence needed for self-management [2]. According to the developers, patients go through four stages of patient activation and every stage needs a different approach. Patient activation starts with convincing patients that their own actions can have a positive influence on health. Subsequently, attention should be paid to obtaining an adequate knowledge base for making good choices. Thirdly, attention should be



given to confidence building by achieving success in very small behavioural modification steps. In the final stage, attention should be given to extending and maintaining of behaviour change [4].

A lower PAM level could possibly lead to poorer health outcomes, as studies have shown that a lower PAM level is associated with poorer HbA1c control, fewer feet checks and eye examinations, lower rates of regular physical exercise, and more use of hospital resources [4–6].

Studies concerning differences in patient activation between men and women with chronic diseases show contradictory results [6–10]. Two studies found a higher level of patient activation in men [7, 9], whereas three other studies did not find a difference between men and women in the level of patient activation [6, 8, 10]. However, all of these studies did not adjust for some important factors, which could have influenced the relation between gender and patient activation. Women with T2D have a lower degree of well-being, a lower health-related quality of life, and a higher body mass index (BMI) and use more often insulin whereas they are less often smokers and have less macrovascular complications compared to men with T2D [11–13]. Well-being, physical health status, and BMI are all associated with patient activation [8]. Therefore, we hypothesized that differences in patient activation between men and women might possibly be influenced by well-being, quality of life, and lifestyle factors. If differences in patient activation between men and women exist, this may indicate that the level of self-management tasks should be more gender specific to achieve optimal health outcomes in both genders. It is unknown whether there are other factors associated with patient activation in men or women. Identifying these associations may indicate gender specific factors to focus on when improving patient activation. Therefore, the aim of our study was to investigate whether the level of patient activation differs between men and women with T2D. Furthermore, we have investigated whether there are other factors associated with degree of patient activation in men compared to women.

## 2. Materials and Methods

**2.1. Study Population and Setting.** The study population consisted of patients with T2D who were treated in primary care in three regions in the eastern part of the Netherlands. These patients were approached for a quality assessment concerning patient satisfaction performed by Medrie, an organization which facilitates and supports general practitioners (GPs). All patients were asked by their care provider to fill out a survey including questionnaires on quality of life, level of patient activation, and experience with the received care. Patients were included in the period from July 2014 until April 2015. A total of 5925 sets of questionnaires were sent to all general practices in the regions together. All general practices were asked to invite patients with T2D to fill out these questionnaires. Finally, 2319 patients with T2DM gave written informed consent. The other patients refused participation or the GPs did not include the requested number of patients.

The final study sample consisted of 1688 (72.8%) patients; see for more details the flowchart in Figure 1.

**2.2. Patient Activation Questionnaire.** In this study the Dutch version of the PAM was used which was validated by NIVEL (Netherlands Institute for Health Services Research) [9]. The questionnaire consists of 13 items which measure knowledge, skills, confidence, and behaviours needed for self-management. Each item has five different response categories: (1) disagree strongly, (2) disagree, (3) agree, (4) agree strongly, and (5) not applicable. In the current study, the same scoring rules as in the Dutch validation study of the PAM were used [9]. Patients who filled out less than 7 items or who answered all items with disagree strongly or agree strongly were excluded. Subsequently, mean scores for the PAM were calculated leaving out items which were responded to with not applicable. The mean scores were transformed into a PAM score ranging from 0 to 100 based on scoring rules of Insignia Health [14]. Based on the same rules, the PAM score was also converted into the four levels of patient activation.

**2.3. Data Collection.** All patients filled out a survey which consisted of the PAM questionnaire for measuring degree of patient activation, the WHO-5 for measuring well-being, and the EQ5D for measuring quality of life [15–17]. The WHO-5 questionnaire consists of descriptions of five different positive feelings: “I have felt cheerful and in good spirits,” “I have felt calm and relaxed,” “I have felt active and vigorous,” “I woke up feeling fresh and rested,” and “my daily life has been filled with things that interest me.” Each feeling has 6 answer options ranging from 0 (not present) to 5 (constantly present) [15]. The EQ5D measures health-related quality of life on five health dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 3 answer options: no problems, some problems, and extreme problems [16]. In this study, the sum scores for the WHO-5 and EQ5D were used.

Demographic and clinical data were collected from the personal health record systems of the GPs. These data were collected during the annual check-up of the patients by their GP and were already routinely sent to the Diabetes Centre (Zwolle, the Netherlands) for benchmark and study purposes. Clinical data that were collected in the period from 9 months before till 5 months after the questionnaire were used. The following data were extracted: age, gender, diabetes duration, BMI, smoking status, HbA1c, use of glucose lowering medication, and the presence of micro- and/or macrovascular complications. The presence of microvascular complications was defined as having microalbuminuria, diabetes retinopathy, and/or diminished sensibility of the feet. The presence of macrovascular complications was defined as (a history of) angina pectoris, myocardial infarction, percutaneous transluminal coronary angioplasty, coronary artery bypass grafting, stroke or transient ischemic attack, or the use of thrombocyte aggregation inhibitors.

**2.4. Statistical Analysis.** Statistical analyses were performed using SPSS version 22 (IBM Corporation, Somers, NY, USA).

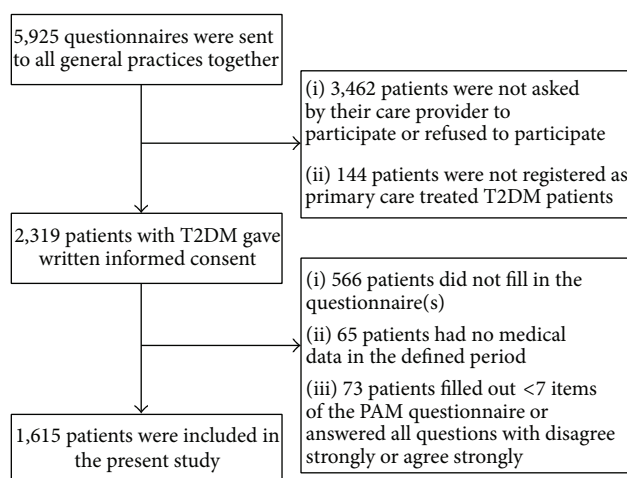


FIGURE 1: Flowchart of inclusion.

Multiple imputations were used for missing data on the independent variables, assuming that data was missing at random (MAR) or completely at random (MCAR). Ten imputed datasets were created and the pooled results are described. The patient characteristics are expressed as mean with standard deviation (SD) or median with interquartile range (IQR) for normally distributed and nonnormally distributed data, respectively. Categorical variables are described in numbers and percentages. Differences were considered to be significant at a  $p$  value of  $<0.05$ . The association between gender and patient activation was investigated with multivariate linear regression using the continuous PAM score. Four models were used: (1) a crude model, (2) a model adjusted for age, (3) a model adjusted for age, well-being, quality of life, BMI, smoking, presence of macrovascular complications (MVC), and the use of insulin, and (4) an explorative model with all variables in model (3) and the following diabetes-related factors: HbA1c, diabetes duration, use of oral glucose lowering drugs, and the presence of microvascular complications. These diabetes-related confounders were added to investigate whether the burden of T2D may confound the relation between gender and PAM. Interaction was tested at the 0.10 probability level between gender and well-being, gender and quality of life, gender and BMI, and gender and smoking in models (3) and (4). Interaction terms were only tested if interaction was plausible based on theoretical grounds, and they were only included in the fully adjusted model when they were statistically significant. Stratified analyses according to gender were performed to investigate which factors are associated with patient activation in men and women. For this purpose, model (3) and model (4) were used. The degree to which the different models determined the PAM score was evaluated by the explained variance, shown as adjusted  $R^2$ . Before analyses, the WHO-5 and EQ5D scores were tested for presence of multicollinearity.

**2.5. Ethical Approval.** All patients gave written informed consent for the use of the survey data and the clinical data.

According to Dutch guidelines this research does not fall under the scope of the Medical Research Involving Human Subjects Act, and therefore this study does not need a formal approval of an accredited METC (The Medical Ethics Committee of the Isala, Zwolle, the Netherlands).

### 3. Results

**3.1. Patient Characteristics.** The patient characteristics are described in Table 1. Fifty-four percent of the patients were male. Mean age was 67.1 (SD: 9.2) years in men and 68.9 (SD: 10.1) years in women, who were significantly older than men ( $p < 0.001$ ). Men had significantly higher scores on the WHO-5 and EQ5D questionnaires compared to women. Men smoked more frequently and they had also more often micro- and macrovascular complications compared to women. The BMI was significantly higher in women. A higher percentage of men used oral glucose lowering drugs.

**3.2. Association of Gender.** The median PAM score and the distribution of the PAM levels are described in Table 1. The median PAM score was 55.6 (IQR: 51.0–63.1) in men and 55.6 (IQR: 48.9–61.9) in women. The distribution of the PAM levels did not significantly differ between men and women ( $p = 0.294$ ). The results of the regression analyses are described in Table 2. In all models gender was not associated with the PAM score. In the final model (model (3)) a lower age ( $b = -0.13$ ;  $p < 0.001$ ), a higher WHO-5 score ( $b = 0.16$ ;  $p < 0.001$ ), and a lower BMI ( $b = -0.16$ ;  $p < 0.010$ ) were associated with a higher PAM score. No interaction was found between gender and WHO-5 score, gender and EQ5D score, gender and BMI, and gender and smoking. In the explorative model (model (4)), all diabetes-related factors (HbA1c, diabetes duration, use of oral glucose lowering drugs, and the presence of microvascular complications) were not associated with the PAM score. Adding these diabetes-related variables did not significantly affect the results of model (3).

TABLE 1: Patient characteristics.

	Men	Women	<i>p</i> value
<i>n</i> (%)	874 (54.1)	741 (45.9)	—
Mean age (years)	67.1 (9.2)	68.9 (10.1)	<0.001
Median WHO-5 score	76 (60–80)	72 (52–80)	<0.001
Median EQ5D score	0.9 (0.8–1.0)	0.8 (0.8–1.0)	<0.001
Median BMI	28.0 (26.0–31.4)	30.0 (26.7–34.0)	<0.001
Smoking, <i>n</i> (%)	136 (15.6)	73 (9.9)	0.001
MVC, <i>n</i> (%)	411 (47.0)	244 (32.9)	<0.001
Use of glucose lowering drugs, <i>n</i> (%)	697 (79.7)	560 (75.6)	0.047
Use of insulin, <i>n</i> (%)	144 (16.5)	133 (17.9)	0.466
Median diabetes duration	8.3 (4.8–12.1)	8.3 (4.4–12.7)	0.884
Median HbA1c (mmol/mol)	50 (45–56)	51 (45–57)	0.426
Microvascular complications, <i>n</i> (%)	401 (45.9)	292 (39.4)	0.006
Median PAM score	55.6 (51.0–63.1)	55.6 (48.9–61.9)	0.235
PAM level			0.294
1	151 (17.3)	131 (17.7)	
2	200 (22.9)	187 (25.2)	
3	433 (49.5)	334 (45.1)	
4	90 (10.3)	89 (12.0)	

Values are depicted as *n* (%), mean (SD), or median (IQR). Continuous data were analysed using independent *t*-tests or the Mann-Whitney *U* test. Categorical variables were analysed using Chi-square tests.

BMI: body mass index; MVC: macrovascular complications.

Number of patients with missing values: WHO-5: 15, EQ5D: 46, BMI: 23, smoking: 25, MVC: 352, diabetes duration: 8, HbA1c: 22, and microvascular complications: 352.

**3.3. Stratified Analyses According to Gender.** Stratified analyses according to gender are described in Table 3. In men, lower age ( $b = -0.18$ ;  $p = 0.001$ ), a higher WHO-5 score ( $b = 0.15$ ;  $p < 0.001$ ), and a lower BMI ( $b = -0.220$ ;  $p = 0.013$ ) were associated with a higher PAM score in model (3) ( $R^2$  8.5%). In women, a higher WHO-5 score ( $b = 0.17$ ;  $p < 0.001$ ) and the absence of macrovascular complications ( $b = -2.35$ ;  $p < 0.031$ ) are associated with a higher PAM score in model (3) ( $R^2$  10.7%). In the explorative model (model (4)), no associations were found between HbA1c, diabetes duration, use of oral glucose lowering drugs, the presence of microvascular complications, and the PAM score in men or women.

## 4. Discussion

The results of this study show that no difference in degree of patient activation was found between men and women with T2D treated in primary care. Within men, age, well-being, and BMI were found to be associated with degree of patient activation whereas, in women, well-being and MVC were related to patient activation.

Although some studies have investigated differences in patient activation between men and women [6–10], our study is the first study having investigated this relationship in particular. Two other Dutch studies among patients with chronic diseases found a slightly higher level of patient activation in men [7, 9]. Another Dutch study among patients with chronic diseases could not indicate gender as an explanatory determinant for patient activation [8]. Furthermore, two

studies from the USA in patients with T2D could also not ascertain a relation between gender and patient activation [6, 10]. However, all of these studies did not adjust for gender-related confounders. Women with T2D have a lower degree of well-being, a lower health-related quality of life, and a higher BMI compared to men with T2D [11, 12]. Well-being, physical health status, and BMI are all associated with patient activation [8]. Therefore, these factors may confound the effect of gender on patient activation. Although these factors differ between men and women in our present study, adjusting for these factors did not influence the relation between gender and patient activation.

We found that a lower degree of well-being was associated with a lower level of patient activation in both men and women. It attributed for 73% and 90% to the explained variance in the final model in men and women, respectively (data not shown). Although a strong association between well-being and patient activation seems to be present, the effect of well-being is rather small as the total explained variance was only 8.4% and 10.4% in the final models for men and women, respectively. A low degree of well-being could indicate the presence of depression, which was found to be associated with patient activation in a previous Dutch study among patients with chronic diseases [8, 18]. This association is not surprising as one can imagine that the inability to feel pleasure (anhedonia), which is one of the main symptoms of depression, will lead to a low level of patient activation [19]. On the other hand, patients with low patient activation are less capable of performing adequate self-management tasks which may lead to lower well-being.

TABLE 2: Multivariate regression analysis for patient activation.

Variables	Model (1)			Model (2)			Model (3)			Model (4) (explorative)		
	Adjusted $R^2$ (%) = 0.0%	$b$ (95% CI)	$p$ value	Adjusted $R^2$ (%) = 0.1%	$b$ (95% CI)	$p$ value	Adjusted $R^2$ (%) = 9.6%	$b$ (95% CI)	$p$ value	Adjusted $R^2$ (%) = 9.5%	$b$ (95% CI)	$p$ value
Gender		-0.317 (-1.552, 0.917)	0.614									
Age				-0.135 (-1.372, 1.102)	-0.102 (-1.660, -0.380)	0.830	1.060 (-0.179, 2.300)	1.062 (-0.189, 2.134)	0.094	-0.129 (-0.199, -0.058)	1.062 (-0.189, 2.134)	0.096
WHO-5 score						0.002	-0.130 (-0.197, -0.063)	-0.129 (-0.199, -0.058)	<0.001	0.158 (0.123, 0.192)	-0.129 (-0.199, -0.058)	<0.001
EQ5D score							0.158 (0.124, 0.193)	0.158 (0.123, 0.192)	<0.001	0.158 (0.123, 0.192)	0.158 (0.123, 0.192)	<0.001
BMI							3.835 (-0.277, 7.948)	3.958 (-0.202, 8.118)	0.068	3.958 (-0.202, 8.118)	3.958 (-0.202, 8.118)	0.062
Smoking							-0.155 (-0.272, -0.038)	-0.155 (-0.272, -0.037)	0.010	-0.155 (-0.272, -0.037)	-0.155 (-0.272, -0.037)	0.010
MVC							1.473 (-0.327, 3.273)	1.434 (-0.379, 3.248)	0.109	1.434 (-0.379, 3.248)	1.434 (-0.379, 3.248)	0.121
Use of insulin							-1.386 (-2.813, 0.041)	-1.436 (-2.879, 0.008)	0.057	-1.436 (-2.879, 0.008)	-1.436 (-2.879, 0.008)	0.051
Diabetes duration							0.158 (-1.408, 1.724)	0.668 (-1.112, 2.449)	0.843	0.668 (-1.112, 2.449)	0.668 (-1.112, 2.449)	0.462
HbA1c								-0.034 (-0.146, 0.078)		-0.034 (-0.146, 0.078)	-0.034 (-0.146, 0.078)	0.548
Use of glucose lowering drugs								-0.036 (-0.107, 0.034)		-0.036 (-0.107, 0.034)	-0.036 (-0.107, 0.034)	0.310
Microvascular complications								-0.439 (-1.928, 1.050)		-0.439 (-1.928, 1.050)	-0.439 (-1.928, 1.050)	0.563
								0.206 (-1.467, 1.879)		0.206 (-1.467, 1.879)	0.206 (-1.467, 1.879)	0.806

BMI: body mass index; MVC: macrovascular complications;  $b$ : unstandardized regression coefficients.

TABLE 3: Stratified analyses for men and women.

Variables	Men			Women		
	Model (3) Adjusted $R^2$ (%) = 8.5% $b$ (95% CI)	$p$ value	Model (4) (explorative) Adjusted $R^2$ (%) = 8.4% $b$ (95% CI)	Model (3) Adjusted $R^2$ (%) = 10.7% $b$ (95% CI)	Model (4) (explorative) Adjusted $R^2$ (%) = 10.4% $b$ (95% CI)	$p$ value
Age	-0.177 (-0.272, -0.083)	0.001	-0.173 (-0.272, -0.074)	-0.081 (-0.177, 0.015)	-0.075 (-0.176, 0.027)	0.150
WHO-5 score	0.152 (0.104, 0.201)	<0.001	0.149 (0.100, 0.198)	0.166 (0.116, 0.214)	0.166 (0.117, 0.215)	<0.001
EQ5D score	3.828 (-1.947, 9.603)	0.194	3.944 (-1.913, 9.800)	4.102 (-1.808, 10.013)	4.371 (-1.616, 10.358)	0.152
BMI	-0.220 (-0.394, -0.047)	0.013	-0.220 (-0.394, -0.046)	-0.104 (-0.265, 0.057)	-0.095 (-0.258, 0.068)	0.255
Smoking	1.839 (-0.387, 4.066)	0.105	1.866 (-0.374, 4.106)	0.894 (-2.153, 3.942)	0.810 (-2.262, 3.881)	0.605
MVC	-0.594 (-2.371, 1.183)	0.512	-0.704 (-2.500, 1.098)	-2.346 (-4.473, -0.220)	-2.333 (-4.468, -0.198)	0.032
Use of insulin	0.451 (-1.708, 2.610)	0.682	1.030 (-1.368, 3.427)	-0.149 (-2.438, 2.139)	0.423 (-2.284, 3.130)	0.759
Diabetes duration			-0.049 (-0.205, 0.108)		-0.024 (-0.185, 0.138)	0.775
HbA1c			-0.028 (-0.121, 0.065)		-0.055 (-0.164, 0.055)	0.327
Use of glucose lowering drugs			-1.427 (-3.483, 0.629)		0.750 (-1.452, 2.952)	0.504
Microvascular complications			0.184 (-1.973, 2.341)		0.115 (-2.358, 2.588)	0.926

BMI: body mass index; MVC: macrovascular complications;  $b$ : unstandardized regression coefficients.



The direction of this association should be investigated in further research. The relationships in men between a lower age and a lower BMI with a higher level of patient activation are in line with the results of previous studies [7, 8]. The relation between macrovascular complications and patient activation, which was found in women in the present study, has not been investigated before. Whether this association is actual gender specific or more a matter of coincidence should be investigated in further research.

Some limitations need to be mentioned. Due to the cross-sectional design, causal conclusions could not be drawn. Furthermore, although we have investigated important confounders, still some potentially important factors were not taken into account. We were not able to adjust for educational level, socioeconomic status, and marital status. Inclusion of those variables might increase the explained variance. Educational status and financial distress, which could be used as markers for socioeconomic status, were associated with patient activation in a previous Dutch study [8]. In the same study, living together versus alone was not associated with patient activation. It should be investigated further whether adjusting for these factors will lead to a difference in patient activation between men and women. At last, selection bias could have occurred. However, no difference was found in age or degree of glycaemic control between the study population and the whole T2D population from the three regions.

As no differences between patient activation level between men and women exist, there is no indication that the approach to men and women with respect to self-management tasks should be different. However, this does not directly mean that the same self-care tasks could be given to men and women, as the effectiveness of self-care interventions could still be different. This should be investigated in further research.

## 5. Conclusion

There is no difference in the degree of patient activation of men and women with T2D. Furthermore, no significant influence was found for well-being, quality of life, BMI, and smoking on the relationship between gender and patient activation. Age, well-being, and BMI were found to be associated with patient activation in men, whereas well-being and macrovascular complications were found to be associated with patient activation in women. Based on these results, there is no indication that different levels of self-management tasks should be given to men and women with T2D.

## Competing Interests

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

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## Research Article

# The Influence of Health Literacy and Depression on Diabetes Self-Management: A Cross-Sectional Study

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Despite an increasing focus on health literacy in the clinical setting and in the literature, there is still ongoing debate about its influence on diabetes self-management. The aim of the study was to examine the relationships of sociodemographic, clinical, and psychological factors on health literacy and diabetes self-management. A cross-sectional survey was undertaken on 224 patients with type 2 diabetes at two diabetes centres in Sydney, Australia. Findings showed that people with low health literacy were more likely to (a) have lower educational attainment; (b) be migrants; and (c) have depressed mood. Unexpectedly, those who met HbA<sub>1c</sub> threshold of good glucose control were more likely to have low health literacy. Predictors of low diabetes self-management included (a) younger age group (AOR: 2.58, 95% CI: 1.24–4.64); (b) having postsecondary education (AOR: 2.30, 95% CI: 1.05–5.01); (c) low knowledge of diabetes management (AOR: 2.29, 95% CI: 1.25–4.20); and (d) having depressed mood (AOR: 2.30, 95% CI: 1.30–4.06). The finding that depressed mood predicted both low health literacy and low diabetes self-management stresses the importance of screening for depression. Increasing people's understanding of diabetes self-management and supporting those with depression are crucial to enhance participation in diabetes self-management.

## 1. Introduction

The rapid rise in the global prevalence of diabetes lends urgency to the need for investigations beyond the walls of traditional factors such as poor nutrition, obesity, and sedentary behaviour. In 2013, diabetes was reported in 382 million people worldwide, a figure projected to increase by 55% to 592 million in 2035 [1]. Type 2 diabetes mellitus (T2DM) is the most prevalent form affecting 90% of adults with diabetes [2] and is increasingly being diagnosed in younger age groups [3]. While biochemical and clinical research is important, grassroots level sociocultural research is needed to understand the underlying sociodemographic and cultural environment which influences the self-efficacy of patients to perform the daily tasks of self-managing their chronic condition. For example, among migrants to many developed countries like Australia, acculturation to host culture, language and cultural barriers, and socioeconomic factors contribute to an

increased incidence of lifestyle diseases, approximating that of the receiving country [4]. Migrants encounter many personal and systemic barriers in managing chronic conditions like diabetes [5, 6], which adds to the complexity of implementing self-management interventions in this population. Understanding how these factors interrelate and influence self-management is important to provide person-centred strategies to enhance the health of people living with diabetes.

Diabetes self-management (DSM) is considered an essential cornerstone of good diabetes control [7]. It is reported to reduce the level of glycated haemoglobin level (HbA<sub>1c</sub>), a clinical measure of adequate control, by as much as 37% [8]. Having a lower HbA<sub>1c</sub> value ( $\leq 7\%$  or  $\leq 53$  mmol/mol) reduces the likelihood of developing micro- and macrovascular complications over time [9]. Despite the increasing evidence that supports the benefits of DSM, uptake remains low, especially in culturally diverse populations [10, 11]. Among people with T2DM, knowledge deficit and understanding about diabetes

and its complications have been found to be low in those with low health literacy [11], posing a barrier to DSM [12]. Given this association, improving health literacy, defined as “the capacity to look for, process and understand health information to make informed decisions” [13] seems an important priority to empower patients to self-manage their diabetes [14]. Paasche-Orlow and Wolf [15] postulated that the mechanisms contributing to poorer outcomes among those with low health literacy include low self-efficacy, lack of access to and utilisation of resources and services, and language and cultural issues in clinical encounters. It is important, however, to acknowledge that socioeconomic and demographic factors such as age, educational level, ethnocultural background, and having conditions that require complex care are underscoring limited health literacy [6, 10, 16]. Low levels of health literacy have been found to be common among patients who are from lower socioeconomic backgrounds and among migrants with limited English language proficiency, the elderly, and those with chronic diseases [17]. While some studies have found that low health literacy is associated with poor diabetes self-management, poor control, and more complications [12], the evidence regarding this association is inconsistent [18]. This could be due to other psychosocial and demographic factors that may affect health literacy and/or differences in measuring this construct [19].

Adding to the complications of suboptimal self-management is reduced psychological well-being [20]. This is a vicious cycle that may further disempower patients. For example, psychological comorbidity, like depression, contributes to lower self-care [21], which in turn leads to poorer health status leading to more depression and comorbidities which further reduce DSM [22].

The aim of the study was to examine the relationships between sociodemographic, clinical, and psychological factors and health literacy and its relationship with DSM within a culturally diverse urban population with T2DM. Specifically, we sought to investigate the relationship between health literacy and other factors influencing DSM. The hypotheses in this study were as follows:

- (1) Self-management in patients with T2DM is associated with sociodemographic factors (age, gender, educational level, marital status, and country of birth), clinical factors (self-rated general health, HbA<sub>1c</sub>), and psychological factors (depression, confidence, knowledge, and health literacy).
- (2) Health literacy in patients with T2DM is associated with sociodemographic factors (age, gender, educational level, marital status, and country of birth), clinical factors (self-rated general health, HbA<sub>1c</sub>), and psychological factors (depression, confidence, and knowledge).

## 2. Methods

**2.1. Study Design and Setting.** We used a cross-sectional design, patients with T2DM attending the diabetes outpatient clinics at two centres in South Western Sydney Australia. The study setting is a culturally diverse region with 52% of its

population born overseas. Of these, 59% speak a language other than English at home and 13% are new arrivals, settling in Australia within the last five years [23]. Southwest Sydney is also one of the largest and most rapidly growing districts within the Sydney metropolitan area [24] with approximately 21% of the population in the low socioeconomic stratum [25] and only about 30% of its population completing secondary school. Unemployment rates are high, with a mean rate of 8% (range 5%–31%), ranking some of these suburbs (10 out of 38) among the most disadvantaged areas in Australia [25].

**2.2. Participants and Recruitment.** Using convenience sampling, participants were recruited between May and December 2015 from the outpatient diabetes clinics of two large centres in the South Western Sydney Local Health District (SWSLHD). Eligibility criteria included (1) age of 18 years and above; (2) being diagnosed with T2DM; (3) having HbA<sub>1c</sub> test in the last two years recorded in their clinical file. Patients attending the outpatient clinics for their regular appointment with the diabetes educator, specialists, or dietician were identified and referred to the research team by the clinicians. One of the researchers then explained the purpose of study and sought consent from potential participants. Those who consented to participate in the study were asked to complete a questionnaire. Consent included access to participants' hospital records to retrieve their latest recorded clinical data including HbA<sub>1c</sub>, height, and weight. Researchers measured height and weight of participants to compute for their body mass index (BMI) after they have completed the questionnaire if this was not available in their clinical records.

**2.3. Instruments.** A pilot study was initially undertaken with 20 participants. The initial questionnaire consisted of 63 questions including items from five validated instruments: the English language acculturation scale [26], PHQ-2 depression scale [27], diabetes knowledge [28], diabetes self-efficacy [29], and diabetes self-management [30]. Results of the pilot testing indicated that participants found the questionnaire to be too complex and lengthy, including those whose first language was English. Following discussion with the research team, a consensus was reached to simplify the questionnaire and reduce the survey to only include 34 items. These were items related to demographic and clinical characteristics, three brief validated measures, namely, the (a) 3-item Health Literacy Scale [31]; (b) 2-item PHQ-2 to assess depressed mood and anhedonia [27]; and (c) 16-item Diabetes Self-Management Scale [30]. As single item questions have been found to be as valid and reliable as multiple-item scales, particularly when constructs that are being measured are fairly homogenous [32, 33] the two standardised scales that measured diabetes self-efficacy and diabetes knowledge were replaced with two single items; namely, “In a scale of 1 to 10 (1 being not confident to 10 being very confident), how confident are you that you will be able to manage your diabetes?” and “In a scale of 1 to 10 (1 being very poor to 10 being excellent), how do you rate your knowledge about diabetes?” Subjective assessment of perceived overall health was likewise assessed with a single question: “In general, how would you describe



*your general health?*” with a five-point Likert scale response, *excellent, very good, good, fair, and poor*.

Cronbach's alpha was calculated for each validated instrument used. This is a measure of the extent to which the items in the questionnaire consistently assess the same idea or concept [34]. The internal consistency is expressed as a numerical value between 0 and 1 with scores between 0.70 and 0.90 indicating good correlation among items in the questionnaire [35].

**2.3.1. Brief Health Literacy Scale.** Health literacy was evaluated using the 3-item Health Literacy Scale [31] and included the following: (1) *How often do you have problems learning about your medical condition because of difficulty understanding written information?* and (2) *How confident are you filling out forms by yourself?* and (3) *How often do you have someone help you read hospital materials?* Each item was rated with a 5-point Likert scale with lower scores indicating lower health literacy.

**2.3.2. Depression Scale.** The 2-item Patient Health Questionnaire (PHQ-2) [27] was used to assess anhedonia and depressed mood over a 2-week period. This 4-point Likert scale has been used extensively to determine the presence of depression, with higher scores indicating the presence of depression [36]. A cut-off aggregate score of 2 has been found to have high sensitivity in detecting major depressive disorder (92.7%) and any depressive disorder (80.4%), with specificity of 73.7% and 80.4%, respectively [27].

**2.3.3. Diabetes Self-Management Scale.** The 16-item Diabetes Self-Management Questionnaire (DSMQ-16) [30] was used in this study because of its brevity relative to other related scales. More importantly it had significantly stronger correlation with HbA<sub>1c</sub> which is an important measure of diabetes control.

**2.3.4. Glycated Haemoglobin (HbA<sub>1c</sub>).** The glycated haemoglobin level or HbA<sub>1c</sub> is recommended in the monitoring of glucose control as it reflects the average blood glucose level over three months and has a good correlation with diabetes complications [37]. A cut-off value of 7% has been recommended to indicate good control [37, 38].

**2.4. Analysis.** Sample size calculation for the outcome variable was based on low DSM rate of 50%. Taking into account the 11 sociodemographic, clinical, knowledge, and psychological predictor variables as listed in the hypothesis and using the sample size calculation based on Peduzzi et al. [39] of  $N = 10k/p$  (where  $N$  is the minimum number of cases needed,  $k$  is the number of predictor variables, and  $p$  is the proportion of low DSM rate), the minimum sample size required was 220.

We used SPSS version 23 software [40] for all data analysis. Frequencies and percentages were computed for categorical variables, and mean, median, and standard deviation and interquartile range were computed for continuous variables. As none of the continuous variables were normally distributed, age, duration of diabetes diagnosis, BMI, medical

comorbidities, confidence, knowledge, health literacy, and DSMQ-16 scores were dichotomised at the median. However, the PHQ-2 score was dichotomised at 2 to represent “not depressed” (0-1) and “depressed” (2-6) to be consistent with the high sensitivity of this cut-off shown in previous studies [36]. While dichotomisation of variables may have the disadvantage of loss of analytical power and some important information, it has the benefits of reducing the variability in a skewed data and consequently the random error, making the results more accurate [41]. In addition, it simplifies the results and thus presents findings that are easily understandable to a wide range of audience [42]. Data in this study was skewed with a high variability in the responses. Furthermore, corrective logarithmic transformation calculations performed did not produce findings dissimilar to the dichotomised results obtained.

The Chi-square test was used to assess relationships between two categorical variables, and logistic regression analysis (forward conditional method, with listwise deletion of cases with missing data [43]) was used to identify predictors of depression and predictors of DSM. The variables included in these regression analyses were demographic, clinical, and psychological characteristics of participants as previously described in the hypotheses.

### 3. Results

In total, 275 patients who met the inclusion criteria were approached. Of these 11 refused to participate and 40 were excluded from the final analysis as they were not able to complete the questionnaire and/or they did not have a recorded HbA<sub>1c</sub> in the last two years. Cronbach's alpha for the following instruments used in the study showed good item correlation and internal consistency: Brief Health Literacy Scale ( $\alpha = 0.83$ ); Depression Scale (PHQ-2) ( $\alpha = 0.88$ ); and the Diabetes Self-Management Scale (DSMQ-16) ( $\alpha = 0.79$ ).

The demographic profile of our sample approximated the statistical profile of the study setting. Of the 224 participants included in the final analysis, 56% were born overseas and 7% were newly arrived migrants (less than 5-year duration of stay in Australia) with 40% speaking a language other than English at home. Nineteen percent (19%) of the sample had postsecondary schooling. Table 1 shows the clinical, knowledge, and psychological characteristics of participants. Although the overall health literacy score was high (median: 10; range: 0–12), the overall diabetes knowledge score was lower (median: 7, range: 0 to 10). While the overall DSM-16 score was high (median: 35, range: 7 to 47), 61% of the sample were obese (BMI:  $\geq 30 \text{ kgm}^2$ ), and 81% had an HbA<sub>1c</sub> over 7% with 30% having more than two comorbidities. Forty-seven percent (47%) of the participants rated their general health as fair to poor. Fifty percent of the participants had a score of 2 or more in the PHQ-2 suggesting the presence of depressed mood or anhedonia [27, 36]. Those who had PHQ-2 score more than 2 were also found to have longer duration of diabetes diagnosis (more than 10 years), more comorbidities (more than 2), lower confidence, and less DSM behaviours.



TABLE 1: Characteristics of T2DM participants ( $n = 224$ ).

Characteristics	
<i>Sociodemographic</i>	
Age, median (IQR) years (range: 22–90)	60 (17)
Sex: male, $n$ (%)	119 (53)
Marital status: with partner, $n$ (%)	147 (66)
Highest educational attainment*	
(i) Up to primary schooling, $n$ (%)	33 (15)
(ii) Secondary schooling (years 7 to 12, TAFE, trade), $n$ (%)	146 (65)
(iii) More than secondary schooling (postgraduate), $n$ (%)	42 (19)
Country of birth: overseas-born	125 (56)
<i>Clinical characteristics</i>	
Self-rated health: fair or poor, $n$ (%)	98 (47)
Duration of diabetes diagnosis: median (IQR) years (range: 0–46)	10.0 (11)
Body mass index (BMI): median (IQR) (range: 19.0–64.5)	32.4 (11)
HbA <sub>1c</sub> : median (IQR) (range: 4.8–14.0)	8.4 (3)
Number of medical comorbidities: median (IQR) (range: 0–7)	2.0 (2)
<i>Knowledge and psychological factors</i>	
Depression: PHQ-2 score: median (IQR) (range: 0–6)	1.5 (3.0)
Confidence in managing their diabetes: median (IQR) (range: 1–10)	8.0 (3.0)
Knowledge about diabetes: median (IQR) (range: 0–10)	7.0 (3.0)
Health literacy score: median (IQR) (range: 0–12)	10.0 (–7.0)
DSMQ-16 score: median (IQR) (range: 7–47)	35.0 (12)

\* Missing data.

TABLE 2: Group comparison of high and low health literacy levels by participant characteristics.

Characteristics	Low health literacy ( $\leq 10$ )	High health literacy ( $> 10$ )	Unadjusted odds ratio	$p$
<i>Sociodemographic</i>				
Age: $< 60$ years, $n$ (%)	56 (44)	57 (58)	0.58 (0.34–0.98)	0.042
Sex: male, $n$ (%)	65 (52)	54 (55)	1.15 (0.68–1.96)	0.601
Marital status: with partner, $n$ (%)	86 (68)	61 (62)	0.77 (0.44–1.34)	0.348
Highest educational attainment				
(i) Up to primary schooling	27 (22)	6 (6)	0.24 (0.09–0.61)	$< 0.001$
(ii) Secondary schooling	81 (66)	65 (66)	1.09 (0.63–1.91)	
(iii) More than secondary schooling	15 (12)	27 (28)	2.81 (1.40–5.66)	
Country of birth: overseas-born, $n$ (%)	80 (64)	45 (46)	0.49 (0.29–0.84)	0.009
<i>Clinical characteristics</i>				
Self-rated health: fair or poor, $n$ (%)	111 (90)	88 (90)	0.97 (0.41–2.32)	0.946
HbA <sub>1c</sub> : high ( $> 7\%$ ), $n$ (%)	96 (76)	85 (87)	2.04 (1.00–4.17)	0.047
<i>Knowledge and psychological factors</i>				
Confidence diabetes management: low (up to 8), $n$ (%)	94 (75)	60 (61)	1.86 (1.05–3.29)	0.032
Knowledge about diabetes: low (up to 7), $n$ (%)	83 (66)	53 (54)	1.64 (0.95–2.82)	0.073
Psychological status, depressed (PHQ-2: $\geq 2$ )	71 (56)	41 (42)	0.56 (0.33–0.95)	0.031
DSMQ-16 score: low (up to 35), $n$ (%)	64 (51)	57 (58)	0.74 (0.44–1.26)	0.283

**3.1. Group Comparisons of Low and High Health Literacy.** Using the median score of 10 as the cut-off for the Brief Health Literacy scale, group comparisons of sociodemographic, clinical, and knowledge and psychological factors were computed using the Chi-square test. As shown in Table 2, those who were older, had up to primary schooling, were overseas-born, were less confident about diabetes management, and had

PHQ-2 score  $\geq 2$ , had low health literacy. Surprisingly, those with HbA<sub>1c</sub>  $> 7\%$ , indicating poor control, were more likely to have high health literacy ( $p = 0.047$ ).

**3.2. Predictors of Low Health Literacy.** Using forward step-wise logistic regression analysis, four variables emerged as independent and significant predictors of low health literacy:

TABLE 3: Predictors of low health literacy in T2DM patients ( $n = 224$ ).

Variables	Adjusted odds ratio (95% CI)	Std error (SE)	$p$
(i) Highest educational attainment (reference: secondary schooling)			
(a) Up to primary schooling	3.12 (1.17 to 8.30)	0.50	0.023
(b) More than secondary schooling	0.35 (0.16 to 0.74)	0.39	0.006
(ii) Country of birth: overseas-born	2.17 (1.21 to 3.91)	0.30	0.010
(iii) Poor glucose control ( $HbA_{1c} > 7\%$ )	0.41 (0.19 to 0.90)	0.40	0.026
(iv) Psychological status, depressed (PHQ-2: $\geq 2$ )	2.01 (1.12 to 3.59)	0.30	0.019

CI denotes confidence interval.

Nagelkerke  $R^2 = 0.191$ .

Hosmer-Lemeshow goodness-of-fit for the model: Chi-square = 2.937, df = 7, and  $p = 0.891$ .

TABLE 4: Predictors of low diabetes self-management in T2DM patients ( $n = 224$ ).

Variables	Adjusted odds ratio (95% CI)	Std error (SE)	$p$
(i) Age: $\leq 60$ years	2.58 (1.25 to 4.64)	0.30	0.001
(ii) Highest educational attainment: more than secondary schooling	2.30 (1.05 to 5.01)	0.40	0.037
(iii) Diabetes knowledge: less than $\leq 7$	2.29 (1.25 to 4.20)	0.31	0.007
(iv) Psychological status, depressed (PHQ-2: $\geq 2$ )	2.30 (1.30 to 4.06)	0.29	0.004

CI denotes confidence interval.

Nagelkerke  $R^2 = 0.166$ .

Hosmer-Lemeshow goodness-of-fit for the model: Chi-square = 11.635, df = 7, and  $p = 0.113$ .

(i) education; (ii) country of birth; (iii) glucose control as measured by  $HbA_{1c}$ ; and (iv) depression. In relation to educational attainment, those with up to primary schooling were more likely to have low health literacy (AOR: 3.12, 95% CI: 1.17 to 8.30); conversely, those with postsecondary school were less likely to have low health literacy (AOR: 0.35, 95% CI: 0.16 to 0.74). Table 3 also shows that those born overseas were over two times (AOR: 2.17, 95% CI: 1.21 to 3.91) more likely to have low health literacy; similarly, those who were depressed were also over two times (AOR: 2.01, 95% CI: 1.12 to 3.59) more likely to have low health literacy. Unexpectedly, those with good glucose control, as indicated by  $HbA_{1c}$  of up to 7%, had low health literacy (AOR: 0.41, 95% CI: 0.29 to 0.90). These four variables explained approximately 19% of the variance (Nagelkerke  $R^2 = 0.191$ ), and Hosmer-Lemeshow goodness-of-fit statistics was not significant (Chi-square = 2.937, df = 7, and  $p = 0.891$ ), indicating good model fit.

**3.3. Predictors of Low Diabetes Self-Management.** Forward stepwise logistic regression analysis was likewise used to determine predictors of DSM, using the median of up to 35 as the cut-off score. Four variables emerged as independent and significant predictors of low DSM: (i) younger age group ( $\leq 60$  years); (ii) having postsecondary schooling; (iii) low diabetes management knowledge score ( $\leq 7$ ), and (iv) being depressed (PHQ-2:  $\geq 2$ ). The magnitude of the adjusted odds ratios was similar for all four predictor variables, ranging from 2.30 to 2.58, explaining approximately 17% of the variance (Nagelkerke  $R^2 = 0.166$ ). The Hosmer-Lemeshow goodness-of-fit statistics was not significant (11.635, df = 7,  $p = 0.113$ ), indicating good model fit (Table 4).

## 4. Discussion

In the current study, those with only primary school education, migrants, and those who reported depressed mood were more likely to have low health literacy. The relationship between education and health literacy has previously been reported [44]; while this was not an unexpected finding it was encouraging to find that participants with secondary schooling and above reported adequate health literacy. Further analysis of those with primary school education revealed that they were also more likely to be older (79%) and overseas-born (70%), which has important implications for targeting this group considering the demographic profile of the current study setting and its being a major area for immigrant settlement in Australia [23]. This is particularly important given that migrants have a disproportionately high prevalence of diabetes [45] and face a number of barriers such as limited English language proficiency, access issues, cultural beliefs, and socioeconomic factors that could have direct and indirect effects on health literacy and DSM [5, 45–47]. Compared with Australian-born participants, migrants in this study had significantly lower confidence in their ability to manage their diabetes ( $p = 0.019$ ). Culturally tailored resources and lifestyle interventions addressing these barriers including fostering problem-solving skills, cultivating motivation by setting appropriate goals, and consistent follow-up could be important tools to build confidence for self-managing diabetes in this population.

Depression has been found to affect diabetes control through both physiological pathways [48], effects of treatment [49], and/or increasing demand for psychological and behavioural tasks involved in DSM [50]. Our study confirmed

the finding that depressed mood and anhedonia are associated with low self-efficacy in carrying out DSM. The PHQ-2 is sensitive, quick, and easily administered in a busy clinic setting which could allow for referral for psychological support. Given the negative influence of depression on diabetes control through several mechanisms, an important recommendation from this study would be that clinicians consider screening all patients who attend diabetes clinics for depression using the PHQ-2.

An unexpected outcome of our study was that poorer glucose control, as demonstrated by high HbA<sub>1c</sub>, was correlated with higher health literacy. This may be explained by two factors: the Health Literacy Scale used in this study measured general health literacy rather than health literacy specific to diabetes and therefore may not be suitable for the sample in this study. For example, one of the questions in this tool *“How often do you have someone help you read hospital materials?”* was answered by a number of participants with *“never, because there was never anybody there to help me, I had to read them by myself,”* which reflected lack of support rather than a high level of health literacy. Secondly, having high health literacy may not necessarily translate into self-management actions that could result in better biochemical diabetes control. This contention is supported by the findings in this study that those who were highly educated had high health literacy but reported low DSM however; those who had higher diabetes knowledge score had higher DSM. A study on English-speaking adults with type 2 diabetes likewise found that health literacy (measured using S-TOFHLA) was not associated with HbA<sub>1c</sub> or with the presence of diabetes complications [18]. In contrast, Schillinger et al. [12] found an association between low health literacy, poor diabetes control, and retinopathy in an ethnically diverse population.

Older participants in this study practiced more DSM although they had lower health literacy, perhaps because of heightened awareness of mortality whereby health becomes a main concern. It could also be that older participants spent more time engaging in DSM tasks as they had less external competing priorities compared with younger and more educated participants who, presumably, had job demands and family concerns which took priority over DSM. This study found no significant correlation between health literacy and DSM; however, it was lack of knowledge about diabetes specifically that predicted lower DSM.

A number of variables measured in this study were self-assessed constructs that were useful in illuminating the perceptions of participants regarding their resources in effecting DSM. For example, despite more than half of the participants' rating their health as good (53%) and reporting adequate self-management (54%), objective measurements of BMI and HbA<sub>1c</sub> showed that a high number (61% and 81%, resp.) of participants were obese and/or had poorly controlled diabetes. This discordance between what participants perceived as “good” DSM and clinical parameters of good control is also consistent with previous studies of people with diabetes and other chronic conditions. For example, in a sample of rural Taiwanese residents Huang et al. [51] found that those who had HbA<sub>1c</sub>  $\geq 7\%$ , indicating a poor level of control, assessed their health as good [51]. Large population-based studies

have also demonstrated a “disconnect” between perceived and actual health in approximately one out of five individuals, with younger age, ethnicity (non-Hispanic Blacks), and higher socioeconomic status predicting this disconnect [52]. This discrepancy between self-perceived health status and objective measures of diabetes control is likely to have clinical implications for DSM education as improving the convergence between perceived and actual health may help promote self-management and, ultimately, improve health outcomes. It is therefore important for health professionals to stress the importance of maintaining a healthy weight and achieving optimal HbA<sub>1c</sub> in patient diabetes education programs.

This study has several limitations. The participants were sampled from a cohort that is already accessing the diabetes clinics of two major centres in the region. This may not be representative of the general population with type 2 diabetes. Secondly, the study was cross-sectional and, given the chronicity of diabetes, a longitudinal study may have been more useful in assessing the effect of the variables under examination in relation to self-management over a period of time. Thirdly, the use of Chew's brief measure of health literacy may not accurately have reflected the level of health literacy in our participants. The tool had ceiling effects which may not be due to high health literacy. Another limitation of the study was the lack of recent (within the last three months) HbA<sub>1c</sub> level, as some of the HbA<sub>1c</sub> results used in this study were taken within the last two years (2014–2016) and, therefore, may not have been contemporaneous with data collection. Finally, as with all studies that collect data using self-report measures, social desirability bias may have impacted on these findings and, given the discrepancy between self-reported health and HbA<sub>1c</sub>, this seems possible. Notwithstanding these limitations, this study presented findings that refute the relationship between health literacy and DSM in a culturally diverse urban population.

## 5. Conclusion

Sociocultural research exploring the factors affecting DSM is important to determine areas that may be amenable to implementing cost-effective interventions. In culturally diverse populations with T2DM, while sociocultural factors are determinants of health literacy, this study has demonstrated that it was not health literacy per se but having knowledge specific to diabetes that was more important in predicting the practice of DSM behaviours. Addressing the discordance in perception of health and objective measures of diabetes control in DSM education may improve patient compliance and monitoring. Importantly, the finding that depression was a significant predictor of both low health literacy and low DSM underscores the need for clinicians to screen for depression to ensure that people with T2DM are provided with appropriate support which in turn may enable them to engage in self-managing their condition.

## Ethical Approval

Ethics approval was obtained from the South Western Sydney Local Health District (HREC/14/LPOOL/133).

## Competing Interests

The authors declare that they have no competing interests.

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## Research Article

# Social Support Groups in the Maintenance of Glycemic Control after Community-Based Intervention

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Native Hawaiians and other Pacific Islanders (NH/PI; e.g., Samoan and Chuukese) have higher type 2 diabetes prevalence compared to other groups in Hawai'i. Partners in Care (PIC), a culturally tailored, community-based, diabetes self-management education intervention (DSME), is effective at improving participants' glycemic control and self-care behaviors. Maintenance of improvements is challenging. Diabetes-related social support groups (SSG) are a promising maintenance component for DSME. This study examined the effects of a diabetes-specific SSG component relative to a control group, after the receipt of the 3-month PIC intervention, which was delivered to 47 adult NH/PI with type 2 diabetes. Participants were then randomized to either a 3-month, 6-session SSG or a control group. Hemoglobin A1c (HbA1c), blood pressure, triglycerides, cholesterol, and diabetes self-management knowledge and behaviors were assessed at baseline, 3 months, and 6 months. Results indicated significant improvements in HbA1c, diabetes-related self-management knowledge, and behaviors from baseline to 3-month assessment. However, no differences between the SSG and control group from 3-month to 6-month assessment suggest that all participants were able to maintain initial improvements. The SSG group had a significant decrease in systolic blood pressure from 3-month to 6-month assessment while the control group did not. Study limitations and future directions are discussed.

## 1. Introduction

Type 2 diabetes is a public health concern across the United States, with certain ethnic groups bearing a disproportionate burden [1, 2]. Native Hawaiians and other Pacific Islanders (NH/PI; e.g., Samoan, Chuukese) have higher type 2 diabetes incidence and prevalence compared to other ethnic groups [3, 4]. They are two times more likely to die from diabetes than the general population and suffer from high rates of

diabetes-related medical complications and preventable hospitalization [5, 6]. Addressing the burden of type 2 diabetes is a priority in eliminating health disparities among NH/PI [7].

Culturally relevant, diabetes self-management interventions are important in treating type 2 diabetes among NH/PI [4, 8, 9]. Sinclair et al. found that a culturally adapted diabetes self-management intervention, called Partners in Care (PIC), significantly improved glycemic control and diabetes self-care behaviors in NH/PI compared to a wait-list control [10].

Despite the effectiveness of diabetes self-management education intervention, the maintenance of improved glycemic control continues to be a challenge across ethnic groups [11]. The long-term, postintervention maintenance of optimal glycemic control is important in judging an intervention's effectiveness [12].

Diabetes-related social support groups for those with type 2 diabetes have shown promise as a maintenance component for diabetes self-management interventions to improve long-term glycemic control and diabetes-related psychosocial functioning, self-care activities, and quality of life [13, 14]. Diabetes-related social support can include four types: appraisal support (e.g., alternative perspectives of stressors), informational support (e.g., knowledge), emotional support (e.g., expression of care), and tangible support (e.g., providing material help) [15].

The incorporation of a diabetes-related social support group for NH/PI as a maintenance component to a diabetes self-management intervention is also consistent with their shared ethnocultural values and preferences for group-based interactions [16]. They often rely on their immediate and extended family network (e.g., friends and neighbors) for emotional, physical, and spiritual support and daily decision-making [17]. Group participation with other NH/PI offers a safe and supportive environment that can increase the cultural relevance of activities and participation and enhances diabetes self-care.

To examine the effects of a diabetes-specific social support maintenance component, the community-academic partnership, the PILI 'Ohana Project (POP), involved in Sinclair et al.'s study conducted another study of PIC with an added social support component that emphasized the four types of support [10]. The POP partnership designed a 3-month, 6-session, semistructured support group (SSG) to reinforce positive changes made during the 3-month PIC intervention. Specifically, the maintenance effects of a novel SSG on HbA1c control and diabetes self-care behaviors were examined against a control group in a sample of NH/PI with type 2 diabetes who were randomized into these conditions following their completion of PIC.

## 2. Methods

**2.1. Participant Recruitment.** The Institutional Review Boards of the Native Hawaiian Health Care Systems and University of Hawai'i at Mānoa approved this study. Community researchers recruited NH/PI from their respective communities and the larger NH/PI population on the Island of Oahu. Eligibility criteria were HbA1c >7%, NH/PI ethnicity, age ≥18 years, and physician-diagnosed type 2 diabetes. Eligible participants provided consent and baseline assessments ( $T_1$ ) were done just prior to starting PIC. The study design is shown in Figure 1.

**2.2. Intervention and Study Procedures.** PIC involves 12, 1-hour weekly group meetings, providing information on diabetes self-management and encouraging participants to work with their diabetes team that includes the individual, their family, physician, and other diabetes experts (e.g.,

certified diabetes educator). The intervention is based on the American Diabetes Association and the National Diabetes Education Program guidelines. PIC was culturally adapted for NH/PI based on information from focus groups with NH/PI living with diabetes and NH/PI community leaders as described in Sinclair et al. [10].

The community partners included Kula no na Po'e Hawai'i (a nonprofit serving urban Hawaiian Homesteads), Hawai'i Maoli (a nonprofit serving the Hawaiian Civic Clubs), Ke Ola Mamo (the Native Hawaiian Health Care System for Oahu), and Kōkua Kalihi Valley (a health clinic serving low-income PI). These community organizations are described in detail by Nacapoy et al. [18]. The community partners recruited participants, delivered the intervention, and conducted the baseline and outcomes assessments at their respective organizations. All participants completed a baseline assessment ( $T_1$ ), received PIC, and underwent a second assessment at 3 months ( $T_2$ ). The protocol used at each assessment and measures were the same as used by Sinclair et al. [10]. Following assessment at  $T_2$ , participants were randomized, based on a 1:1 randomization by site, to either the 3-month SSG or standard follow-up control group.

Participants randomized to the SSG attended six bimonthly, semistructured group meetings, lasting for about 1 hour, to reinforce skills taught in PIC. Trained community facilitators (CF) led two of the sessions and health professionals (i.e., pharmacist, nutritionist, physician, and psychologist) led the remaining four sessions. Community facilitators were instructed to provide appraisal and emotional support (e.g., talking through difficulties and encouraging connection between group members) on how to garner additional support from family/friends for diabetes self-management activities (i.e., healthy eating, physical activity, and medication adherence). The health professionals concentrated on providing informational and appraisal support around managing diet, medications, diabetes-related complications, and maintaining self-care activities. The control group received only six bimonthly postcards reminding them of performing diabetes self-management activities. All participants underwent a final assessment at  $T_3$  after the 3-month maintenance component (i.e., six months after  $T_1$ ).

### 2.3. Measures

**2.3.1. Primary Outcome Measures.** Clinical measures included HbA1c, measured with the Bayer DCA 2000 via a fingerstick sample of whole blood. The same blood sample was used to measure total cholesterol, high-density lipoprotein (HDL), and low-density lipoprotein (LDL) and triglycerides with the Cholestech LDX lipid profile system. Blood pressure, weight (kg), and height (cm) were measured twice at each assessment with the average of the two values used in the analysis.

**2.3.2. Secondary Outcome Measures.** The understanding subscale of the diabetes care profile (DCP) measured understanding of diabetes self-care activities [19]. It consists of 12 items with a 1 (poor understanding) to 5 (excellent

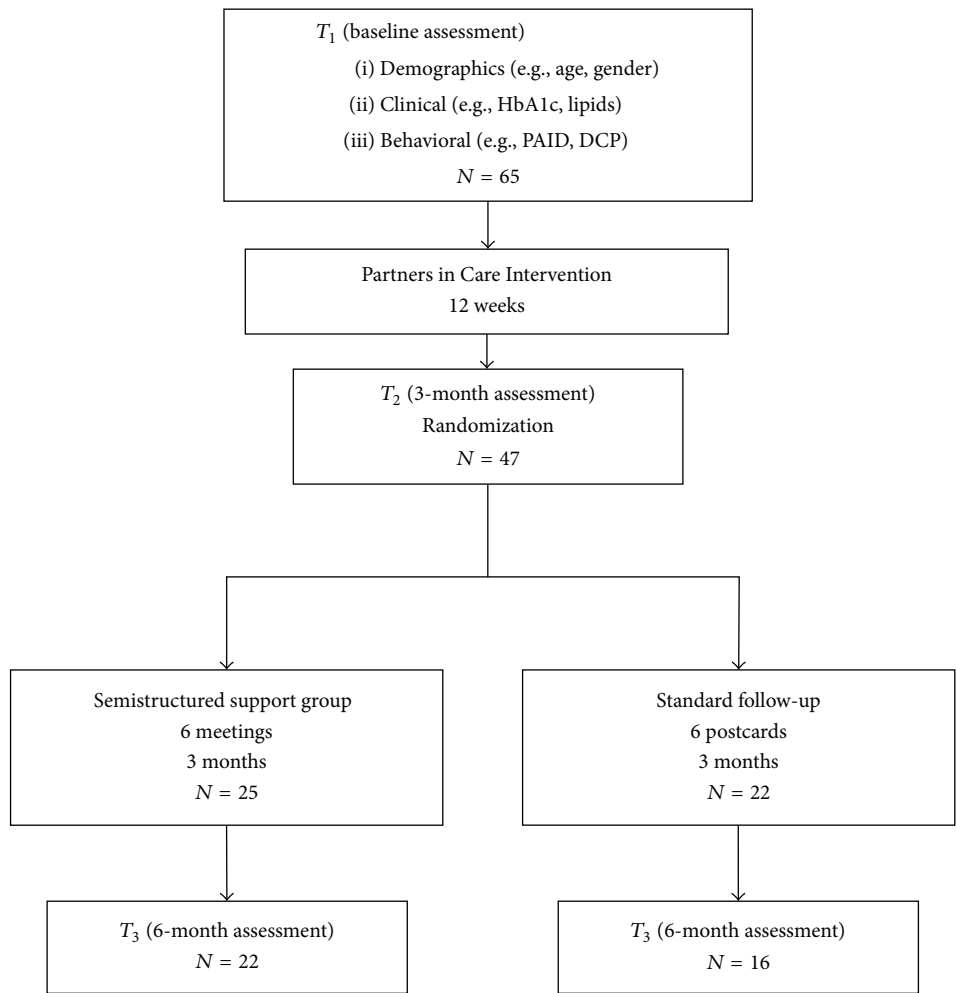


FIGURE 1: CONSORT diagram of PIC social support group study participation.

understanding) Likert-type response scale. The scores for the 12 items were averaged to yield a total score between 1 and 5. Higher scores indicate greater understanding. Seven of the 11 items from the Summary of Diabetes Self-Care Activities (SDSCA) were used to measure the frequency with which participants conducted self-care activities (e.g., checked their feet) during the previous week [20]. The scoring for each item was as follows: 1 (not at all during the past 7 days), 2 (2-3 days), 3 (4-6 days), and 4 (7 days). The summed total scores ranged from 7 to 28. Higher scores indicate greater frequency of self-care activities. The 20-item problem areas in diabetes (PAID) assessed quality of life such as physical/social functioning and mental/emotional well-being specific to living with diabetes [21]. The possible responses to each item ranged from 0 (not a problem) to 4 (serious problem). The total score was the sum of all items multiplied by 1.25 so that scores ranged from 0 to 100. Higher scores indicate greater diabetes-related emotional distress.

**2.4. Statistical Analysis.** Demographic and clinical measures were summarized by frequencies and percentages for categorical variables and means (M) and standard deviations (SD) for

continuous variables. Independent two sample *t*-tests were used to examine changes within subject. Support and control groups were compared using Chi-square or Fisher's exact test when appropriate for continuous and categorical variables. Analysis of covariance (ANCOVA) was used to test between group differences at  $T_2$  and  $T_3$ , adjusting for between-group differences at  $T_1$  and  $T_2$ , respectively. Statistical analyses were performed using SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA). A *p* value < 0.05 is statistically significant.

### 3. Results

**3.1. Baseline and  $T_2$  Characteristics.** The baseline characteristics for the 47 NH/PI receiving the PIC intervention are summarized in Table 1. It indicates that, among the participants, slightly over half were female, married, and Native Hawaiian and had a high school diploma or its equivalent. Participants on average had BMI in the severely obese category ( $M = 36.01 \pm 6.77$ ), blood pressure in the prehypertensive range (SBP  $M = 129.59 \text{ mmHg} \pm 15.77$ ; DBP  $M = 76.46 \text{ mmHg} \pm 11.00$ ), and mean HbA1c of  $9.98 \pm 2.23$ . Although mean total cholesterol ( $M = 183.45 \text{ mg/dL} \pm 43.77$ )

TABLE 1: Participants' sociodemographic, behavioral, and biological characteristics for combined sample at  $T_1$  and by group at  $T_2$ .

Variable	Baseline = $T_1$	3 months = $T_2$	
	Total ( $N = 47$ )	SSG ( $N = 25$ )	Control ( $N = 22$ )
Age (years)	54.53 $\pm$ 10.18	54.62 $\pm$ 11.06	54.42 $\pm$ 9.29
Sex			
Female	23 (50)	10 (40)	13 (62)
Ethnicity			
Hawaiian	27 (57)	14 (56)	13 (59)
Micronesian	16 (34)	8 (32)	8 (36)
Filipino	2 (4)	2 (8)	0 (0)
Other	2 (4)	1 (4)	1 (5)
Education			
Less than high school	6 (13)	2 (8)	4 (19)
High school diploma/GED	27 (60)	16 (67)	11 (52)
Some college/tech	10 (22)	5 (21)	5 (24)
College degree	2 (4)	1 (4)	1 (5)
Marital status			
Never	5 (11)	4 (16)	1 (5)
Currently	26 (58)	14 (56)	12 (60)
Disrupted	14 (31)	7 (28)	7 (35)
Weight (kg)	100.77 $\pm$ 24.39	106.42 $\pm$ 28.36	97.05 $\pm$ 12.90
BMI (kg/m <sup>2</sup> )	36.01 $\pm$ 6.77	37.27 $\pm$ 7.66	35.42 $\pm$ 4.63
HbA1c (%)	9.98 $\pm$ 2.23	8.96 $\pm$ 1.82	9.47 $\pm$ 2.69
Cholesterol (mg/dL)	183.45 $\pm$ 43.77	171.79 $\pm$ 36.82	171.24 $\pm$ 38.80
LDL cholesterol (mg/dL)	93.36 $\pm$ 38.49	92.38 $\pm$ 37.84	81.36 $\pm$ 37.41
HDL cholesterol (mg/dL)	40.72 $\pm$ 13.40	42.00 $\pm$ 14.90	38.33 $\pm$ 7.34
Triglycerides (mg/dL)	240.59 $\pm$ 171.07	234.00 $\pm$ 175.38	268.19 $\pm$ 142.08
Systolic blood pressure (mmHg)	129.41 $\pm$ 15.77	137.48 $\pm$ 24.81	132.03 $\pm$ 21.43
Diastolic blood pressure (mmHg)	76.46 $\pm$ 11.00	81.72 $\pm$ 14.22	76.50 $\pm$ 12.96
Diabetes care profile score	2.93 $\pm$ 0.86	3.55 $\pm$ 0.80	3.52 $\pm$ 0.87
Problem areas in diabetes score	34.41 $\pm$ 23.43	26.80 $\pm$ 20.70	26.46 $\pm$ 27.52
Summary of diabetes self-care activities score	17.00 $\pm$ 4.81	18.52 $\pm$ 4.12	18.06 $\pm$ 5.02

Note. Body mass index is abbreviated as BMI, high-density lipoprotein as HDL, low-density lipoprotein as LDL, and social support group as SSG. HbA1c is the measure of glycated hemoglobin.

Data shown as mean  $\pm$  SD or  $n$  (%).

No significant differences between SSG and control group at  $T_1$  or  $T_2$ , all  $p$  values  $> 0.15$ .

and LDL cholesterol ( $M = 93.36$  mg/dL  $\pm 38.49$ ) were within the recommended range, participants had low HDL cholesterol ( $M = 40.72$  mg/dL  $\pm 13.40$ ) and high triglyceride levels ( $M = 240.59 \pm 171.07$ ).

Table 1 also summarizes participant characteristics by group at 3-month assessment ( $T_2$ ). At  $T_2$ , both the SSG and control group had mean BMIs that remained in the severely obese category ( $M = 37.27 \pm 7.66$  and  $M = 35.42 \pm 4.63$ , resp.). The SSG had slightly higher mean systolic ( $M = 137.48 \pm 24.81$ ) and diastolic blood pressure ( $M = 81.72 \pm 14.22$ ) but lower HbA1c ( $M = 8.96 \pm 1.82$ ) compared to the control group ( $M = 132.03 \pm 21.43$ ,  $M = 76.50 \pm 12.96$ ,  $M = 9.47 \pm 2.69$ , resp.). However, none of these differences between groups at  $T_1$  or  $T_2$  were statistically significant.

### 3.2. Pre- and Post-PIC Intervention Outcomes

**3.2.1. Combined Sample.** Data in Table 2 shows the mean changes in behavioral and biological measures across three assessment periods and for the combined sample for both the complete case and the intent-to-treat analysis. In the complete case analysis, there were significant improvements in the following variables from  $T_1$  to  $T_2$ : HbA1c ( $M = -0.76 \pm 1.86$ ,  $p < 0.01$ ), DCP ( $M = 0.73 \pm 0.97$ ,  $p < 0.001$ ), PAID ( $M = -11.1 \pm 21.87$ ,  $p < 0.001$ ), and SDSCA ( $M = 2 \pm 5.12$ ,  $p < 0.01$ ). Except for HbA1c, significant improvements in these variables were also found from  $T_1$  to  $T_3$ . Examining change between  $T_2$  and  $T_3$  shows a significant increase in LDL ( $M = 13.55$  mg/dL  $\pm 26.42$ ,  $p < 0.05$ ), decrease in SBP

TABLE 2: Mean change in behavioral and biological measures across three assessments for the combined sample.

Variable	$T_1$ to $T_2$ ( $N = 47$ )	$T_2$ to $T_3$ ( $N = 34$ )	$T_1$ to $T_3$ ( $N = 38$ )
Weight (kg)	$0.08 \pm 4.97$	$5.41 \pm 22.13$	$4.96 \pm 21.36$
ITT weight (kg)	$0.44 \pm 5.11$	$0.27 \pm 2.13$	$0.71 \pm 5.49$
BMI ( $\text{kg}/\text{m}^2$ )	$0.08 \pm 1.78$	$2.09 \pm 8.16$	$2 \pm 7.82$
ITT BMI ( $\text{kg}/\text{m}^2$ )	$0.22 \pm 1.82$	$0.11 \pm 0.75$	$0.33 \pm 1.91$
HbA1c (%)	$-0.76 \pm 1.86^{**}$	$0.24 \pm 1.14$	$-0.57 \pm 1.88$
ITT HbA1c (%)	$-0.73 \pm 1.80^{**}$	$0.17 \pm 1.02$	$-0.53 \pm 1.80^*$
Cholesterol (mg/dL)	$-10.7 \pm 37.73$	$4.4 \pm 27.92$	$-1.74 \pm 52.59$
ITT cholesterol (mg/dL)	$-11.38 \pm 36^*$	$3.14 \pm 23.57$	$-5.43 \pm 49.94$
LDL cholesterol (mg/dL)	$-6.25 \pm 31.5$	$13.55 \pm 26.42^*$	$6.73 \pm 36$
ITT LDL cholesterol (mg/dL)	$-5.94 \pm 29.05$	$7.32 \pm 20.38^*$	$5.82 \pm 35.09$
HDL cholesterol (mg/dL)	$1.39 \pm 15.15$	$-0.67 \pm 8.46$	$-0.77 \pm 11.93$
ITT HDL cholesterol (mg/dL)	$-0.22 \pm 11.24$	$-0.45 \pm 6.91$	$-15.20 \pm 168.24$
Triglycerides (mg/dL)	$-1.24 \pm 170.99$	$-30.83 \pm 160.55$	$-37.87 \pm 170.51$
ITT triglycerides (mg/dL)	$9.68 \pm 151.76$	$-21.8 \pm 135.08$	$-15.20 \pm 168.24$
Systolic blood pressure (mmHg)	$2.59 \pm 20.43$	$-7.62 \pm 16.6^*$	$-2.28 \pm 16.07$
ITT systolic blood pressure (mmHg)	$4.95 \pm 19.47$	$-6.02 \pm 15.05^*$	$0.00 \pm 17.25$
Diastolic blood pressure (mmHg)	$2.61 \pm 12.05$	$-3.34 \pm 12.46$	$0.61 \pm 11.62$
ITT diastolic blood pressure (mmHg)	$3.16 \pm 11.48$	$-2.64 \pm 11.13$	$0.65 \pm 11.44$
Diabetes care profile	$0.73 \pm 0.97^{***}$	$-0.2 \pm 0.64$	$0.39 \pm 0.99^*$
ITT diabetes care profile	$0.65 \pm 1.00^{***}$	$-0.16 \pm 0.57$	$0.48 \pm 1.04^{**}$
Problem areas in diabetes	$-11.1 \pm 21.87^{***}$	$1.51 \pm 11.53$	$-7.04 \pm 18.21^*$
ITT problem areas in diabetes	$-8.64 \pm 20.2^{**}$	$1.19 \pm 10.24$	$-7.93 \pm 18.63^{**}$
Summary of diabetes self-care activities	$2 \pm 5.12^{**}$	$1.7 \pm 4.67^*$	$2.94 \pm 5.54^{**}$
ITT summary of diabetes self-care activities	$1.59 \pm 5.11^*$	$1.27 \pm 4.10^*$	$2.74 \pm 5.26^{**}$

Note: Data shown as mean  $\pm$  SD. Baseline =  $T_1$ , 3-month assessment =  $T_2$ , and 6-month assessment =  $T_3$ . Body mass index is abbreviated as BMI, high-density lipoprotein as HDL, and low-density lipoprotein as LDL. A1c is the measure of glycated hemoglobin. Values are expressed as mean  $\pm$  SD. Significance in change within group during the specified time period is tested by paired  $t$ -test and denoted by \* $p < 0.05$ , \*\* $p < 0.01$ , and \*\*\* $p < 0.001$ .

( $M = -7.62 \text{ mmHg} \pm 16.6$ ,  $p < 0.05$ ), and increase in SDSCA ( $M = 1.7 \pm 4.67$ ,  $p < 0.05$ ). The intent-to-treat analysis provided similar results, with the exception of change in HbA1c from  $T_1$  to  $T_3$ , which showed a significant decrease ( $M = -0.53 \pm 1.80$ ,  $p < 0.05$ ).

**3.2.2. Social Support Group versus Control.** A comparison of the mean changes in variables between  $T_2$  and  $T_3$  by group is presented in Table 3. At  $T_2$ , 25 participants were randomized to the SSG and 22 to the control group, with 22 and 12 participants being retained at  $T_3$ , respectively. There were no significant differences in the changes in variables between the SSG and control group from  $T_2$  to  $T_3$ , controlling for  $T_2$  values. There was a statistically significant reduction in SBP in the SSG ( $M = -8.36 \text{ mmHg} \pm 16.22$ ,  $p = 0.025$ ) but not in the control group ( $M = -6.25 \text{ mmHg} \pm 17.93$ ,  $p = 0.253$ ). There were marginally significant improvements in DCP ( $M = -0.24 \pm 0.55$ ,  $p = 0.054$ ) and SDSCA ( $M = 1.41 \pm 3.49$ ,  $p = 0.072$ ) scores in the SSG but not in the control group ( $M = -0.12 \pm 0.80$ ,  $p = 0.621$ , and  $M = 2.27 \pm 6.62$ ,  $p = 0.281$ , resp.).

## 4. Discussion

Type 2 diabetes is a serious threat to the health and well-being of NH/PI as culturally tailored, diabetes self-management interventions, such as PIC, can help attenuate. The 12-week PIC intervention led to significant improvements in HbA1c, diabetes self-care knowledge and activities, and emotional well-being. However, we did not find significant differences in the maintenance of these improvements between participants randomized to either the SSG or control group following completion of PIC. Participants' glycemic control at 6 months was not significantly different from their control immediately after PIC. This suggests that participants were able to maintain initial improvements from PIC with or without the SSG. While not significantly different between groups, the SSG group had a significant within-group decrease in systolic blood pressure from  $T_2$  to  $T_3$  while the control group did not. The SSG also had improvements in understanding of diabetes and frequency of self-care activities that were marginally significant.

Although this study did not support the hypothesis that SSG can improve the maintenance of glycemic control



TABLE 3: Mean change in behavioral and biological measures from  $T_2$  to  $T_3$  by group.

Variable	SSG ( $N = 22$ )	Control ( $N = 12$ )
Weight (kg)	$0.19 \pm 2.28$	$0.64 \pm 2.78$
BMI ( $\text{kg}/\text{m}^2$ )	$0.11 \pm 0.76$	$0.20 \pm 1.07$
HbA1c (%)	$0.35 \pm 1.11$	$-0.04 \pm 1.12$
Cholesterol (mg/dL)	$5.33 \pm 26.62$	$3.00 \pm 30.93$
LDL cholesterol (mg/dL)	$12.75 \pm 29.80$	$14.75 \pm 22.30$
HDL cholesterol (mg/dL)	$0.47 \pm 6.66$	$-2.60 \pm 11.01$
Triglycerides (mg/dL)	$-17.72 \pm 174.9$	$-52.27 \pm 139.14$
Systolic blood pressure (mmHg)	$-8.36 \pm 16.22^{**}$	$-6.25 \pm 17.93$
Diastolic blood pressure (mmHg)	$-3.02 \pm 11.45$	$-3.92 \pm 14.65$
Diabetes care profile score	$-0.24 \pm 0.55^*$	$-0.12 \pm 0.80$
Problem areas in diabetes score	$2.50 \pm 9.71$	$-0.31 \pm 14.61$
Summary of diabetes self-care activities	$1.41 \pm 3.49^*$	$2.27 \pm 6.62$

Data shown as mean change  $\pm$  SD. Significance in change is tested by paired  $t$ -test and denoted by  $^* p < 0.1$  and  $^{**} p < 0.05$ .

after intervention, we did find some improvements in other outcomes (e.g., systolic blood pressure). To date, the literature on social support and HbA1c is mixed. The findings of our research suggest that social support alone may not reduce HbA1c. Our results are consistent with other studies that found modest improvements in diabetes understanding and self-care activities but no change in HbA1c [14, 22].

Our results indicate that the social support provided to the SSG may have helped to improve their systolic blood pressure. A similar study in African Americans found that despite no improvements in HbA1c after a 3-month diabetes self-management intervention, participants randomized to a 12-month social support group had significant improvements in systolic blood pressure while the control group did not [23]. This finding is important given that over time cardiovascular disease risk factors, such as systolic blood pressure, tend to worsen [24]. Additionally, the UKPDS study found that maintaining blood pressure in the normal range resulted in an 11% decrease in diabetes complications over 10 years [25]. Other studies have found that intensive blood pressure control can save approximately \$2,000 per quality-adjusted life-year in patients with type 2 diabetes [26].

Despite mixed findings in the research on the impact of social support on HbA1c in patients with diabetes, the association between social support and blood pressure is well established [27]. Based on communication with community researchers, there is a belief that social support groups can help to build relationships among community members and encourage interaction outside of the intervention. This could provide participants with a sense of accountability and opportunities to learn from each other, which may increase motivation to maintain positive behavior changes and improve psychosocial functioning [14, 28]. Thus, the use of social support groups remains a preference in our communities.

Our study has several limitations relevant to the SSG component. The sample size may have been too small to detect between group differences. Also, participants in the control group received bimonthly postcards reminding them of the skills they learned in the PIC intervention. These postcards may have been effective at helping participants maintain the self-care activities they initiated during the intervention, lessening any between group differences at  $T_3$ . As a RCT, participants were randomized after the 12-week PIC intervention. Due to the fact that several of these groups were small (e.g., 8 people), the number of people randomized to SSGs was very small, which may have limited the amount of support each group was able to provide. Additionally, some participants formed relationships in PIC but were separated by randomization into different groups, which possibly decreased the motivation of these participants. The structure of the SSG was set a priori; however some participants expressed an interest in diabetes-related topics not included and/or in an order different from what was scheduled, which may have caused participants to lose interest.

Our study concurs with the review done by Tomioka et al., in which they state that future research on the use of social support groups in improving HbA1c and blood pressure is necessary, a belief with which the community agrees [9]. The use of RCTs in which participants are randomized at the individual level after intervention may not be an appropriate design in testing support group components. Future designs could randomize by community site, allowing relationships built during the intervention to continue during support groups. Other recommendations include the use of support groups that occur on an ongoing basis facilitated by health professionals with diabetes expertise. Consequently, participants could attend as they feel necessary and exercise control in determining topics discussed. In conclusion, the PIC diabetes self-management intervention is effective at

decreasing participants' HbA1c and improving their self-management skills. However, maintaining improvements in HbA1c warrants further research.

## Disclosure

The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIMHD, the NIH or the Queen's Health Systems.

## Competing Interests

The authors declare that they have no competing interests.

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## Research Article

# Smoking Cessation Carries a Short-Term Rising Risk for Newly Diagnosed Diabetes Mellitus Independently of Weight Gain: A 6-Year Retrospective Cohort Study

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**Background.** The effects of smoking on human metabolism are complex. Although smoking increases risk for diabetes mellitus, smoking cessation was also reported to be associated with weight gain and incident diabetes mellitus. We therefore conducted this study to clarify the association between smoking status and newly diagnosed diabetes mellitus. **Methods.** An analysis was done using the data of a mass health examination performed annually in an industrial park from 2007 to 2013. The association between smoking status and newly diagnosed diabetes mellitus was analyzed with adjustment for weight gain and other potential confounders. **Results.** Compared with never-smokers, not only current smokers but also ex-smokers in their first two years of abstinence had higher odds ratios (ORs) for newly diagnosed diabetes mellitus (never-smokers 3.6%, OR as 1; current smokers 5.5%, OR = 1.499, 95% CI = 1.147–1.960, and  $p = 0.003$ ; ex-smokers in their first year of abstinence 7.5%, OR = 1.829, 95% CI = 0.906–3.694, and  $p = 0.092$ ; and ex-smokers in their second year of abstinence 9.0%, OR = 2.020, 95% CI = 1.031–3.955, and  $p = 0.040$ ). **Conclusion.** Smoking cessation generally decreased risk for newly diagnosed diabetes mellitus. However, increased odds were seen within the first 2 years of abstinence independently of weight gain.

## 1. Introduction

Smoking is the leading avoidable cause of premature death [1–5]. Cessation of tobacco use undoubtedly benefits health. However, many studies have reported that smoking cessation may implicate some hazard effects on health. It may sometimes cause weight gain and result in obesity [6–13], the second important preventable risk for premature death [14]. It may also increase diabetes mellitus risk in the short-term, presumptively owing to associated weight gain [13, 15]. But there are controversies among studies regarding smoking cessation, weight gain, and risk of incident diabetes mellitus. Baum and Chou reported in their NBER study that smokers were 7.8% less likely to be obese. The declining use of cigarettes was the most significantly attributing factor for the soaring prevalence of obesity in USA [16]. The average weight gain after smoking cessation varied widely and was roughly

estimated to be around 4–5 kg in two large-scale studies [12, 17], approximately equal to the amount different between the mean weight of smokers and nonsmokers. However, Weitzman et al. reported that environmental exposure to tobacco smoke or active smoking in American adolescents was associated with higher rate of metabolic syndrome and abdominal obesity [18]. In Williamson et al.'s national cohort study, people who never smoked and smokers weighed nearly the same at a 7 to 13 years' follow-up. Marked weight gain (i.e., greater than 13 kg) may sometimes be strongly associated with smoking cessation, but it usually occurs in a minority of smoking quitters (i.e., in Williamson et al.'s study, 9.8 percent of the men and 13.4 percent of the women who quit smoking) [12].

Additionally, there are debates about the risk for incident diabetes mellitus following smoking cessation, although the association between smoking and diabetes mellitus has been

well established [13, 19–24]. In this regard, Willi et al. did a meta-analysis on 25 prospective cohort studies including 1.2 million participants, with 45844 incidental cases of diabetes mellitus during a study follow-up period ranging from 5 to 30 years [19]. Compared with people who never smoked, the relative risk (RR) for diabetes mellitus in smokers was pooled and adjusted to be 1.44 (95% CI = 1.31–1.58). The risk was highest in heavy smokers (more than 19 cigarettes a day; RR = 1.61, 95% CI = 1.43–1.80) and lower in former active smokers (RR = 1.23, 95% CI = 1.14–1.33), consistent with a dose-response phenomenon. However, several studies disclosed controversial results. In Nagaya et al.'s longitudinal study, the risk for diabetes mellitus was increased by heavy smoking in obese men but decreased by light smoking in lean men [25]. On the other hand, study of Nakanishi et al. told another story. They found that smoking may dose-dependently increase risk for incident diabetes mellitus. But the relative risk was stronger in men with lower body mass index (body mass index less than 24.2 kg/m<sup>2</sup> versus body mass index (BMI) of 24.2 kg/m<sup>2</sup> or more) [26]. Nevertheless, Oba et al. suggested that “smoking cessation increases short-term risk of type 2 diabetes irrespective of weight gain” [27]. Likewise, Yeh et al.'s prospective cohort study found that the hazard for incident diabetes mellitus after smoking cessation reached its peak during the first 3 years (hazard ratio = 1.91; 95% CI = 1.19–3.05) and then gradually decreased to 0 at 12 years [15]. Furthermore, Kamaura et al. reported that smoking cessation only raised the rate of BMI increase briefly. There was even no increase in incidence of impaired fasting glucose [28]. Importantly, a prospective cohort study using the data from the Framingham Offspring Study disclosed that the cardiovascular benefit of smoking cessation was weakened by the presence of diabetes mellitus. But it was not influenced by subsequent weight gain [29]. Therefore, the occurrence of diabetes mellitus rather than weight gain following smoking cessation is the critical issue for care providers to encourage their clients abstaining from smoking.

Taking all the above together, it is crucial to clarify whether smoking cessation may indeed bring individuals harmful metabolic effects (i.e., sustained overweight or obesity and incident diabetes mellitus) and identify individuals vulnerable to its adverse effects. In this regard, there are fairly few studies exploring smoking cessation, incident diabetes mellitus, and weight change together. We therefore conducted this study to examine the association between smoking cessation and incident diabetes mellitus and its correlation with weight gain.

## 2. Materials and Methods

This retrospective cohort study was done after being approved by Chang Gung Memorial Hospital Institutional Review Board (Document number IRB 102-1014B). The profiles for analysis were extracted from the mass health examination performed for employees in an industrial park in middle Taiwan annually from 2007 to 2013. Self-reported smoking status (including how long they have smoked or quit smoking), drinking habit, and medical history (including diseases such as diabetes mellitus, hypertension, dyslipidemia,

and viral hepatitis and medication currently prescribed) were recorded by standardized questionnaires and were reconfirmed by a nurse-administered check-up. A total of 11032 people were included for screening. The female employees (455 in number) were excluded because they counted less than 5% of the total number, and all did not smoke ever. To avoid complexity, people (2125 in number) who did not have complete data, smoked just socially or resumed smoking during the study period, or were diagnosed as DM at first examination were all excluded as well. There were 8452 male employees eventually included in this study. All the included individuals were categorized into never-smokers who had never smoked before, ex-smokers who had quit smoking, and current smokers who had been smoking until the final health examination. The ex-smokers were further divided by the number of years they had quit smoking. The odds ratios (ORs) for newly diagnosed diabetes mellitus were then calculated with adjustment for potential confounders and compared among groups.

**2.1. Laboratory Measurement.** All biochemical tests were performed with fresh samples as instructed by manufacturer (7600 Clinical Analyzer, Hitachi High-Tech, Tokyo, Japan) under standardized quality control in the Clinical Laboratory Department at Chang Gung Memorial Hospital at Chiayi, Taiwan.

**2.2. Definition of Diabetes Mellitus and Newly Diagnosed Diabetes Mellitus.** The confirmation of diabetes mellitus usually needs two separated occasions of elevated plasma glucose higher than 6.9 mmol/L (125 mg/dL) or even strictly meeting the requirement of standard oral glucose tolerance test. In this retrospective study, it is hard to use these criteria. To avoid missing potential cases, people without history of diabetes mellitus but with just one occasion of fasting plasma glucose higher than 6.9 mmol/L (125 mg/dL) or newly receiving drug therapy for hyperglycemia were regarded as newly diagnosed diabetes mellitus.

**2.3. Definition of Other Variables in the Analysis.** The status of alcohol consumption was categorized as “drinks often,” “drinks occasionally,” and “drinks seldom.” People who just drank less than twice a month were regarded as “drinks occasionally.” Those who drank twice a month or more frequently were regarded as “drinks often.” Man with waist circumference 90 cm or higher was regarded as abdominal obesity. Systolic blood pressure equal to or higher than 130 mmHg, or diastolic blood pressure equal to or higher than 85 mmHg, or current use of antihypertensive medicines was regarded as high blood pressure. Serum triglyceride equal to or higher than 1.7 mmol/L (150 mg/dL) was regarded as dyslipidemia. Fasting plasma glucose from 5.6 to 6.9 mmol/L (100 to 125 mg/dL) was regarded as impaired fasting glucose.

**2.4. Statistical Analysis.** Logistic regression in SPSS 18.0 for Windows (SPSS Inc., Chicago, IL, USA) was used to estimate the ORs for newly diagnosed diabetes mellitus with smoking status as the main independent variable. The analysis was performed with adjustment for potential confounders including



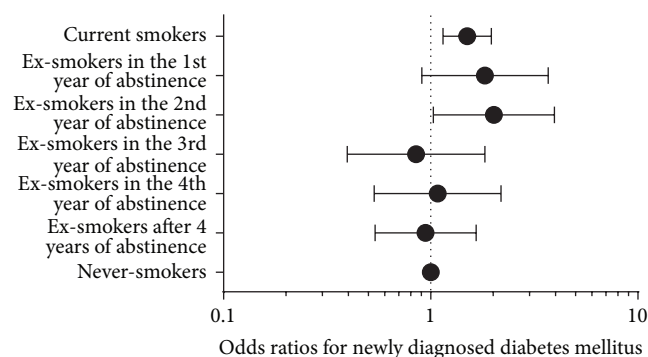


FIGURE 1: The comparison of the odds ratios for the incidence of newly diagnosed diabetes mellitus by smoking status. With never-smokers as reference (OR = 1), current smokers and ex-smokers in the first and second year of abstinence were inclined to have newly diagnosed diabetes mellitus, though the increased odds ratio for ex-smokers in the first year of abstinence was not statistically significant. All odds ratios were adjusted for age, alcohol consumption, abdominal obesity, high BP, dyslipidemia and impaired fasting glucose at their first examination, and weight gain between the first and the final examination.

age, status of alcohol consumption, abdominal obesity, high blood pressure, dyslipidemia and impaired fasting glucose at the first examination, and weight gain between the first and the final examination. A  $p$  value less than 0.05 and a 95% confidence interval (CI) of OR not containing 1 were considered statistically significant. The numbers of mean are presented with standard deviations in parenthesis.

### 3. Results

The study included 8452 men aged, at their first health examination, from 24 to 70 with mean age 41.4 ( $\pm 7.1$ ) years. There were 4370 (51.7%) men who never smoked, 1169 (13.7%) men who had quit smoking, and 2913 (34.5%) men who kept on smoking. In the group that had quit smoking, there were 146 (1.7%) men within the first year of smoking cessation, 144 (1.7%) within the 2nd, 278 (3.3%) within the 3rd, and 202 (2.4%) within the 4th and 399 (4.7%) had quit smoking longer than 4 years. The characteristics of the grouped individuals by smoking status were summarized in Table 1.

During this 6-year period, 374 men (4.4%) were newly diagnosed as diabetes mellitus. Compared with never-smokers, the current smokers had higher odds to have newly diagnosed diabetes mellitus (as shown in Figure 1). Additionally, the ex-smokers within their first 2 years of abstinence were also inclined to have newly diagnosed diabetes mellitus (never-smokers 3.6%, OR as 1; current smokers 5.5%, OR = 1.499, 95% CI = 1.147–1.960, and  $p = 0.003$ ; ex-smokers in the first year of abstinence 7.5%, OR = 1.829, 95% CI = 0.906–3.694, and  $p = 0.092$ ; ex-smokers in the second year of abstinence 9.0%, OR = 2.020, 95% CI = 1.031–3.955, and  $p = 0.040$ ; ex-smokers in the third year of abstinence 2.9%, OR = 0.850, 95% CI = 0.396–1.826, and  $p = 0.677$ ; ex-smokers in the fourth year of abstinence 5.0%, OR = 1.080, 95% CI =

0.533–2.187, and  $p = 0.831$ ; and the ex-smokers after 4 years of smoking cessation 4.0%, OR = 0.945, 95% CI = 0.539–1.658, and  $p = 0.845$ ).

### 4. Discussion

Tobacco smoking is a well established risk factor for many diseases, including several kinds of cancer [30–32] and cardiovascular and lung diseases. It raises the death rate in middle age by twofold to threefold [2, 4]. In particular, it may predispose to or is associated with type 2 diabetes mellitus [13, 19–25, 27, 33–36], which further contributes to the risk of cardiovascular diseases [37]. However, there are controversies about metabolic benefits from smoking cessation. In terms of smoking cessation, weight gain, and diabetes mellitus, many studies disclose that smoking and excess weight are often inversely related. However, this association seems to interact significantly with age. In MacKay et al.'s study, never-smokers or ex-smokers aged 16–24 years were not more likely to be overweight or obese than active smokers of the same age [11]. Although smoking cessation could be accompanied with a weight gain, most of it occurs during the first 6 months [38]. The usual average weight gain is around 4–5 kg. People at younger age (e.g., <55 years) and lower socioeconomic status and who used to smoke heavily (e.g., more than 25 cigarettes per day) or have history of binge eating are at risk for marked weight gain (i.e., more than 10 kg) [12, 39]. Moreover, in Clair et al.'s study, weight gain following smoking cessation did not influence its cardiovascular benefit unless there was a coexisting diabetes mellitus [29]. Even in patients with diabetes mellitus, smoking cessation may still reduce risk of premature death although it usually takes several years for effect [40]. It then becomes crucial to determine whether smoking cessation *per se* would increase risk for incidental diabetes mellitus despite weight gain or not.

In our study, we found that ex-smokers during their first two years of abstinence have even higher odds than current smokers for newly diagnosed diabetes mellitus, though the increased odds ratio for ex-smokers in the first year of abstinence was not statistically significant (as shown in Figure 1). This tendency is independent of weight gain. It seems incredible that people should immediately face rising odds for incident diabetes mellitus when they start quitting smoking. This contradictory result may arise from the immediate withdrawal of beneficial metabolic effect of certain constituents (e.g., nicotine) in tobacco [41–45] and the delayed subsiding of adverse effects or irreversible harmful effects from smoking [46, 47]. Like some diet drugs (e.g., sibutramine, phentermine, and bupirone), nicotine may suppress appetite and prevent weight gain by increasing central nervous system levels of norepinephrine, dopamine, and serotonin [48]. Smoking may influence appetite partially through the activation of hypothalamic melanocortin system [49]. It may also promote release of catecholamines and cortisol and suppress adiponectin [50, 51]. Moreover, the exposure to nicotine may increase beta cell apoptosis [52]. Although smoking is generally implicated with harmful effects, there are several studies that disclosed beneficial metabolic effects from certain constituents of tobacco [42–45]. Complexity of

TABLE 1: Demographics of the studied individuals by smoking status and metabolic characteristics.

Smoking status	Never-smokers	Ex-smokers in the 1st year of abstinence	Ex-smokers in the 2nd year of abstinence	Ex-smokers in the 3rd year of abstinence	Ex-smokers in the 4th year of abstinence	Ex-smokers after the 4th year of abstinence	Current smokers	Total
Number of people	4370	146	144	278	202	399	2913	8452
Age at the 1st exam.	41.3 (7.4)	43.0 (7.4)	45.0 (8.8)	41.6 (4.7)	43.7 (8.3)	42.3 (6.3)	40.9 (6.5)	41.4 (7.1)
Abdominal obesity at the 1st exam.	1080 (24.7)	39 (26.7)	43 (29.9)	73 (26.3)	52 (25.7)	115 (28.8)	923 (31.7)	2325 (27.5)
Dyslipidemia at the 1st exam.	1280 (29.3)	52 (35.6)	51 (35.4)	76 (27.3)	60 (29.7)	124 (31.1)	1227 (42.1)	2870 (34.0)
High blood pressure at the 1st exam.	3405 (77.9)	119 (81.5)	126 (87.5)	212 (76.3)	164 (81.2)	327 (82.0)	2285 (78.4)	6638 (78.5)
Impaired fasting glucose at the 1st exam.	1020 (23.3)	47 (32.2)	47 (32.6)	64 (23.0)	62 (30.7)	111 (27.8)	696 (23.9)	2047 (24.2)
Weight gain (kg) at the final exam.	1.08 (4.07)	2.41 (3.87)	0.99 (5.66)	1.28 (4.23)	0.91 (4.41)	1.07 (4.43)	1.33 (4.32)	1.19 (4.22)
Newly diagnosed DM	157 (3.6)	11 (7.5)	13 (9.0)	8 (2.9)	10 (5.0)	16 (4.0)	159 (5.5)	374 (4.4)

Data are number of people or mean. Percentage and standard deviation are shown in parenthesis. Continuous variables such as age and weight gain were calculated as means with standard deviation (SD) in parenthesis.

all the above findings could partially explain why smokers are prone to develop insulin resistance and have higher cardiovascular risk and the controversy why smoking cessation may sometimes not only cause weight gain [9, 53] but also increase incidence of diabetes mellitus [27, 28, 54].

There are a number of limitations in our study. The reasons people quitted smoking could not be explored. In particular, some of the ex-smokers might quit smoking because of great ill health. It may make us overestimate the smoking associated risk for incident diabetes mellitus. Additionally, the smoking status could not be further categorized by quantity of exposure. Given that smoking may reflect a clustering of risky life styles, there should be quite a few residual confounders in this study. In particular, diagnostic bias defining diabetes mellitus by only one occasion of abnormal fasting glucose, monogender, and the lack of counting the quantity of cigarette smoking all make the results of our study biased and of limitation. However, it may still provide some useful information. It discloses that smoking cessation generally decreases risk for incidental diabetes mellitus. But it may meanwhile carry a short-term (i.e., within the first couple of years) rising risk for incident diabetes mellitus. This association is independent of weight change.

## 5. Conclusion

Smoking cessation generally tends to decrease the incidence of newly diagnosed diabetes mellitus. However, rising odds are seen in the first 2 years after quitting smoking in our study. In particular, it is independent of weight gain. Therefore, we suggest that intensified modification of life style or other strategies for prevention of diabetes mellitus may be needed before and immediately after smoking cessation. At least, for smokers and ex-smokers at risk for diabetes mellitus, monitoring at shorter intervals should be considered for early detection.

## Competing Interests

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

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