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Factors Associated with Insulin Reluctance in Individuals with Type 2 Diabetes

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Factors Associated with Insulin Reluctance in Individuals with Type 2 Diabetes

by

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ABSTRACT

Background: There are many barriers to effective diabetes management for people with type 2 diabetes (T2D) and clinicians. Patients' reluctance to start insulin therapy is one of the barriers to effective management that may be influenced by patients' sociodemographic and psychosocial factors. Significant delay in starting insulin may increase complications and impair patients' quality of life. Little is known about insulin reluctance (IR) and its relationship with associated factors.

Purpose: 1) Summarize existing knowledge regarding various barriers to diabetes management from the perspectives of both patients and clinicians; 2) investigate the concept of IR, resistance to using insulin therapy, by describing patients' perceived barriers and their relationships with associated factors; and 3) examine the effectiveness of culturally competent diabetes education (CCDE) among ethnic minorities with T2D.

Methods: The first paper was a literature review regarding various barriers to diabetes management. The second study was a cross-sectional descriptive study. Data were collected from 178 people with T2D, who were 18 years or older, being treated with diabetic oral agents and able to speak English. The participants from general medicine practice clinics completed validated measures: *Diabetes Attitude Scale, Diabetes Knowledge Test, Diabetes Self-efficacy Scale, Interpersonal processes of Care and Barriers to Insulin Treatment.* Biomedical data were obtained from medical record reviews. The third study was a meta-analysis to evaluate the effectiveness of CCDE for ethnic minorities with T2D.

Findings: The first paper revealed that patients' adherence, attitude, knowledge about diabetes, culture, language capability, financial resources, comorbidity and social support may affect diabetes management. Clinician barriers to following treatment guidelines include beliefs, attitudes and knowledge, patient-clinician interaction and communication, and the health care system. The second study demonstrated that people with T2D had moderate IR. Fear of hypoglycemia was the strongest barrier to insulin treatment. Women were more reluctant to use insulin than men. Ethnic minorities had more psychological barriers to insulin treatment than whites. Greater diabetes self-efficacy scores predicted significantly less IR and better perceived interaction with the clinician may reduce IR. The third study showed that CCDE appears to be effective in improving glycemic control for ethnic minorities.

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TABLE OF CONTENTS

LIST OF TABLES

Chapter Three

Chapter Four

LIST OF FIGURES

Chapter Three

Chapter Four

CHAPTER ONE

Introduction

The prevalence of diabetes is increasing worldwide. Today, approximately 250 million people worldwide are living with diabetes and by 2025 this number is expected to increase to over 380 million (Worldwide Prevalence of Diabetes 2000-2030, 2009). Diabetes is the seventh leading cause of death in the United States (US) and the estimated diabetes care cost in the US is approximately $174 billion in 2007 (National Diabetes Statistics, 2007). For American men and women born in 2000, the lifetime risk of diabetes is projected at 33% and 38%, respectively (Narayan, Boyle, Thompson, Sorensen, & Williamson, 2003). According to the Center for Disease Control and Prevention (CDC, 2007), more than 20 million Americans have diabetes. In the next 50 years, diagnosed diabetes is predicted to increase by 165 % in the US, with the largest relative increases seen among African Americans, American Indians, Alaskan and Native Americans, Asian and Pacific Islanders, and Hispanics/Latinos (Boyle et al., 2001). In adults, type 2 diabetes accounts for about 90 to 95 % of all diagnosed cases of diabetes (National Diabetes Statistics, 2007).

Type 2 diabetes is a progressive, chronic illness that requires continuing medical care and patient self-management to prevent acute complications and reduce the risk of long-term complications. Diabetes is the leading cause of blindness, end-stage renal disease, and non-traumatic amputation, and people with diabetes are two or three times more likely to develop coronary artery disease (Nesto, 2001). Intensive control of blood glucose and associated cardiovascular risk factors is required in order to reduce the disease burden in people with type 2 diabetes (Collins, Armitage, Parish, Sleigh, & Peto, 2003; United Kingdom Prospective Diabetes Study (UKPDS) Group 33, 1998).

Many studies indicate patient education is a fundamental prerequisite for diabetes self-management and that people with diabetes have the primary role of performing their own care; currently, 90% to 98% of diabetes management is conducted by the person with diabetes (Anderson et al., 1994; Coonrod, Betschart, & Harris, 1994; Etzwiler, 1994). Since the 1990s, diabetes self-management interventions have integrated educational and behavioral strategies with a patient-centered approach. That is, the focus has shifted from provider-centered “compliance” approaches to patient-centered “empowerment” approaches and considerable research has been undertaken to evaluate the efficacy of self-management interventions designed to assist people with the complex endeavor of diabetes self-management (Anderson & Funnell, 2000; Anderson & Rubin; 2002; Glasgow & Anderson, 1999). Patient-centered approaches involve a collaborative relationship between the patient and the provider in which the provider assists the patient in making decisions about the daily management of diabetes. In addition to providing educational and behavioral strategies, coping skills and empowerment training are also included to address the psychosocial context of diabetes self-management (Anderson et al., 1995; Grey, Boland, Davidson, Li, & Tamborlane, 2000). However, the literature indicats that there are many barriers to effective diabetes treatment for both patients and clinicians (Snoek, 2000; Jerant, von Friederichs-Fitzwater, & Moore; 2005; Grant & Meigs, 2006). Adherence, knowledge, attitude, culture, ethnicity, financial resources, comorbidities and social supports are most frequently noted barriers to patient self-management. The most common barriers to follow diabetes treatment guidelines for clinicians are clinician’s attitude, knowledge, lack of effective communication, and health system. Identifying and understanding these barriers to diabetes management are critical to improve diabetes self-management education and quality of diabetes care.

Studies show that after 3 years of treatment, approximately 50% of patients with type 2 diabetes require more than one pharmacological agent and will eventually require insulin (DeWitt & Hirsch, 2003; Turner, Cull, Frighi, & Holman, 1999), given the progressive nature of type 2 diabetes (Wright, Burden, Paisey, Cull, & Holman, 2002). Based on the American College of Endocrinology (ACE) and American Diabetes Association (ADA) guidelines, health care providers should consider initiating insulin therapy in patients with glycosylated hemoglobin (HbA1c) concentrations greater than 7.0%, despite treatment with oral antidiabetic agents (DeWitt & Hirsch, 2003; Standards of medical care in diabetes, 2009). Unfortunately, many patients have negative preconceptions about insulin therapy, and thus, initiation of insulin therapy is often delayed longer than it should be. Patients' negative attitude toward insulin therapy may affect patients' ability to agree to the therapy and participate in self-management of type 2 diabetes using the prescribed therapy. Therefore, the delay of this important treatment for significant periods of time may increase complications and impair quality of life. Although there are several qualitative studies and surveys that address patients' beliefs and attitudes toward insulin therapy and the prevalence of patients' reluctance to initiate insulin therapy (Insulin Reluctance:IR) (Hunt, Valenzuela, & Pugh, 1997; Polonsky, Fisher, Dowe, & Edelman, 2003; Peyrot et al., 2005; Polonsky, Fisher, Guzman, Villa-Caballero, & Edelman, 2005; Polonsky & Jackson, 2004), research is limited in the area of what factors are associated with IR.

In 2004–2006, national survey data reported that 7.8% of Americans have diabetes, with prevalence rates of 6.6% among non-Hispanic whites compared to 7.5% among Asian Americans, 10.4% among Hispanics, and 11.8% among non-Hispanic blacks (CDC, 2007). Ethnic minorities also have significantly higher rates of diabetes-related complication and mortality compared to non-Hispanic whites (Harris, Klein, Cowie, Rowland, & Byrd-Holt, 1998; Lavery, van Houtum, Ashry, Armstrong, & Pugh, 1999; Carter, Pugh, & Monterrosa, 1996; Lanting, Joung, Mackenbach, Lamberts, & Bootsma, 2005)

Despite published evidence that supports diabetes education is an important intervention that improves quality of life and glycemic control for most patients (Gary, Genkinger, Guallar, Peyrot, & Brancati, 2003; Norris, Lau, Smith, Schmid, & Engelgau, 2002), the effect of diabetes education for ethnic minorities with type 2 diabetes has not been investigated. Therefore, this dissertation study had three main aims. The first aim was to summarize existing knowledge regarding various barriers to diabetes management from the perspective of both patients and clinicians. The second aim was to investigate the concept of insulin reluctance (IR), resistance to starting and using insulin therapy, by describing patients perceived barriers and their relationships with associated factors. Lastly, the third aim was to examine the effect of culturally competent diabetes education (CCDE) among ethnic minorities with type 2 diabetes because many studies demonstrated that ethnic minorities not only have many barriers to diabetes treatment but the prevalence of type 2 diabetes and the rate of diabetes complications in these groups are much higher than the white population.

The complete dissertation is organized into five chapters. Chapter one serves as the introduction, chapters 2-4 are comprised of the three original papers that will be submitted for publication. Finally, the last chapter (Chapter 5) summarizes findings from the three original papers and makes recommendations for future area of investigation. To address the aims of the dissertation, it includes three separate papers. The first paper (Chapter 2) entitled: "*Barriers to diabetes management: Patient and provider factors*" describes patient barriers to diabetes self-management and clinician barriers to treatment of type 2 diabetes. The purpose of this paper is to identify barriers to diabetes management to improve quality of diabetes care and to guide future research. The second paper (Chapter 3), entitled: "*Factors associated with insulin reluctance in individuals with type 2 diabetes*" presents the findings of an original research study with a sample of 178 adults with type 2 diabetes residing in San Francisco Bay area. The purpose of this investigation was two-fold: (1) to describe the relationship between IR in patients with type 2 diabetes and a) sociodemographic factors (age, gender, race/ethnicity, income, and education); b) biomedical factors (HbA1c, co-morbidities, and diabetes complications); and c) psychosocial factors (attitudes/beliefs, diabetes knowledge, diabetes self-management self-efficacy, and patient-provider interaction), and (2) to develop and test a predictive model of IR based on significant sociodemographic, biomedical, and psychosocial correlates of IR. The third paper (Chaper 4), entitled: "*Effect of culturally competent diabetes education in ethnic minorities with type 2 diabetes*" presents findings from an original meta-analysis of 15 studies examining the effect of culturally competent diabetes education (CCDE) on glycemic control in ethnic minorities with type 2 diabetes. The purpose of the meta-analysis was to summarize the direction and magnitude of the effect of diabetes education among ethnic minorities. Each of these three papers will be submitted for publication to relevant journals.

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CHAPTER TWO

Barriers to Diabetes Management: Patient and Provider Factors

Abstract

The prevalence of type 2 diabetes is increasing in all ethnic groups and its burden on the health care system requires efforts to more optimally treat those with the disease and improve their quality of life. Type 2 diabetes is a chronic illness that requires continuing medical care and patient self-management education to prevent acute complications and to reduce the risk of long-term complications. Despite significant advances in diagnosis and treatment, the persistence of inadequate metabolic control continues. Poor glycemic control may reflect both the failure of diabetes self-management by patients and the inadequate intervention by clinicians. There are many barriers to effective diabetes management for both patients and clinicians. Patients' adherence, attitude, beliefs, knowledge about diabetes may affect diabetes self-management. Culture and language capability influence health beliefs, attitudes, health literacy, thereby affecting diabetes self-management. Other influential factors are patient's financial resources, comorbidities and social support. Clinicians' attitude, beliefs and knowledge about diabetes also influence diabetes management. Clinicians may further influence patient's perception through effective communication skills and by having a well-integrated health care system. Identifying barriers to diabetes management is necessary to improve the quality of diabetes care, including improvement of metabolic control, and diabetes self-management.

Key Words: type 2 diabetes, self-management, barriers.

Introduction

The prevalence of type 2 diabetes is increasing worldwide. Type 2 diabetes is a chronic disease, associated with serious complication and comorbidity (Zimmet, Alberti, & Shaw, 2001; Schwarz, Schwarz, Schuppenies, Bornstein, Schulze, 2007). Despite recent improvements in glucose control in adults with diabetes (Hoerger, Segel, Gregg, & Saaddine, 2008), <15% of adults with diabetes simultaneously meet the goal for three important components of care (i.e. glucose, blood pressure and LDL cholesterol) as recently as 2007 (Minnesota Community Measurement, 2009). Unsatisfactory medical outcomes reflect contributions from not only lack of the patient's self-management, but also the failure of the health care provider to initiate or intensify therapy appropriately (Aljasem, Peyrot, Wissow, & Rubin, 2001). For this review, diabetes self-management refers to the various tasks which persons with type 2 diabetes need to perform and engage in on a regular basis, including self-monitoring of blood-glucose, taking medications properly, physical activity, healthy eating, and foot examinations at regular intervals, among other self-management activities.

Identifying and understanding barriers to patient's self-management and clinician interventions to ensure adherence to diabetes standards of care are the first step in improving diabetes care and for successful diabetes management.

Patient Factors

Adherence. Better adherence to a self-care regimen, a characteristic of active patient self-management can reduce mortality and disability, improve quality of life, and reduce health care costs (Gallagher, Viscoli, & Horwitz, 1993; Horwitz & Horwitz, 1993; Horwitz et al., 1990). Glycemic control is affected by poor patient adherence to the treatment regimen, for example, failure to keep appointments or to take medications as recommended (Nicolucci, Carinci, & Ciampi, 1998). Several studies compared cohorts with different regimens in medication adherence. Once-daily regimens had higher adherence than twice-daily regimen (61 vs. 52%) (Dezii, Kawabata, & Tran, 2002). Monotherapy regimens demonstrated higher adherence than polytherapy regimens (49 vs.36%) (Chiechanowski, Katon, & Russo, 2000). Among patients with diabetes, adherence rates were lower for insulin use than for oral hypoglycemic agents (73-86%) (Rajagopalan, Joyce, Smith, Ollendorf, & Murray, 2003). Poor adherence among persons with type 2 diabetes has been attributed to misperceptions regarding the potential seriousness of the disease as well as to differences between patients' understanding of the disease and those of health care providers (Lawton, Peel, Parry, Araoz, & Douglas, 2005). In a qualitative study, Anon (1997) demonstrated that the most salient influence on adherence to the treatment regimen is a person's beliefs about the disease and its treatment and the beliefs are influenced by one's culture and disease chronicity.

Attitudes and beliefs. People with diabetes hold a wide range of attitudes and beliefs about diabetes and its treatment that affect the way they perceive the need for and importance of self-management education. Anderson et al. (1990) surveyed 1,202 persons with type 2 diabetes, using a revised version of the Diabetes Attitude Scale (DAS). The mean age of the sample was 50.7 years; 65% of the sample was female. Findings revealed an association between persons with positive attitudes and adherence outcomes.

Similar findings were seen in the study conducted by Farmer, Kinmouth, and Sutton (2006). Beliefs about the benefits of medications were positively and strongly associated with the intention to take medications regularly by a sample of 121 persons with type 2 diabetes, age 40 years and older in a general practice. Other studies confirm that persons who have positive attitudes toward managing their diabetes will be more likely to change their behavior in order to control their blood glucose levels than those with negative attitudes (de Weerdt et al., 1990; Dunn, 1990; Masaki, Okada, & Ota, 1990).

The natural progression of type 2 diabetes suggests 60% of people with the disease will eventually require insulin treatment to optimally control blood glucose levels (Wright et al., 2002). Unfortunately, people with type 2 diabetes often hold negative attitudes toward treatment due to fears, misconceptions, and prejudices, especially as they relate to the reluctance to initiate necessary insulin therapy (Davis & Renda, 2006). Despite the demonstrated efficacy of insulin therapy in achieving and maintaining glycemic control in people with type 2 diabetes, many people who could benefit from insulin therapy do not receive it, or do not receive it in a timely manner (Brown, Nichols, & Perry, 2004; Dailey, 2005; Davidson, 2005). In a recent survey of insulin-naïve patients with type 2 diabetes, 24.7% reported an unwillingness to take insulin if it were prescribed (Polonsky, Fisher, Dowe, & Edelman, 2003). Similarly, in another survey of persons with type 2 diabetes, 33 % of the respondents were unwilling to take insulin (Larkin, Capasso, Chen, Mahoney, Hazard, Cagliero, & Nathan, 2008). The reluctance to initiate insulin therapy in a timely manner is based on a variety of factors, primarily beliefs and perceptions regarding diabetes and treatment.

Several studies have identified that patients' attitudes and beliefs contribute to the non-acceptance of insulin therapy (Freemantle et al., 2005; Hunt, Valenzuela, & Pugh, 1997; Mollema, Snoek, Pouwer, Heine, & van der Ploeg, 2000; Zambanini, Newson, Maisey, & Feher, 1999). Patients perceive insulin therapy as evidence of personal failure and well-deserved punishment for failing to manage their disease (Davis & Renda, 2006). Many patients may have received subtle messages from their health care providers that insulin will be a last resort and initiated only if they fail to control the disease with diet, exercise and oral agents (Wallace & Matthews, 2000). In addition, patients have a fear of daily insulin injections. Other negative attitudes include the belief that taking insulin means life will be more restricted and that taking insulin will not be effective, rather that it will make the disease worse and produce more severe complications (Davis & Renda, 2006). Common misconceptions about the need for transitioning to insulin therapy may affect a patient's ability to agree and participate in self-management of type 2 diabetes.

Knowledge. The relationship between knowledge and health outcome is inconsistent. Knowledge does not necessarily lead to risk-reducing behavior: people may engage in unhealthy behaviors despite knowledge of their risks (Avis, McKinlay, & Smith, 1990).

Heisler et al. (2005) examined whether knowing one's most recent HbA1c test result is associated with a more accurate assessment of diabetes control and better diabetes self-care understanding, self-efficacy, and behaviors related to glycemic control. The study sample consisted of 843 adults with type 2 diabetes receiving care in five southeast Michigan health care facilities: a Veterans Affairs medical center (VAMC), an academic medical center (AMC), and three inner city health systems. Respondents who knew their HbA1c values reported better understanding of diabetes self-management and assessment of their glycemic control as compared to respondents who did not know their

HbA1c values. Knowledge of one's HbA1c level alone, however, was not sufficient to translate increased understanding of diabetes care into the increased confidence and motivation necessary to improve one's diabetes self-management.

Findings from a study of 670 adults with diabetes suggested that knowledgeable patients were more likely to perform self-management activities. However, the patients did not reach metabolic outcome goals, nor did they receive the recommended ambulatory care for persons with diabetes (Persell et al., 2004).

Similarly, in an observational study of 284 insulin-treated veterans with stable type 2 diabetes, subjects with higher knowledge scores also perceived fewer barriers to blood glucose monitoring ($r=0.211$; $p=0.006$). However, performance on the diabetes knowledge test was not related to perceived adherence to self-care, diet, exercise or medication. In the study, multivariate analysis showed that age, years of schooling, duration of treatment, cognitive function, sex and level of depression were independent determinants of the knowledge score (Murata, Shah, Adam, Wendel, Bokhari, Solvas, Hoffman, & Duckwirth, 2003). In another study, investigators found that limited knowledge about diabetes and its causes and symptoms affected the prevention of diabetes-related complications (Pace, Ochoa-Vigo, Caliri, & Fernandes, 2006). In contrast, Anderson and colleagues (1990) demonstrated that the less people knew about diabetes, the less likely they were to develop strong attitudes towards the condition and its self-care, positive or negative.

Thus, knowledge itself may not be sufficient to motivate one to manage diabetes. However, knowledge is intermittently but not consistently linked to disease outcome. Even when people adhere to the prescribed diabetes regimen, many of them report they do not know why they are performing the self-management strategies, nor do they know the benefits of performing such actions (Holmstrom & Rosenqvist, 2005). Thus, misunderstandings about diabetes and its treatment were both common and numerous, despite regular check-ups and adequate access to care.

Culture/Ethnicity/Language. Culture influences one's beliefs, attitudes, knowledge, and behaviors, and thereby, can affect diabetes self-management (Bruce, Davis, Cull, & Davis, 2003; Ford, Mai, Manson, Rukin, & Dunne, 2000; Friedman, 1990; Holmstrom & Rosenqvist, 2005). Fitzgerald et al. (2000) examined patients' attitudes (n=672) toward diabetes by treatment modality (insulin vs. no insulin), race/ethnicity, and the interaction of these two variables for Caucasians and African Americans with type 2 diabetes (Fitzgerald et al., 2000). Caucasians not using insulin reported the most positive attitude and the least negative attitude toward diabetes care. The reverse was true for the Caucasians using insulin: this group reported the least positive attitudes and the most negative attitudes toward diabetes care. In contrast, African Americans had less differences in the scores for this attitude scales between insulin users and non-insulin users. The study also showed that in comparison to Caucasians, African Americans reported receiving more support from family and friends. Furthermore, the support they received was interpreted more positively (Fitzgerald et al., 2000).

Lipton and colleagues (1998) reported that the misconception that insulin is potentially harmful is a common belief among traditional Mexican Americans and probably inhibits participation in insulin treatment. They also reported that in many cases, the emotional barriers and cultural beliefs of Latinos were more important than financial barriers, even among low-income, urban residents. The investigators noted that because family needs are considered most important, adhering to a treatment regimen might be viewed as self-indulgent to Latino clients.

Cultural factors to consider in diabetes management include food and dietary preference, lifestyle, and traditional and religious belief and belief about general health. In Chinese culture, the freedom to enjoy food plays a critical role in one's quality of life (Yao et al., 2002). Lai et al. (2005) conducted in-depth interviews with 22 Taiwanese persons with type 2 diabetes to examine their perceptions about their condition and self-management strategies. Self-management strategies included dietary restriction and physical activity. Many of participants believed sweating related to a spa bath would decrease drug absorption and avoid the renal toxicity of hypoglycemic agents.

To date, no research has been done comparing cultural beliefs in diabetes self-management across different racial ethnic groups. Caban and colleagues (2006) conducted a systematic review of research on culturally relevant issues for Hispanics with diabetes. In the review, they demonstrated that the perceived cause of diabetes, perspectives about God, living with diabetes, the use of folk healers, the use of alternative treatment and fatalism differed by subgroups of Hispanics within United States and level of acculturation. The authors concluded that while clinician and educators will benefit from understanding individual perspectives about diabetes, understanding these perspectives within a larger socio-environmental context is also important because a statement regarding Hispanics' cultural belief may not be applicable across all Hispanic subgroups.

A review of spirituality and diabetes self-management in African American conducted by Polzer et al. (2005) showed that spirituality is deeply embedded in African

American cultural heritage and is intertwined in all aspect of life including beliefs about health and illness. Although little research has focused on how spiritual beliefs and practices affect self-management of diabetes in African American, the authors suggested that spirituality may enhance self-management of diabetes, as shown in studies of other illness such as cancer and HIV, by serving as a source of support when they turn to God.

Greater understanding of health issues related to culture is important because cultural beliefs and practices may facilitate or deter diabetes management.

While difference in culture can explain some of the barriers in diabetes care, more research is needed to better understand the role of the culture in health issues and its mechanism within complex socio-structural contexts.

The patient-provider relationship is built through communication and the effective use of language. Language ability in English is a primary barrier for many ethnic minorities to fully access mainstream health services. Hispanic minority populations in particular have poor access to treatment and services because of language and literacy barriers (Dagogo-Jack, Funnell, & Davidson, 2006).

Lasater and associates (2001) conducted a retrospective cohort study with 183 Hispanic patients with type 2 diabetes who were Spanish-speaking (SS) only and control patients were English-speaking (ES) or bilingual. In the study, Spanish-speaking patients were less likely to understand their prescriptions; 22% of SS patients reported no comprehension vs. 3% of ES patients (p=.001). Although there was not a statistically significant difference between two groups, a trend was observed that SS patients were less likely than ES patients to be taking insulin (30% vs. 42%, respectively; p=.07) (Lasater, Davidson, Steiner, & Mehler, 2001). These findings suggest that language discordance between clinicians and patients may impact the process of patient education and thus adversely affects glycemic control in Hispanic patients with type 2 diabetes.

Financial resources. In addition to culture, cost of treatment may be a significant barrier to diabetes treatment, particularly for patients with a low socioeconomic status and limited to no health insurance coverage. In a diabetes screening program in New Mexico, low annual income and lack of health insurance were identified as primary reasons why patients (n=118) with newly diagnosed type 2 diabetes did not seek and obtain medical care (Burge, Lucero, Rassam, & Shade, 2000). Sixty percent of uninsured patients failed to obtain care following diagnosis compared with 6% of those who were insured. In addition, in a 7 year study of Mexican Americans with diabetes (n=908), inadequate health insurance was significantly associated with inconsistent use of medications, which related to increased likelihood of reporting kidney problems (p=0.008), all-cause mortality (p=0.003) and diabetes associated death (p=0.002) (Kuo, Raji, Markides, et al., 2003)

In one qualitative study, patients (n=54) reported they would cut pills in half to reduce medication costs if they could not afford to take medications as prescribed (Jerant et al., 2005). Other patients reported they missed medical appointments because they did not have transportation and could not afford to take the bus or a cab.

Co-morbidities. People with multiple chronic conditions frequently experience barriers to self-management due to the simultaneous demands of competing co-morbidities, such as back pain, arthritis, asthma, congestive heart failure, chronic obstructive pulmonary disease, fatigue, and depression (Bayliss, Steiner, Fernald, Crane, & Main, 2003; Jerant, von Friederichs-Fitzwater, & Moore, 2005). A study of seniors with multiple morbidities showed the potential barriers to self management that were significantly associated with low levels of physical functioning were high level of morbidity, compound effects of conditions and persistent depressive symptom (Bayliss, Ellis, & Steiner, 2007).

Up to 33% of people with diabetes suffer an episode of major depression during their lifetime (Lustman, Clouse, & Freedland, 1998). Depression is twice as high among people with diabetes as compared to those without chronic disease (Anderson, Freedland, Clouse, & Lustman, 2001; Peyrot & Rubin, 1997). Many people with type 2 diabetes do not seek professional help to deal with the depression (Jerant et al., 2005). Depression interferes with diabetes self-management and glycemic control because it has the potential to alter the perception of disease self-management and is associated with increased morbidity, mortality, functional limitation, and health care costs (Lustman et al., 2000). Depression is an independent risk for increased diabetes complications, particularly macrovascular disease and retinopathy (Kovacs, Mukerji, Drash, & Iyengar, 1995; Lustman et al., 1998; Mazze, Lucido, & Shamoon, 1984).

Social support. Numerous studies have demonstrated that social support, particularly from family members, is health promoting and risk reducing (Berkman, 2000). Lack of social support affects perceived barriers to self-care (Bayliss, 2003). Wang and Fenske (1996) examined the relationships among the source of support, universal self-care, and health-deviation self-care behaviors in 75 adults with type 2 diabetes who controlled their blood glucose with oral agents. The sample was 53% female and 47% male with age range between 31 and 84 years and predominantly white. Seventy-three of the participants were white and two were black. The group with family and friend support reported significantly more universal self-care and health-deviation self-care behaviors as compared to the group without support.

Jerant and colleagues (2005) found that because persons with type 2 diabetes and other chronic conditions often do not outwardly look “sick,” family members have difficulty believing that the patient needs support to adhere to diet and exercise regimens. They concluded that people who perceive they have strong, positive social support seem better able to cope with their various conditions. However, not all social support is equally helpful; social support can have negative as well as positive effects. Wing and associate (1991) conducted a study to test a family-oriented approach for obese patients with type 2 diabetes. Spouse participation in weight loss education groups had a negative impact for obese men with type 2 diabetes while obese women with type 2 diabetes reached more weight loss with their spouse support (Wing, Marcus, Epstein, & Jaward, 1991).

Health Care Provider Factors

Most of the published literature related to diabetes self-management focuses exclusively on patients, rather than clinicians or patient-clinician interactions. Patients and clinicians differ substantially in their perceptions, knowledge and attitudes, which may lead to confusion and conflict, and in turn, to poor outcomes (Anderson, Fitzgerald, Gorenflo, & Oh, 1993). Better understanding of clinician factors is needed to improve diabetes self-management education and quality of diabetes care. The following topics on provider’s barriers were evaluated: belief, attitude, knowledge, communication, and health system.

Beliefs, attitudes, and knowledge. Physicians' attitudes toward diabetes management may be more important than their actual knowledge of the disease. Puder and Keller (2003) mentioned in their reviews that clinicians' beliefs, attitudes, and knowledge influence patients' adherence to the prescribed regimen. Many clinicians still consider type 2 diabetes to be a non-serious disease (Puder & Keller, 2003).

Dietrich (1996) found that physician's attitude at the time of diagnosis was critical in patient's attitudes about the seriousness of diabetes and subsequent self-management behavior. Feelings at the time of diagnosis ranged from being scared, shocked, and panicky to being mad and resigned. Dietrich found that if the physician reacted by downplaying the seriousness of the disease, it was perceived as less serious by the patient. Similarly, Hunt and colleagues (1997) found that patient attitudes toward insulin therapy were influenced by clinicians' attitudes, as well as personal experiences and observations.

Larme and associate (1998) studied attitudes of primary care providers toward diabetes. They found most providers considered diabetes harder to treat than hypertension ($p=.03$) and angina ($p=.03$). A majority also rated hyperlipidemia and arthritis as easier to treat than diabetes, but the ratings were not statistically significant (Larme & Pugh, 1998). Larme and associates also did qualitative analysis to gain an in-depth understanding of provider attitudes. The qualitative analysis revealed that the clinicians actually doubted the efficacy of diabetes treatment and their abilities to carry it out. This finding suggests that clinician attitude toward treatment efficacy can counteract the diabetes management, during the patient encounter because both clinicians and patients share frustrations with diabetes. The patient may perceive the inability of either party to achieve a sense of control over the disease and thus the patients' perception may affect their empowerment in diabetes self-management (Larme, & Pugh, 1998).

Clinician's lack of knowledge of recent evidence-based guidelines may affect the diabetes care outcome. In particular, physicians are uncertain about when to start insulin and which and how much insulin they should use (Brown et al., 2002).

The clinician's lack of knowledge about patients' psychological well-being has also been reported (Peyrot et al., 2005). In a cross-sectional study of 3,827 providers and 5,104 adults with type 1 and 2 diabetes in 13 countries, only 10% of patients reported receiving psychological treatment. Despite awareness that up to 41% of patients with diabetes experience psychological symptoms that affected their ability to self-manage their diabetes, many clinicians reported a lack of confidence in their ability to identify and evaluate psychological problems and to provide support for patients who suffer from these problems (Peyrot et al., 2005).

Implications from these studies are that training should be provided to health care providers in order to increase their knowledge of diabetes and influence their beliefs and attitudes about collaborative self-care diabetes management (Brown et al., 2002; Larme & Pugh, 1998). Additional skill training in recognizing and managing psychological distress is also warranted.

Patient-provider interaction and communication. Patients' disease perceptions are influenced by the types of services they receive and the type of health care professionals they encounter as part of their diabetes care (Lawton et al., 2005). Good patient-provider communication predicts better diabetes self-care, better diabetes outcomes, or both (Schillinger et al., 2003). Unfortunately, many patients report significant barriers to collaborative diabetes management, which affect adherence (Schillinger, Bindman, Wang, Stewart, & Piette, 2004). Most clinicians recognize that they lack effective communication tools and skills in counseling and shared decision-making (Wens, Vermeire, Royen, Sabbe, & Denekens, 2005) and perceive this lack of skill to be a barrier to effective diabetes treatment (Day, 1995; Hunt et al., 1997; Kaplan, Chadwick, & Schimmel, 1985). In a study that involved 367 patients with types 1 and 2 diabetes in a primary care setting, poor patient-provider communication was associated with poor treatment adherence (Ciechanowski, Katon, Russo, & Walker, 2001).

Several randomized controlled trials (RCTs) were conducted to test whether clinician-focused interventions improved clinician-patient interaction and communication and patients' diabetes outcomes (Kinmonth, Woodcock, Griffin, Spiegal, & Campbell, 1998; Pill, Stott, Rollnick, & Rees, 1998;Woodcock, Kinmonth, Campbell, Griffin, & Spiegal, 1998). Unfortunately, Kinmonth et al. (1998) found that clinician training produced some improvement in communication and patient satisfaction but did not significantly change diabetes outcome such as knowledge, HbA1c, BMI, and other cardiovascular risk factors in the patients. In contrast, in the five other RCTs that tested a patient-focused interventions, improvements in patients' psychosocial factors (i.e. diabetes knowledge, attitude and self-efficacy) and biomedical factors (i.e. HbA1c, BMI and cardiovascular risk factors) were seen (Anderson, Funnell, Butler, Arnold, Fitzgerald, & Feste, 1995; Greefiled, Kaplan, Ware, Yano, & Frank, 1998; Piette, Weinberger, & McPhee, 2000; Piette, Weinberger, McPhee, Mah, Kraemer, & Crapo, 2000; Trento, Passera, Tomalino, Bajardi, Pomero, Allione, et al., 2001).

It may be difficult for clinicians to change their communication style to one that is more effective, even when supported by special training programs. Furthermore, it may not be feasible for clinicians providing diabetes care in primary care settings to implement in their daily work the most comprehensive type of intervention that addresses patient psychosocial issues and encourages participation in diabetes self-management in addition to medication and metabolic management.

Health care system. Over 75% of persons diagnosed with type 2 diabetes receive diabetes care exclusively from primary care providers (Vogt, 1993). Yet, only about one-third of patients with type 2 diabetes follow correctly the health care provider's directions for diabetes care (Vogt, 1993). In the current health care system, overstretched primary care providers need to complete many preventive activities, deal with chief complaints, write prescriptions and referrals, and handle other issues within a 10- to 15-minute office visit (Vogt, 1993). Thus, it is difficult for primary care providers to devote extensive time to the behavioral, psychosocial, and emotional issues of persons with type 2 diabetes.

Research suggests that longer appointment times for patients with chronic diseases, provision of automated reminder systems, and tools such as flowsheets or checklists can improve diabetes care (Eytan & Goldberg, 2001; Larme & Pugh, 1998; "Standards of medical care for patients with diabetes mellitus," 2009). Ziemer and colleagues (2006) conducted a 3-year RCT to determine whether receiving computerized reminders that provide patient-specific recommendations at each visit and/or performance improvement feedback every 2 weeks will lead providers' intensifying diabetes therapy appropriately and improve diabetes outcomes in a primary care setting as compared to a control group. The sample was comprised of 345 internal medicine residents. After 3 years, providers who received computerized reminders alone showed no statistical difference in tendency to intensify therapy when compared to a control group of providers. On the contrary, after 3 years, providers who received computerized reminders plus performance improvement feedback and providers who received performance improvement feedback only demonstrated a statistically significant improvement in their efforts to intensify diabetes therapy when compared to the control group of providers. Results indicate that feedback on performance improved provider behavior and lowered patient's HbA1c levels.

Another RCT assessed the effect of a multifaceted intervention directed at general practitioners (GP) on six year mortality, morbidity, and risk factors of patients with newly diagnosed type 2 diabetes (Olivarius et al., 2001). The multifaceted intervention provided to 484 GPs included regular follow up and individualized goals for patients supported by prompting doctors, clinical guidelines, feedback, and continuing medical education. In addition, follow-up every 3 months and annual screening for diabetic complications were evaluated by sending a questionnaire to the GP one month before the next expected consultation. The GP was also requested to define, together with the patient, the best possible goals for blood glucose concentration, HbA1c, blood pressure, and lipid level within three predefined categories (good, acceptable, poor control). At each quarterly consultation, the GP was asked to compare the achievements with the goals and consider changing either goals or treatment. The GPs received annual descriptive feedback reports on individual patients. In the control group, GPs were free to choose any treatment and change it over time. The following risk factor levels were significantly lower for intervention patients than for comparison patients (median values):

fasting plasma glucose concentration (7.9 vs. 8.7 mmol/l, p=.0007), HbA1c (8.5% vs. 9.0%, p<.0001), systolic BP (145 vs 150 mm Hg, p=.0004) and cholesterol concentration (6.0 vs. 6.1 mmol/l, p=.029). Intervention GPs arranged more follow up consultations and became more focused on lowering risk factors through setting goals. The results indicate that in a primary care setting, individualized goals with educational and surveillance support for GPs may reduce risk factors associated with diabetes-related complications in persons with type 2 diabetes.

Summary

Effective type 2 diabetes management is widely acknowledged to be challenging to both patients and health care providers.

Several patient factors may contribute to type 2 diabetes management: adherence, beliefs, attitudes, knowledge, ethnicity/culture, language ability, financial resources, co-morbidities, and social support. Adherence to self-management, which is commonly influenced by a person's beliefs, attitudes, and knowledge about the disease and effectiveness of the treatment regimen, positively affects glycemic control. Knowledge alone, however, does not necessarily lead to a change in behavior. Fears and misconceptions can negatively affect adherence, particularly when patients perceive insulin therapy to be evidence of personal failure. Culture is also an influential factor in diabetes care. Studies reveal cultural differences related to beliefs and attitudes about taking or not taking insulin. The relationship between culture and diabetes self-management is complex and varied among different cultural groups; continued research is needed to understand cultural beliefs within larger sociostructural contexts. Co-morbidities are barriers to self-management because of competing treatment regimens.

Depression decreases perceived ability to self-manage the illness. Positive social support may serve as a mediating/modifying factor to patients' perceived barriers of self-care, health promotion, and risk reduction. Thus, it is important that patients are guided in learning actively about the disease and treatment, that patient beliefs and attitudes toward the disease and its treatment are explored, and that skills necessary to adjust behavior and psychological barriers to manage health outcomes are taught. A number of methodological issues, including causality, selection bias, self-report, confounders, and measurement issues limit the studies reviewed for exploring patient factors. Despite these limitations, study findings suggest there multiple patient factors that influence diabetes self-management for people with type 2 diabetes can be efficaciously addresseed.

Clinician factors include failing to follow treatment guidelines, beliefs, attitudes and knowledge, patient-clinician interaction and communication, and the health care system. The evidence RCTs bring to support their findings is methodologically strong but the flaw of RCTs is that they often have limited generalizeability. Most RCTs reviewed were conducted in primary care settings and research subjects were physician providers and not nurse practitioners, dieticians, pharmacist and other diabetes educators who commonly provide diabetes care. The patients in reviewed RCTs were primarily Whites. Therefore inference from these studies may be applied only to physicians who work in primary care settings with a White population.

There is a significant gap between what is known about diabetes care and what is commonly practiced, especially in primary health care. This gap between research and practice is the result of several interacting factors, including limited time and resources of practitioners, insufficient training, lack of feedback and incentives for use of evidence-based practices, and inadequate infrastructure and systems organization to support translation. Future research is needed to address theses gaps in the literature and to develop the effective strategies to treat type 2 diabetes.

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CHAPTER THREE

Factors Associated with Insulin Reluctance in Individuals with Type 2 Diabetes

Abstract

Objective: The purpose of this study was to describe the relationship between reluctance to use insulin and sociodemographic, biomedical and psychosocial factors in patients with type 2 diabetes.

Research Design and Methods: Using a cross-sectional, descriptive correlational design, a total of 178 women and men with type 2 diabetes in San Francisco Bay Area were enrolled and participated in this study. Cross sectional data were obtained by patient interview using the following validated measures: Diabetes Attitude Scale, Diabetes Knowledge Test, Diabetes Self-efficacy Scale, Interpersonal Processes of Care (IPC) and Barriers to Insulin Treatment (BIT). Sociodemographic data was obtained by patient self-report. Study investigators reviewed the patient medical record to obtain biomedical data.

Results: Women had higher fear of injections [mean difference (MD) 4.5, $p<.001$] and stigmatization than men [MD 2.8, $p=.01$]. Asians had significantly higher fear of injections [MD 5.4, $p=.003$] and expected greater hardship in using insulin than Whites [MD 3.9, $p=.03$]. Other minority groups (Hispanics, American Indians and Pacific Islanders) also had significantly higher fear of injection than Whites [MD 6.14, $p=.031$]. Patients with a higher level of education were less fearful of hypoglycemia. Younger people tended to have more positive expectations regarding insulin treatment but expected greater hardship. Individuals who believed in potential benefit of tight glucose control were less reluctant to start insulin treatment ($r=-.284$, $p<.01$). Greater diabetes self-efficacy scores predicted significantly less IR ($r=-.312$, $p<.01$). The IPC had a negative association with the IR ($r=-.436$, $p<.01$), indicating that better perceived interaction with the clinician may reduce IR.

Conclusions: Theses findings suggest that women and ethnic minorities with type 2 diabetes have more psychological barriers to insulin treatment. Diabetes self-efficacy and better interaction with clinicians were important in decreasing IR. Further research is needed to develop interventions to reduce psychological barriers to insulin treatment for this large and growing population.

Key Words: type 2 diabetes, insulin treatment, psychosocial barriers, ethnic minority.

Introduction

Diabetes mellitus is a major health concern in the United States, with the prevalence increasing in all ethnic groups. According to the Center for Disease Control and Prevention (CDC, 2007), more than 20 million Americans, approximately 8 % of the total population now have diabetes. Type 2 diabetes accounts for 90 to 95 % of all cases. Diabetes is a chronic illness that requires continual medical care and patient self-management to prevent acute complications and to reduce the risk of long-term complications. Although there has been substantial research showing that diabetes management through lifestyle modification improves glycemic control and prevention of diabetes complications, a large percentage of individuals with type 2 diabetes will eventually require exogenous insulin therapy to achieve and maintain recommended targets for glycemic control given the progressive nature of this disease (UKPDS 26, 1996; UKPDS 24, 1998; UKPDS 33, 1998). Unfortunately, many patients are reluctant to use insulin therapy. In the United Kingdom Prospective Diabetes Study (UKPDS), 27% of patients randomized to receive insulin initially refused treatment (UKPDS 13, 1995). In the Diabetes Attitudes, Wishes, and Need (DAWN) study, more than half of insulin-naive patients expressed anxiety about starting insulin therapy (Peyrot et al., 2005). Okazaki et al. (1999) reported that 73 % of type 2 patients beginning a diabetes education program in which insulin was to be initiated were reluctant to start insulin therapy at first. Lastly, Polonsky et al. (2003) surveyed insulin-naive type 2 diabetes patients and found that 24.7 % of respondents reported an unwillingness to take insulin if it was prescribed (Polonsky, Fisher, Dowe, & Edelman, 2003).

The delay of insulin initiation for significant periods of time in patients not meeting glycemic targets, prolongs poor glycemic control, may increase complications and impair quality of life. Factor affecting the delay in or reluctance to use insulin may include patient beliefs, attitudes and knowledge about the disease and its treatment and other barriers. Patients' self-efficacy and interaction with health care provider have been shown to be potential predictors of health beliefs and outcomes in type 2 diabetes (Holden, 1991; Lawton, Peel, Parry, Araoz, & Douglas, 2005; Sarkar, Fisher, & Schillinger, 2006; Schillinger et al., 2003). Common misconceptions about the need for transitioning to insulin therapy may affect patients' ability to agree to the therapy and participate in self-management of type 2 diabetes using the prescribed therapy.

Current approaches to address reluctance to begin and/or increase insulin therapy are largely educational, using classes and workshops to change attitudes and behavior. Little research exists, however, to determine which factors influence patients' reluctance to initiate insulin therapy. Therefore, the overall purpose of this study was to identify the factors related to reluctance to initiate insulin therapy (Insulin Reluctance: IR) in individuals with type 2 diabetes. The specific aims were:

1. To describe the relationship between IR in patients with type 2 diabetes and
    a. sociodemographic factors (age, gender, race/ethnicity, income, and education);
    b. biomedical factors (HbA1c, co-morbidities, and diabetes complications); and
    c. psychosocial factors (attitudes/beliefs, diabetes knowledge, diabetes self-management self-efficacy, and patient-provider interaction).

2. To develop and test a predictive model of IR based on significant sociodemographic, biomedical, and psychosocial correlates of IR.

Theoretical Framework

Social cognitive theory (SCT) serves as a framework to understand the phenomenon of IR. According to SCT (Bandura, 1977), human motivation and action are extensively regulated by forethought. This anticipatory control mechanism involves expectations that might refer to outcomes of undertaking a specific action. The theory outlines a number of crucial factors that influence behavior. The first factor is perceived self-efficacy, which is concerned with people's beliefs in their capabilities to perform a specific action required to attain a desired outcome. Self-efficacy levels can enhance or impede motivation. Self-efficacy is directly related to self-management behavior and is based on different sources: mastery experience, vicarious experience, social persuasion and physiological information (Bandura, 1997).

Self-efficacy can be enhanced through personal accomplishment or mastery experience. Practicing a behavior is most effective for self-efficacy enhancement because it provides observable evidence of goal attainment. People who have negative beliefs and attitudes or IR may have experienced a failure in their diabetes self management in the past. The past experiences of failure may diminish their self-efficacy expectation regarding insulin therapy.

Vicarious experience, such as observing a model person who is able to perform a difficult behavior, can also enhance self-efficacy. In addition, self-efficacy beliefs can be enhanced through verbal persuasion by others (e.g. a health care provider reassures a patient that she will certainly perform insulin injection properly due to her competence).

The last source of influence is emotional arousal which can influence a person's estimation of the capability to perform a specific behavior. In judging their own capacities, people use information about their physiological and emotional situations (Shortidge-Baggett, 2001). In activities that require strength and perseverance, they interpret fatigue, depression, hypoglycemia or pain as indicators of low physical efficacy.

Bandura defined stress as a somatic arousal that decreases appraisal of self-efficacy (1986). People expect to be more successful when they are not stressed than when they are. Similarly, what patients believe about their illness and how they interpret their symptoms influence their self-efficacy to deal with the illness (Shortidge-Baggett, 2001). For example, people with negative beliefs and attitudes about their insulin treatment may perceive insulin therapy as a stressor, and may therefore be less likely to have strong self-efficacy to cope with insulin therapy. Thus, they may experience depression, anxiety, tension or self-blame for needing to initiate insulin therapy.

Outcome expectancy is the other core construct of SCT and it is concerned with people's beliefs about the possible consequences of their actions. Physical outcome expectations, such as expectations of weight gain or side effects of insulin therapy, refer to the anticipation of what will be experienced after the behavior change takes place. Social outcome expectations refer to anticipated social responses, after the behavior change, such as stigma related to injections. Self-evaluative outcome expectations refer to the anticipation of how people may respond to the new behavior, such as being ashamed, proud of oneself, or satisfied. Perceived self-efficacy may create outcome expectancies, such as an individual's belief that he/she can produce the responses necessary to achieve the desired outcomes (Conner & Norman, 2005).

In adopting a desired behavior, individuals first form a goal and then attempt to execute the action. Goals (or intentions) are seen as direct predictors of behavior. People may not set goals if they think that the pursuit of such goals would have more disadvantages than advantages. According to SCT, forming a goal is a necessary, but not a sufficient condition; it is a precondition, but does not ensure that an individual will actually pursue the goal (Bandura, 1997).

Socio-structural factors refer to the impediments (barriers) or opportunities that reside in living conditions, health systems, political, economic or environmental systems (Bandura, 1997). For example, the relationship between the patient and provider, including the communication, may contribute to the patient's acceptance of insulin treatment. A patient's self-efficacy belief may influence insulin acceptance behavior directly by having confidence in self-monitoring of blood glucose and insulin injection. Socio-structural factors, such as socioeconomic and educational background, affect a patient's insulin acceptance by providing barriers or opportunities and social support. However, persons with high self-efficacy have confidence that they can employ the skills necessary to overcome barriers to insulin treatment, cope with stress and mobilize resources required to meet the demand of insulin treatment (Figure 1).

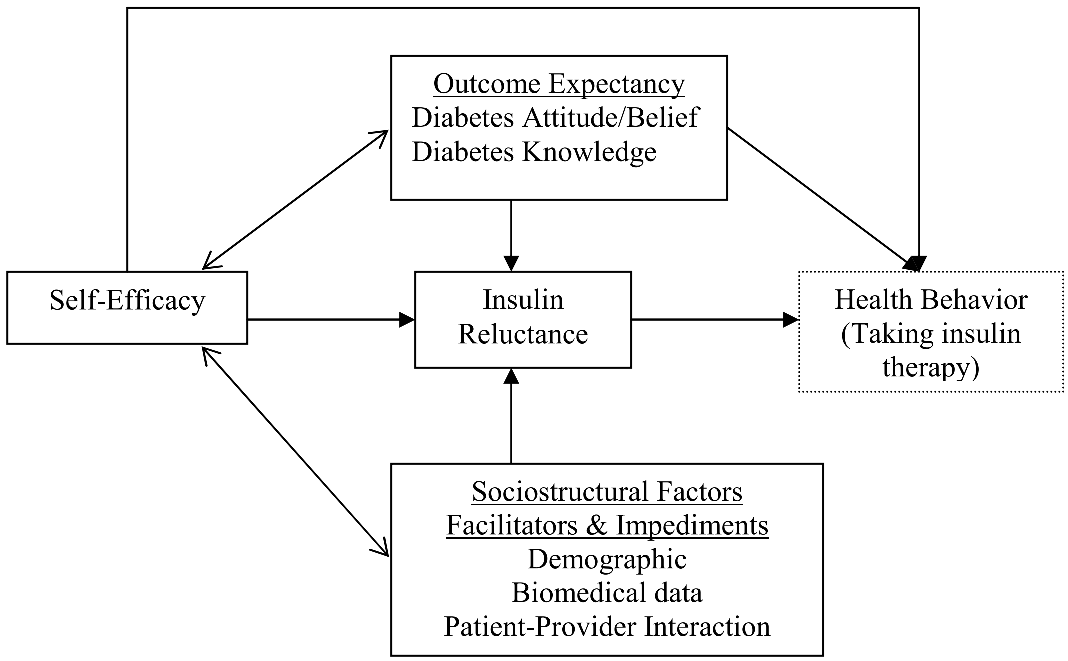

Figure1. Interplay of the Constructs- Adapted from Social Cognitive Theory (Bandura, 1986)

Research Design and Methods

Sample and Setting

A descriptive correlational cross-sectional survey of 82 men and 96 women recruited from urban residential areas of the San Francisco Bay Area was conducted. The participants were recruited through flyers that were posted at the two adult general internal medicine clinics and Diabetes Teaching Center at the University of California, San Francisco, two local community clinics and three churches. Ethical approval for the study was obtained from University of California, San Francisco Committee on Human Research, and all participants provided written informed consent.

Inclusion criteria were 18 years or older, diagnosed with type 2 diabetes, being treated with diabetic oral agents, and able to speak English. Patients with type 1 diabetes, severe psychiatric disease, such as active schizophrenia and drug dependency, dementia or on current insulin treatment were excluded. Data were collected by face-to-face interview in doctors' offices or phone interview and medical records were reviewed for clinical data related to diabetes.

Variables and Measures

Demographic and biomedical data. Demographic data (age, gender, race/ethnicity, income and, education) were obtained by patient self-report. HbA1c level (the most recent value within the last 4 months), co-morbidities (other chronic diseases, e.g. congestive heat failure, chronic obstructive pulmonary disease, and arthritis) and diabetes related complications (nephropathy, retinopathy, neuropathy) were obtained from the patient's self-report and medical record.

Diabetes attitude. Attitude toward diabetes was measured with the Diabetes Attitude Scale (DAS-3) (Anderson, Fitzgerald, Funnell, & Gruppen, 1998). The DAS-3 is a self-reported measure whose items are scored on a five-point Likert scale that ranges from "strongly disagree" (scored 1) to "strongly agree" (scored 5). Ten items are reverse scored (i.e. items 2, 3, 7, 11, 13, 15, 16, 23, 26 and 28) so that a high score consistently reflects positive attitudes toward diabetes. The possible score of each subscale ranges from 1 to 5; it is calculated by summing the score and dividing by the total number of items in that subscale. The five subscales are: Need for special training to provide diabetes care (5 items), Seriousness of type 2 diabetes (7 items), Values of tight control (7 items), Psychosocial impact of diabetes (6 items), and Patient autonomy (8 items) (Egede & Michel, 2002; Oosthuizen, Riedijk, Nonner, Rheeder, & Ker, 2002). The internal consistency reliability as measured by Cronbach's alpha coefficient has been reported as 0.67 for the need for special training to provide diabetes care; 0.80 for seriousness of type 2 diabetes; 0.72 for value of tight control; 0.65 for psychological impact of diabetes; and 0.76 for attitude toward patient autonomy (Anderson, Fitzgerald, Funnell, & Gruppen, 1998).

Diabetes Knowledge. Knowledge was measured with the Diabetes Knowledge Test (DKT) (Fitzgerald et al., 1998). The DKT has two components: a 14-item general test and a 9-item insulin use subscale. Only the 14 item general test was administered to these participants. The test is scored as a percentage of questions answered correctly. The coefficient alpha values for the general test and insulin use subscale indicate that both are reliable ($\alpha \geq 0.70$). The validity of a short form, 14 item-DKT, was supported in both a community sample and a health department sample. The knowledge scores increase as the years of formal education completed increase in both samples. The scores were higher for patients who received diabetes education than those who did not receive diabetes education (Fitzgerald et al., 1998).

Diabetes Self-efficacy. Self-efficacy was measured with the Diabetes Self-Efficacy Scale (DSES) (Rapley, Passmore & Phillips, 2003). The response options are rated on a Likert scale ranging from 1 (strongly agree) to 6 (strongly disagree). The 13 positively worded items are reverse-scored, so higher scores indicate a higher level of self-efficacy. The range of possible scores is 1 to 6. Either the total scale score or the five subscales, *Diabetic routine* (4 items), *Self-treatment* (5 items)*, Certainty about self-care* (4 items)*, Diet* (3 items) and *Exercise* (2 items) scores can be used. Cronbach's alpha internal consistency reliability coefficient for the total scale ranged from 0.82 to 0.84, indicating that the DSES has good reliability (Rapley et al., 2003).

Provider-patient interaction. Provider-patient interaction was measured with the Interpersonal Processes of Care Survey-18 (IPC-18) (Stewart, Napoles-Springer, & Perez-Stable, 1999). Respondents report on the care they have received from their providers over the past 12 months. The measurement included three broad domains (*communication, decision making, and interpersonal style*); each had several subdomains. Communication has three subscales (*lack of clarity, elicited concerns, and explained results*). Decision making has one subscale (*worked together*) and interpersonal style has three subscales (*provider's compassionate and respectful interpersonal style, discrimination due to race/ethnicity, and disrespectful office staff*). For each item, they are asked how often that type of care had been provided using a five-point scale (1, never; 2, rarely; 3, sometimes; 4, usually; 5, always). Higher scores indicate "better" processes (e.g., decided together). The items that are worded negatively (e.g., lack of clarity) will be reversed prior to summary scoring. Internal consistency reliability for seven subscales ranged from 0.65 to 0.90 (Stewart, Napoles-Springer, Gregorich, & Santoyo-Olsson, 2007).

Insulin reluctance. Insulin reluctance was measured with the Barriers to Insulin Treatment (BIT) (Petrak et al., 2007). The BIT scale measures various aspects of psychological obstacles to insulin treatment and attitude toward insulin treatment in patients who have type 2 diabetes. The BIT questionnaire includes 14 items. Each item is measured with a 10-point numerical rating scale. It has the following five subscales: *Fear of injection and self testing, Expectations regarding positive insulin-related outcomes, Expected hardship from insulin treatment, Stigmatization by insulin injection and Fear of hypoglycemia*. The numerical values for a set of items in a particular subscale are added and the total is divided by the number of items in the subscale. The resulting value is the score for that subscale. An overall score for the BIT can be calculated by adding all of the item scores and dividing by 14. The coefficient alpha values for each subscale ranges from 0.62 to 0.85 and the evidence of validity is provided in a study with patients with type 2 diabetes (Petrak et al., 2007).

Statistical Analysis

Descriptive statistics, univariate and bivariate analyses, and multiple linear regression were performed using Statistical Package for the Social Science (SPSS) Release 15.0 for Windows (Chicago, IL). All hypothesis testing was 2-sided, and type I error was controlled at the 0.05 level. Descriptive statistics provided information on the variables in this study.

To describe the relationships among IR, sociodemographic factors, biomedical factors, and psychosocial factors, Pearson correlation coefficients and Spearman's ρ correlation were computed. Differences in IR between groups by race and gender were examined using ANOVA and two-group t-test. To develop a predictive model of IR, multiple linear regression was conducted. Since three instruments with five to seven subscales were used, including DAS-3 (5 subscales), DSES (5 subscales), IPC (7 subscales), a two-step approach was employed to develop the final multivariate model. First, we constructed a separate multivariate model for each of the three instruments to choose significant subscales ($p<0.05$) related to IR from each instrument to put into the final model. From the separate multivariate models we then selected *value of tight control* from the DAS-3; *diabetes routine self-efficacy* and *exercise self-efficacy* from the DSES; and *lack of clarity in communication, compassionate and respectful interpersonal style, discriminated due* *to race, and disrespectful office staff* from the IPC. Age, gender, race, and education were also included in the final model, but diabetes knowledge, HbA1c, complications and comorbidities were not included in the final model because they were not significantly related to the outcome of interest, IR, and any other independent variables.

Finally, we constructed a hierarchical multiple regression to examine the effects of the four selected demographic variables, the seven subscales, and some possible interactions among the IPC subscales, the DAS-3 and DSES subscales on IR. Interaction terms were created with the combination of the four subscales of IPC (*lack of clarity in communication, compassionate and respectful interpersonal style, discriminated due to race and disrespectful office staff*) and DAS-3 (*value of tight control*) and DSES (*diabetes routine*, *exercise self-efficacy)*. Age, sex, education, and the seven subscales were entered in the first block. Because race is a categorical variable with 4 groups, it was coded into 3 dummy variables that together represented the concept of race. The set of these 3 dummy variables were entered in the second block. In the last block, the 12 interaction term variables were considered in a stepwise fashion and were only entered if they provided a significant increase in the overall model R-square.

Results

Demographic and Biomedical Characteristics

Of the 196 potential individuals who were approached to be enrolled in this study, 10 did not meet the inclusion criteria and 8 declined participation. A total of 178 patients consented and participated in the study.

The ethnically diverse sample (n=178) included 32.6% Asians, 31.5% Whites, 25.3% African Americans and 10.6% others; 53.9% of the sample were female with mean ±SD age of 64.3±13.5 years. Study sample demographics are described in Table 1 and are representative of the San Francisco Bay Area (Census 2000, 2009). The mean HbA1c level was 6.98 % (SD= 0.99; range=5.2 to 11.0). There were no significant differences in HbA1c level in the respective racial groups. All participants were taking at least one oral antidiabetic medication and the majority of subjects (82%) didn't report diabetes complications. About 34% of the participants had other chronic illness comorbidities (Table 2).

Psychosocial variables

The descriptive statistics for the DAS-3, DKT, DSES and IPC are presented in Table 2. The DAS-3 mean score ranged from 3.68 (psychosocial impact of diabetes and patient autonomy) to 4.20 (need for special training). The mean score for diabetes knowledge was 67.22 (SD= 18.88; range=21.43 to 100), indicating that participants has a high level of knowledge of diabetes. The diabetes knowledge score was significantly correlated with education (r=.427, p<.01), income (r=.423, p<.01) and age (r=-.382, p<.01). The correlations among independent variables are presented in Table 3.

The mean subscale of DSES ranged from 4.20 (certainty) to 5.04 (diabetes routine), indicating a moderately high level of self-efficacy. The IPC-18 score mean ranged from 3.79 (decision making, worked together) to 4.76 (interpersonal style, discriminated due to race/ethnicity).

Insulin Reluctance: Barriers to Insulin Treatment

The mean sum score for BIT was 4.89 (SD=1.63; range=1 to 10), indicating that the participants were moderately reluctant about insulin treatment. The descriptive statistics for subscales of BIT are presented in Table 2. The *fear of hypoglycemia* had the highest mean value (6.38) among the BIT subscales, indicating that subjects were reluctant to start insulin due to concern about the hypoglycemia. The BIT subscale, *expected hardship* had lowest mean values (3.34), indicating relative readiness for managing lifestyle adaptations and restrictions that insulin treatment may require as compared to other barriers to insulin treatment.

Women had higher fear of injections [women (mean±SD) = 5.13±2.97, men (mean±SD) = 3.63±2.55, $p<.001$], stigmatization [women (mean±SD) = 5.74±2.50, men (mean±SD) = 4.80±2.53, $p=.01$] and overall a higher mean BIT score reflecting more reluctant to use insulin than men [women (mean±SD) = 5.20±1.68, men (mean±SD) = 4.54±1.52, $p=.008$]. Asians had significantly higher fear of injections [Asians (mean±SD) =5.13±2.78, Whites (mean±SD) =3.31±2.29, $p=.003$] and expected greater hardship in using insulin compared to White subjects [Asians (mean±SD) =4.03±2.37, Whites (mean±SD) =2.70±2.23, $p=.03$]. Overall Asians were more reluctant to use insulin than Whites [Asians (mean±SD) =5.29±1.52, Whites (mean±SD) =4.36±1.21, $p=.012$]. Other minority groups (Hispanics, American Indians and Pacific Islanders) also had significantly higher fear of injection compared to Whites [Other (mean±SD) = 5.35±3.23, Whites (mean±SD) =3.31±2.29, $p=.031$] respectively. Participants with a higher level of education were less fearful of hypoglycemia ($r = -.170$, $p<.05$). Younger people tended to have more positive expectations regarding insulin treatment ($r = -.227$, $p<.01$) but expected greater hardship ($r = -.157$, $p<.05$). Individuals who believed in potential benefit of tight glucose control were less reluctant to start insulin treatment ($r=-.284$, $p<.01$). Greater diabetes self-efficacy scores were significantly associated with less IR ($r=-.312$, $p<.01$). All subscales of the IPC had a negative association with the IR ($p<.01$), indicating that better perceived interaction with health care providers was associated with lower level of IR. The results of bivariate analyses for IR are presented in Table 4.

Multivariate Analyses for IR

In the final multivariate model, the linear combination of the predictors in the model was significantly related to IR. The R^2 was 0.403, indicating the model explained roughly 40% of the variance in the IR ($R^2=0.403$; F [14,163] =7.867; $p< .0001$). Value of tight control, exercise self-efficacy, lack of clear communication, respectful interpersonal style, discriminated interpersonal style due to race and ethnicity, disrespectful office staff, and the interaction between exercise self-efficacy and respectful interpersonal style were significant predictors of IR. Individuals who believed in the value of tight glucose control and had better interpersonal processes with their health care providers were less reluctant to use insulin treatment. The inverse relationship between IR and exercise self-efficacy was stronger for those with greater interpersonal communication processes scores with health care providers. Those with stronger exercise self-efficacy were less reluctant to initiate insulin treatment. This relationship is modified by interpersonal care process with health care providers.

Table 5 presents the results of the regression analysis.

Discussion

This study examined the factors related to reluctance to use insulin therapy in individuals with type 2 diabetes, and developed and tested a predictive model of IR based on significant sociodemographic, biomedical, and psychosocial correlates of IR. Findings showed that adults whose diabetes is treated by oral agents had moderate IR, which is consistent with results in the prior study by Polonsky et al. (2005). In their study of 178 people with type 2 diabetes who were not taking insulin, negative attitudes toward insulin were common; a mean score of 3.1 for negative beliefs identified per subject by using a six-point Likert scale indicates the participants had moderate IR (Polonksy, Fisher, Guzman, Villa-Caballero, & Edelman, 2005).

In our sample, the fear of hypoglycemia was the strongest barrier to insulin treatment and expected hardship in using insulin influenced the IR minimally. Most participants reported that they were told by or witnessed hypoglycemic episodes in a spouse, relatives or friends who used insulin. This information was the apparent source of fear. Hypoglycemia fear is thus important to discuss with patients to educate them that hypoglycemic episodes can often be avoided through adjustment of insulin and careful vigilance in self-monitoring of blood glucose. Patient education regarding how insulin works (i.e., its pharmacokinetics) and how to avoid hypoglycemia is warranted to overcome this barrier to insulin treatment in people with type 2 diabetes.

Certain sociodemographic factors were associated with IR. Women were more reluctant to begin insulin treatment and indicated a greater fear of injection and social stigmatization in using insulin than men. Theses findings also support those of a previous cross sectional study (Polonksy, Fisher, Guzman, Villa-Caballero, & Edelman, 2005). Similarly, in the study of predictors of adherence with antihypertensive and lipid-lowering therapy, gender was a significant predictor of adherence, with women less likely to be adherent than men (Chapman et al., 2005). Another study investigating gender disparities in the treatment and control of cardiovascular risk factors in type 2 diabetes found women with type 2 diabetes were also less likely to receive lipid-lowering medications than men (Gouni-Berthold, Berthold, Mantzoros, Böhm, & Krone, 2008). All these results are of particular concern, since it has been shown that women with diabetes were less likely than men to have HbA1C <7%, less likely to have LDL cholesterol < 100 mg/dl (Wexler, Grant, Meigs, Nathan, & Cagliero, 2005) and thus are at greater risk of diabetes-associated coronary heart disease than men (Juutilainen et al., 2004). Future studies are needed to investigate why women are less adherent to treatment and have negative beliefs about insulin and possible other medications that prevent diabetes complications and decrease CVD mortality.

Ethnic minorities had greater IR than Caucasians. Asians and other non-black minority groups had significantly higher fear of injections and expected greater hardship in using insulin than Whites. These results confirm those of Polonsky et al. (2005), who found that there was significantly greater insulin therapy reluctance among woman and ethnic minorities. As with other studies younger adults tended to have more positive expectations regarding insulin treatment (Peyrot et al., 2005).

In our study, the HbA1c, number of comorbidities and diabetes complications were not associated with the IR. However, one may not assume that these variables are not important factors in the IR because participants in our study sample had relatively better HbA1c levels than those found in the general diabetes population. Only a small number of our participants had chronic illness comorbidities and complications associated with diabetes (Table 2).

As in previous studies, we did not find a significant relationship between diabetes knowledge and IR. Although education level was not significantly related to overall score of IR, patients completing higher education were less fearful of hypoglycemia. Avis and associates demonstrated that knowledge does not necessarily lead to risk-reducing behavior: people may engage in unhealthy behaviors despite knowledge of their risks (Avis, McKinlay, & Smith, 1990). Similarly, Heisler et al. (2005) examined whether knowledge of one's most recent HbA1c test result is associated with a more accurate assessment of diabetes control and better diabetes self-care understanding, self-efficacy and behaviors related to glycemic control. Respondents who knew their HbA1c values reported better understanding of diabetes self-care and assessment of their glycemic control as compared to respondents who did not know their HbA1c values. Knowledge of one's HbA1c level alone, however, was not sufficient to translate increased understanding of diabetes care into the increased confidence and motivation necessary to improve one's diabetes self-management. In our study, diabetes knowledge was correlated with the patient's age, income, education and their attitude toward diabetes. Thus, knowledge itself may not be sufficient to predict the IR, but knowledge is a critical factor that interacts with other demographic and psychosocial determinants in diabetes self-care.

Diabetes self-efficacy was found to be inversely associated with IR suggesting that individuals with diabetes who have strong diabetes self-efficacy may be less reluctant to start insulin treatment, providing validation and support for SCT. Many studies showed similar findings that higher levels of self-efficacy are associated with more optimal self-care behaviors (Aljasem, Peyrot, Wissow, & Rubin, 2001; Sarkar, Fisher, & Schillinger, 2006). These findings indicate that diabetes education focused on enhancing self-efficacy may be beneficial in decreasing patients' IR.

We found that patient's perception of the interpersonal process with their health care providers was a significant factor related to IR. Participants who perceived that their health care provider showed clarity in communication; elicited their concerns; explained exam or test results had lower IR. Similarly, if participants did not feel discriminated against by race; if they felt their health care providers worked together with them in making treatment decisions; or if the health care providers demonstrated a compassionate and respectful manner, the participants were less reluctant to start insulin. Previously, Hunt and colleagues (1997) found that patients' attitudes toward insulin therapy were influenced by providers' attitudes, as well as personal experiences and observations. Good patient-provider communication predicts either better diabetes self-care, better diabetes outcomes, or both (Schillinger et al., 2003). In a study that involved 367 patients with types 1 and 2 diabetes in a health maintenance organization in a primary care setting, poor patient-provider communication was found to be associated with poorer treatment adherence (Ciechanowski, Katon, Russo, & Walker, 2001).

Our results also suggest that beliefs about the value of tight glucose control are an important correlate of IR. Similar findings are seen in the study conducted by Farmer, Kinmouth and Sutton (2006), where beliefs about the benefits of medications were positively and strongly associated with the intention to take medications regularly in a sample of 121 persons with type 2 diabetes.

Our study also found that stronger exercise self-efficacy is associated with less IR and especially in the patients whose health care providers have a compassionate and respectful interpersonal style, the effect of their exercise self-efficacy became stronger in decreasing IR. This finding may suggest that health care providers play an important role in reducing IR. Therefore, future research should be directed toward understanding and promotion of the interpersonal processes of care between patients and their health care providers. More studies are needed to develop effective interventions to help both patients and health care providers transition to insulin treatment. Finally, our study findings also support the adapted SCT (Figure 1) which posits that health behavior is influenced by an individual's outcome expectancy (i.e. diabetes belief/attitude) related to health outcome either directly or indirectly by interacting with self-efficacy. In addition, continuing interaction among the sociostructural factors (i.e. demographic, patient and provider interaction) and self-efficacy can in turn contribute to an individual's health behaviors.

Limitations and Implications

This study has some limitations. First, because participants' HbA1c was 6.98 ± 0.99 % (mean±SD) and the majority of participants (82%) had no diabetes complications, the study findings may not be generalizable to the patients with severe hyperglycemia or many diabetes complications. Second, since the validated instruments were not available in other languages, we included only English speaking patients. Even though our study sample was racially diverse, the findings may have differed among monolingual, non-English speaking, ethnic minority groups. Third, we used the BIT as a surrogate variable to measure IR and thus, we can not conclude that patients with many barriers to insulin treatment will actually reject insulin treatment when it is recommended by their health care providers. However, Petrak and colleagues (2007) previously demonstrated the clear predictive validity of all BIT questionnaire scales in their study. Patients who opted for oral antidiabetic medications consistently reported significantly higher barriers to insulin treatment than those willing to move onto subcutaneous insulin (Petrak et al., 2007). Fourth, the cross-sectional nature of the study allows us to measure associations and not causality.

Despite these limitations, this is the first study to examine relationships between IR and its potential predictors. Previous studies that investigated how people with type 2 diabetes feel about insulin treatment and barriers to insulin treatment were qualitative studies or surveys; the latter type of study showed only prevalence of people who feel reluctant to start insulin (Hunt, Valenzuela, & Pugh, 1997; Polonsky et al., 2003; Polonsky & Jackson, 2004; Peyrot et al., 2005). Our findings have clinical implications for developing interventions to reduce barriers to insulin treatment. Knowledge of IR is critical to reduce barriers to treatment of type 2 diabetes.

In summary, our findings indicate that certain ethnic minorities have more barriers to insulin treatment compared to non-Hispanic Whites. Providing culturally competent care for the growing ethnic minority diabetes population may result in greater patient satisfaction, understanding, and compliance with insulin therapy. Gender differences in IR should be also considered for more effective diabetes treatments. Better self-efficacy for diabetes self-care and better interaction with health care providers are important factors in decreasing IR. Patient education focused on improving self-efficacy and enhanced patient-provider communications are necessary to decrease IR and optimize treatment adherence and diabetes outcomes. Future studies are needed to develop interventions to help patients overcome the barriers to accepting insulin therapy and furthermore, to determine whether the impact of different intervention strategies for reducing IR results in better glycemic control in patient with type 2 diabetes.

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Table 1

Characteristics of the study sample (n=178)

Characteristics	**Mean ± SD**
Age	64.3±13.54
Characteristics	**N (%)**
Gender	
Male	82(46.1)
Female	96(53.9)
Race	
Asians	58(32.6)
Blacks	45(25.3)
Whites	56(31.5)
Others (American Indians or Alaska Natives, Native Hawaiian or Pacific Islander)	19(10.6)
Education	
Less than high school	14 (7.9)
High school graduate	36(20.2)
Some college 1-3years	65(36.5)
Bachelor's degree	36(20.2)
Graduate degree	27(15.2)
Income	
Less than $10,000	28(15.7)
$ 10,000~$ 29,999	41(23.0)
$30,000~ $49,999	37(20.8)
$50,000~ $69,999	21(11.8)
$70,000~$99,999	19(10.7)
Greater than $100,000	32(18.0)

Table 2

Description of participants biomedical and psychosocial variables (n=178)

Characteristics	**Mean ± SD (Range)**
HbA1C*	6.98 ± 0.99 (5.2-11.0)
Diabetes attitude (DAS-3) (scale range)	
Need for special training (1-5)	4.20 ± 0.37 (2.4-5.0)
Seriousness of diabetes (1-5)	3.75 ± 0.52 (2.57-5.0)
Value of tight control (1-5)	3.71 ± 0.50 (2.14-5.0)
Psychosocial impact of diabetes (1-5)	3.68 ±0.57 (2.0-5.0)
Patient autonomy (1-5)	3.68 ±0.42 (2.5-4.75)
Diabetes Knowledge (DKT) (0-100%)	67.22 ± 18.88 (21.43-100.0)
Diabetes Self-efficacy (DSES) (scale range)	4.54 ±0.77 (2.06-5.94)
Diabetes routine (1-6)	5.04±0.85 (1.75-6.0)
Self-treat (1-6)	4.62± 1.02 (1.0-6.0)
Certainty (1-6)	4.20± 1.23 (1.25-6.0)
Diet (1-6)	4.27±1.28 (1.0-6.0)
Exercise (1-6)	4.41±1.44 (1.0-6.0)
Interpersonal Processes of Care (IPC-18) (scale range)	
Communication, Lack of clarity (1-5)	4.03± 0.99 (1.0-5.0)
Communication, Elicited concern (1-5)	4.16± 0.85 (1.33-5.0)
Communication, Explained results (1-5)	4.46± 0.81 (1.0-5.0)
Decision making, Worked together (1-5)	3.79 ±1.01(1.0-5.0)
Interpersonal style, Compassionate, respectful (1-5)	4.34 ±0.72 (1.33-5.0)
Interpersonal style, Discriminated due to race/ethnicity (1-5)	4.76± 0.60 (2.0-5.0)
Interpersonal style, disrespectful office staff	4.50 ±0.80 (1.5-5.0)
Barriers to Insulin Treatment (BIT) (scale range)	4.89 ± 1.63 (1.0-10.0)
Fear of injection (1-10)	4.44± 2.87 (1.0-10.0)
Expectations regarding positive outcome (1-10)	5.49 ± 2.13 (1.0-10.0)
Expected hardship (1-10)	3.34 ± 2.60 (1.0-10.0)
Stigmatization (1-10)	5.31±2.55(1.0-10.0)
Fear of hypoglycemia (1-10)	6.38 ± 2.71 (1.0-10.0)
Characteristics	**N (%)**
Number of comorbidities** †	
0	118(66.3)
1	42(23.6)
2	7(3.9)
3	1(0.6)
missing	10(5.6)
Number of microvascular diabetic complications**	
0	146(82.0)
1	16(9.0)
2	5(2.8)
3	1(0.6)

missing	10(5.6)

Abbreviation:HbA1C, glycosylated hemoglobin.

*n=158

**n=168

†Comorbidities: congestive heart failure, chronic obstructive pulmonary disease, and arthritis

Table 3
Correlation among the independent variables

Variables	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16-23**
1. Age	-															
2. Sex	-.065	-														
3. Income	-.245**	-.209**	-													
4. Education	-.196**	-.027	.542**	-												
5. DAS-3 subscale1	-.179*	.001	.102	.251**	-											
6. DAS-3 subscale2	-.355**	.076	.155*	.260**	.334**	-										
7. DAS-3 subscale3	-.184*	-.068	.413**	.453**	.331**	.437**	-									
8. DAS-3 subscale4	-.165*	.180*	-.069	-.005	.259**	.435**	.015	-								
9. DAS-3 subscale5	-.166*	-.010	-.022	-.036	.429**	.134	.042	.293**	-							
10. Sum DKT	-.382**	.113	.423**	.427**	.244**	.397**	.434**	.202**	.108	-						
11. DSES subscale1	.068	-.182*	.088	.107	.060	.012	.276**	-.175*	-.028	.048	-					
12. DSES subscale2	-.141	-.005	.087	.057	.137	.187*	.169*	.126	.137	.294**	.344**	-				
13. DSES subscale3	.029	-.189*	.036	.050	-.043	-.010	.138	-.194**	.009	-.005	.560**	.328**	-			
14. DSES subscale4	.095	-.038	-.083	-.150*	.027	-.041	.121	-.126	-.011	-.097	.452**	.281**	.452**	-		
15. DSES subscale5	-.005	-.207**	.068	.077	.132	-.029	.137	-.105	.023	-.039	.354**	.135	.377**	.176*	-	
16. Sum DSES	.024	-.136	.043	.034	.079	.049	.243**	-.119	.068	.077	.728**	.649**	.811**	.670**	.494**	-

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
17. IPC-18 subscale1	.136	-.069	.201**	.041	-.075	.040	.215**	-.102	-.061	.074	.100	-.050	.153*	.075	.000	.108	-		
18. IPC-18 subscale2	.119	-.031	.033	-.005	-.028	.025	.084	-.034	-.081	.066	.111	.175*	.155*	.128	.107	.193**	.383**	-	
19. IPC-18 subscale3	.085	-.042	.089	-.099	-.166*	.064	.096	-.011	-.019	.064	.069	.184*	.195**	.181*	.144	.223**	.356**	.556**	-
20. IPC-18 subscale4	.032	-.085	.047	.000	.001	.006	.108	-.042	.033	-.037	.219**	.135	.318**	.170*	.243**	.323**	.347**	.583**	.526**
21. IPC-18 subscale5	.149*	-.127	-.023	-.092	-.113	-.166	.015	-.109	-.094	-.155**	.186*	.092	.200**	.174*	.235**	.221**	.326**	.569**	.553**
22. IPC-18 subscale6	.076	-.019	.156*	-.022	.005	-.067	.106	-.118	-.068	-.063	.047	.011	.131	.037	.134	.106	.254**	.287**	.307**
23. IPC-18 subscale7	.107	.089	-.086	-.130	-.207**	-.118	-.052	-.115	-.195**	-.125	.161*	.065	.139	.058	.092	.140	.311**	.251**	.202**

	20	21	22	23
17. IPC-18 subscale1				
18. IPC-18 subscale2				
19. IPC-18 subscale3				
20. IPC-18 subscale4	-			
21. IPC-18 subscale5	.642**	-		
22. IPC-18 subscale6	.153*	.286**	-	
23. IPC-18 subscale7	.189*	.231**	.307**	-

Abbreviation: DAS, diabetes attitude scales; DKT, diabetes knowledge test; DSES, diabetes self-efficacy scale; IPC, interpersonal process of care;
DAS-3 subscale1: Need for special training
DAS-3 subscale 2: Seriousness of diabetes
DAS-3 subscale 3: Value of tight control
DAS-3 subscale 4: Psychosocial impact of diabetes
DAS-3 subscale 5: Patient autonomy
DSES subscale1: Diabetes routine
DSES subscale 2: Self-treat
DSES subscale 3: Certainty

DSES subscale 4: Diet
DSES subscale 5: Exercise
IPC-18 subscale1: Communication, Lack of clarity
IPC-18 subscale 2: Communication, Elicited concern
IPC-18 subscale 3: Communication, Explained results
IPC-18 subscale 4: Decision making, Worked together
IPC-18 subscale 5: Interpersonal style, Compassionate, respectful
IPC-18 subscale 6: Interpersonal style, Discriminated due to race/ethnicity
IPC-18 subscale 7: Interpersonal style, disrespectful office staff
* p<.05 (2-tailed) ** p<.01 (2-tailed)

Table 4

Bivariate analyses for insulin reluctance (correlations)

	Sum BIT	Fear of injection	Expectations regarding positive outcome	Expected hardship	stigmatization	Fear of hypoglycemia
age	-.136	-.133	.227**	-.157*	.056	.039
sex	.171*	.263**	-.057	.019	.179*	.159*
education	-.057	-.034	-.012	.104	-.128	-.170*
income	-.088	-.095	-.021	.025	-.105	-.188*
DAS-3 subscale1	-.031	.021	-.051	.085	-.037	-.169*
DAS-3 subscale2	-.071	-.077	.153*	-.041	-.167*	-.043
DAS-3 subscale3	-.284**	-.198**	.022	-.153*	-.295**	-.290**
DAS-3 subscale4	.135	.111	-.065	.079	.187*	.129
DAS-3 subscale5	.094	.035	-.063	.170*	.118	.015
Sum DKT	.038	.004	.147*	.085	-.073	-.030
DSES subscale1	-.281**	-.230**	.083	-.325**	-.250**	-.143
DSES subscale2	-.126	-.118	.090	-.140	-.212**	.042
DSES subscale3	-.205**	-.195**	.073	-.209**	-.172*	-.082
DSES subscale4	-.184*	-.172*	.173*	-.226**	-.187*	-.020
DSES subscale5	-.296**	-.270**	-.077	-.215**	-.252**	-.157*
Sum DSES	-.312**	-.269**	.100	-.311**	-.304**	-.113
IPC-18 subscale1	-.387**	-.281**	-.141	-.235**	-.230**	-.289**
IPC-18 subscale2	-.259**	-.182*	-.037	-.259**	-.204**	-.125
IPC-18 subscale3	-.262**	-.136	-.125	-.328**	-.199**	-.027
IPC-18 subscale4	-.268**	-.147*	-.183*	-.260**	-.157*	-.115
IPC-18 subscale5	-.346**	-.198**	-.183*	-.291**	-.263**	-.187*
IPC-18 subscale6	-.309**	-.278**	-.059	-.213**	-.164*	-.208**
IPC-18 subscale7	-.311**	-.257**	-.095	-.308**	-.174*	-.116

Abbreviation: DAS, diabetes attitude scales; DKT, diabetes knowledge test; DSES, diabetes self-efficacy scale; IPC, interpersonal process of care; BIT, barriers to insulin treatment

DAS-3 subscale1: Need for special training
DAS-3 subscale 2: Seriousness of diabetes
DAS-3 subscale 3: Value of tight control
DAS-3 subscale 4: Psychosocial impact of diabetes
DAS-3 subscale 5: Patient autonomy
DSES subscale1: Diabetes routine
DSES subscale 2: Self-treat
DSES subscale 3: Certainty
DSES subscale 4: Diet
DSES subscale 5: Exercise
IPC-18 subscale1: Communication, Lack of clarity
IPC-18 subscale 2: Communication, Elicited concern
IPC-18 subscale 3: Communication, Explained results
IPC-18 subscale 4: Decision making, Worked together
IPC-18 subscale 5: Interpersonal style, Compassionate, respectful
IPC-18 subscale 6: Interpersonal style, Discriminated due to race/ethnicity

IPC-18 subscale 7: Interpersonal style, disrespectful office staff
* p<.05 (2-tailed) ** p<.01 (2-tailed)

Table 5

Hierarchical multiple regression analysis of insulin reluctance

Source	**R^2**	**beta**	**sr^2**	**df**	**$F(=t^2)$**	**p**
Overall	.403			14, 163	7.867	.000*
Sex		.112	.011		3.010	.085
Age		-.069	.004		1.092	.298
Education		.035	.001		.244	.622
Value of tight control		-.204	.026		7.033	.009*
Diabetes routine self-efficacy		-.075	.004		1.090	.298
Exercise self-efficacy		1.107	.027		7.258	.008*
Communication, Lack of clarity		-.138	.015		4.125	.044*
Interpersonal style, Compassionate, respectful		.532	.025		6.713	.010*
Interpersonal style, Discriminated due to race/ethnicity		-.145	.015		4.107	.045*
Interpersonal style, disrespectful office staff		-.141	.016		4.314	.039*
Race			.007	3, 163	.646	.587
Asian vs White		.093	.006		1.548	.215
Black vs White		.020	.000		0.066	.797
Other vs White		.060	.003		0.712	.400
Exercise self-efficacy X Interpersonal style, Compassionate, respectful		-1.1583	.039		10.563	.001*

* p<.05 (2-tailed)

CHAPTER FOUR

Effect of Culturally Competent Diabetes Education in Ethnic Minorities with Type 2 Diabetes: A Meta-Analysis

Abstract

Background: Diabetes mellitus is a major health concern in the United States, with prevalence increasing in all ethnic groups. Ethnic minorities have a higher prevalence rate than Caucasians, poorer diabetes control, and higher rates of complications. There is little evidence about whether ethnic minorities benefit from diabetes education programs.

Objective: The purpose of this meta-analysis was to evaluate the effectiveness of culturally competent diabetes educational intervention on glycemic control in ethnic minorities with type 2 diabetes.

Methods: Databases within PubMed, CINAHL, ERIC, PsycINFO, and ProQuest were searched for randomized controlled trials (RCTs) or quasi experimental studies. The search was limited to English language, both published and unpublished studies between 1980 and January 2009. The Cochrane Collaboration database, a manual review of *Diabetes Care* and *Diabetes Educator* (1990-2009), previous meta-analysis, and review articles were also used as sources for identifying articles. Extensive searching identified 15 studies that met inclusion criteria. Of the 15 studies, 12 were RCTs and three were quasi-experimental studies. We performed a meta-analysis for the effect of diabetes education intervention (group or individual education) on glycemic control using glycosylated hemoglobin (HbA1c) value in ethnic minority groups with type 2 diabetes. The effect size (ES) was calculated with HbA1c change from baseline to follow-up between control and treatment groups.

Results: A total of 2,326 participants were included in the 15 studies. The pooled ES of glycemic control was -0.20 when measured at last follow up, indicating that ethnic minorities benefit more from culturally competent intervention when compared with usual care. The effect of intervention was greatest and significant when the intervention was delivered in clinic settings (ES:-0.26, 95% CI:-0.44, -0.09, $p<0.05$) rather than the community settings (ES:-0.25, 95% CI:-0.52, 0.03, $p>0.05$) and peaked at 6 months (ES: -0.37, CI: -0.54, -0.21) compared to 3 months (ES:-0.18, 95% CI: -0.38, 0.02) and 12 months (ES:-0.10, 95% CI: -0.28, 0.09). The ES also differed by participant's baseline HbA1c, with lower baseline associated with higher ES. We divided the studies into two groups by the median HbA1c value, 8.5%. The ES for baseline HbA1c ≤ 8.5% group was -0.30 and was -0.08 for HbA1c >8.5% group, indicating that the educational intervention was less beneficial for individuals with relatively poor baseline glycemic control.

Conclusions: Culturally competent diabetes education appears to be effective in improving glycemic control for ethnic minorities. The magnitude of effect is larger when the intervention was delivered in the clinic settings, lasted at least 6 months and when their HbA1c was ≤ 8.5%. There is a need for long term, rigorous RCTs that examine more tailored diabetes education, different combinations of educators and more diverse ethnic minority groups including Asians to improve health disparities in diabetes care.

Key Words: type 2 diabetes, ethnic minority, culturally competent diabetes education, meta-analysis.

Background

Diabetes is a major cause of morbidity and mortality in the United States. It is the seventh leading cause of death (Aubert et al., 1998), and the direct cost of medical care is approximately $100 billion annually (Caravalho & Saylor, 2000). According to the Center for Disease Control and Prevention (CDC, 2005), more than 20 million Americans now have diabetes. This number represents approximately 7 % of the total population and the prevalence rates have continued to increase for the past decade, with racial/ethnic minority populations suffering a disproportionate burden of disease (McBean, Li, & Gilbertson, Collins, 2004).

The CDC (2005) reported that the prevalence rates of diabetes for non-Hispanic Whites is 8.7%, 9.5% among Hispanics, and 13.3 % among African Americans. In addition, African Americans, Hispanic/Latino Americans, American Indians, and some Asian Americans and Native Hawaiians or other Pacific Islanders are at particularly high risk for type 2 diabetes and its complications. African Americans have 2-4 times the rate of renal disease, blindness, amputations and amputation related mortality of non-Hispanic whites (Carter, Pugh, & Monterrosa, 1996; Lanting, Joung, Mackenbach, Lamberts, & Bootsma, 2005). Similarly, Latinos have higher rates of renal disease and retinopathy (Carter et al., 1996; Lanting et al., 2005). While the reasons for the disparities in diabetes prevalence and health outcomes are multifactorial due to genetic, environmental, and cultural factors, there is little evidence that ethnic minority groups benefit from traditional diabetes education programs. The likely reason for this lack of evidence is because ethnic minority groups are often not included as a subgroup in most large trials and the attrition rate of the ethnic minorities is higher than for Non-Hispanic White.

There is substantial evidence that improving glycemic control decreases the risk of microvascular complications in patients with type 2 diabetes (UKPDS, 1998). The relationship between support of diabetes self-management and the outcomes of diabetes care has been demonstrated in people with type 2 diabetes. However, data from the Third National Health and Nutrition Examination Survey (NHANES III) indicate that glycemic control is poorer for ethnic minority groups compared with Whites (Harris, Eastman, Cowie, Flegal, & Eberhardt, 1999) and show that participation rates of ethnic minorities in educational programs were low and attrition was high (Thackerey, Merrill, & Neiger, 2004). Possible barriers to participation in diabetes education may be language, socioeconomic factors, cultural/lifestyle factors and health beliefs. Furthermore, some studies showed that the traditional risk reduction approaches have not been effective with certain ethnic groups. For example, less success with dietary self-management, lifestyle change, weight loss, and adherence among African Americans compared to Whites have been reported frequently (Kumanyika & Ewart, 1990; Kumanyika, Obarzanek, Stevens, Herbert, & Whelton, 1991; Kiley, Lam, & Pollak, 1993; Kumanyika, Herbert, Cutler, Lasser, Sugars, & Steffen-Batey, et al.,1993; Wing & Anglin, 1996). The failure of traditional educational approaches for ethnic minorities may be due to a lack of cultural competency on the part of providers and failure to address issues of relevance to the population (Kumanyika & Ewart, 1990; Maillet, Melkus, & Spollett, 1996).

Thus, designing and evaluating culturally competent interventions has become an important priority of the public health system to reduce the significant health care disparities and improve access to care for various ethnic and racial groups (U. S. Department of Health and Human Resources, 2006). Culturally competent interventions incorporate ethnic beliefs, values, customs, food patterns, language and health practices (Anderson-Loftin, Barnett, Sullivan, Hussey, & Tavakoli , 2005).

Previous meta-analyses demonstrated the effect of various diabetes education interventions on glycemic control, quality of life and other psychosocial factors. However, those studies didn't report the results by ethnic group and their interventions were not culturally competent approaches (Ismail, Winkley, & Rabe-Hesketh, 2004; Norris, Lau, Smith, Schmid, & Engelgau, 2002a). Therefore, the purpose of this meta-analysis was to evaluate the effect of culturally competent diabetes education on glycemic control in people with type 2 diabetes in ethnic minority groups.

Methods

Search Process and Selection of Studies

We searched the PubMed, CINAHL, ERIC, PsycINFO for published studies and ProQuest database for dissertations and theses using the key words, type 2 diabetes, diabetes mellitus, health education, diabetes education, counseling, minority, ethnic minority, and behavioral intervention. The following medical subject heading (MeSH) terms also were used in the search: patient education, diabetes mellitus, type 2, non-insulin-dependent, minority group, ethnic group, intervention, and program. We limited our search to English language, both published and unpublished studies between 1980 and January 2009. The Cochrane Collaboration database, a manual review of *Diabetes Care* and *Diabetes Educator* (1990-2009), previous meta-analyses, and review articles were also used as sources for identifying articles.

Randomized and quasi experimental studies that had diabetes educational interventions (no drug intervention) performed in only ethnic minority groups with type 2 diabetes and reported both pre and post intervention glycosylated hemoglobin (HbA1c) value were included.

Quality Assessment

Study quality was assessed using a 5-point scale developed by Jadad et al that has been shown to be valid and reliable (Jadad, Moore, & Caroll, 1996). This method assigns 1 point for each ordered criterion: randomization; blinding; descriptions of procedures for withdrawals and dropouts; descriptions of procedures for appropriate randomization and finally, 5 points total if all prior criteria are met.

Data Extraction and Calculation of Effect Size

In order to compare studies, a data collection sheet was used and described: year of publication, study design, study sample, setting, type of intervention, type of intervention provider, country, intensity/duration of intervention, and outcome measure. The effect size (ES), which is defined as the difference in the change of a measurement from baseline to follow-up between control and treatment groups, was calculated for HbA1c. Cohen (1988) published guidelines for assessing effect size. Standardized effect sizes of around 0.2 is considered to be small effect, 0.5 is a moderate effect and 0.8 or greater is a large effect.

Analysis

We performed a meta-analysis for the effect of diabetes education intervention on glycemic control only in ethnic minority groups with type 2 diabetes using HbA1c as the outcome measure. We performed the meta-analysis to calculate pooled weighted mean differences (WMD) with 95% confidence intervals (CI) using a random effects model. The random effects model assumes that each study is estimating different effects, which varies according to different methods, outcomes, and participants studied (Lipsey & Wilson, 2000).

Although the main aim of a meta-analysis is to produce an estimate of the average effect seen in trials comparing therapeutic strategies, it is implausible to assume that the effect of a given treatment is identical across different group of patients. Therefore we planned three specific subgroup analyses a priori based on key design issues and conducted the analysis. The first subgroup analysis was conducted by baseline HbA1c. The second one was conducted by intervention setting and the last one was done by month (i.e. three month, six month, and 12 months). Sensitivity analysis was performed based on methodological quality by deleting questionable studies (RCT versus quasi-experimental study).

To generate a summary estimate, we conducted a meta-analysis on the results comparing intervention to control groups. That is, the effect of interest was HbA1c from baseline for the educational intervention group minus the HbA1c change for the control group.

Test for heterogeneity assesses the degree of variability in the summary measures between the included studies. The statistically significant heterogeneity means that the results of studies are not consistent. The presence of heterogeneity often indicates that there are methodological differences in the mechanism of randomization, patient sample, interventions, length of follow-up and the extent of withdrawals between included studies (Thompson, 2001). Heterogeneity should not necessarily always be viewed as a negative aspect of a systematic review. It may simply alert the investigators to different aspects of the intervention or study designs that have the potential to affect the results (Bent, Shojania, & Saint, 2004).

The method for identifying heterogeneity in the studies was planned through (1) observation of the forest plot to examine how well the confidence intervals overlay; (2) performance of Chi-squared (χ^2) test with a p-value of > 0.1 and (3) by quantifying the effect of heterogeneity using I^2, where I^2 values of 25%, 50% and 75% represent low, moderate and high levels of heterogeneity respectively (Higgins, 2003). A small p-value ($p< 0.1$) from the χ^2 test is used to indicate evidence of heterogeneity. When heterogeneity was visually or statistically present, we explored the source of heterogeneity using subgroup and sensitivity analysis. We also used random effects model when heterogeneity was present: this approach provides a more conservative estimate of the pooled estimate and CIs.

We explored publication bias using a funnel plot, in which symmetry about the line of no effect suggest little influence of publication bias (Ferret, 1998). We also used an adjusted rank correlation model proposed by Begg et al (Begg & Mazumdar, 1994) and Egger's linear regression model (Egger, Davey Smith, Schneider, & Minder, 1997). StataSE version 10 was used for this meta-analysis.

Results

Extensive searching identified 15 studies for inclusion. Papers were commonly excluded because the study lacked an intervention, HbA1c levels or ethnicity-specific data. Studies that included type 1 diabetes or gestational diabetes or that did not report the result by type of diabetes or ethnicity were excluded. Of the included studies 12 were randomized controlled trials (RCTs) (Agurs-Collins, Kumanyika, Ten Have, & Adams-

Campbell, 1997; Anderson et al., 2005; Anderson-Loftin, Barnett, Sullivan, Hussey, & Tavakoli, 2005; Brown, Garcia, Kouzekanani, & Hanis, 2002; Gucciardi, DeMelo, Lee, & Grace, 2007; Hawthorne & Tomlinson, 1997; Keyserling et al., 2002; MiddelKoop, Geelhoed-Duijvestijn, & van der Wal, 2001; O'Hare et al., 2004; Rosal et al., 2005; Skelly, Carlson, Leeman, Holditch-Davis, & Soward, 2005; Vincent, Pasvogel, & Barrera, 2007) and three studies were quasi-experimental "before and after" designs (Melkus et al., 2004; Noel et al., 1998; Two Feathers et al., 2005). Unpublished studies were sought by using ProQuest and Clinical Trial registries but none of them was eligible for the review because of the study design (lack of intervention), population of interest (no ethnic specific data) or no HbA1c results.

Participant Demographic Across Studies

A total of 2,326 participants were included in the 15 studies. The mean age of the participant was 57.3 years. Mean percentage of female participants was 75. Among the 15 studies, six studies included African Americans; four studies included Hispanic Americans; one study included both African Americans and Hispanic Americans; and three studies included South Asians and others (e.g. Canadian Portuguese). The mean baseline HbA1c was 8.7 % (SD: 1.4, median: 8.5%).

Study Characteristics

Characteristics of the 15 studies are described in Table 1. Eleven (73%) studies were conducted within the United States (US). The mean sample size of the 15 studies was 155 (SD: 154, median=111). Most of the studies (except Keyserling et al. and Noel et al. study) tested culturally competent interventions with culturally or ethnically matched providers.

Intervention and Intervention Provider

Most studies used group education sessions (60 %), 20% of studies used the combination of group sessions and individual patient counseling, and 20% of studies used only individual sessions as a mode of instruction. Fifty eight percent of studies reported usual care as the control group condition and 42% reported some type of minimal intervention as the control. The following intervention providers were reported: nurse (33%), dietician (30%), certified diabetes educator (11%), other professional (e.g. pharmacist, physiotherapist, psychologist and social worker: 7%), and non professional staff (19%).

Duration, Frequency and Settings

The duration of intervention ranged from one time period to 12 months (median=3 months) with the frequency of one session to 19 weekly or biweekly sessions. Five studies provided the diabetes education intervention for 3 months or less; four studies provided the education intervention for 6 months; and three studies provided the education intervention for 12 months (Table 1). The number of contact hours of the intervention ranged from one session to more than 30 hours but most studies didn’t clearly describe the number of contact hours in one session in the intervention and control groups. Therefore, it was difficult to analyze the relationship between effect of intervention and the intensity/dose of intervention. The setting of interventions was hospital based outpatient clinics and hospital diabetes education centers (54%) and community based settings (46%).

Educational Interventions

Most (13 studies except Keyserling et al. and Noel et al. study) of the interventions focused on culturally competent diabetes education. To ensure the cultural appropriateness of the intervention, bilingual professional educators or non professional workers provided the education. Culturally competent interventions reflect an inclusion of the importance of food, language difference with health care provider, low literacy and health beliefs embedded in the culture.

The main subject of most interventions was diabetes knowledge (e.g. symptoms of hypo/hyperglycemia, complications of diabetes and medications) and diabetes self-management including diet, physical activity and blood glucose monitoring. Other topics included psychosocial strategies (e.g. coping skill, stress management, problem solving) and risk management of cardiovascular diseases. Approximately two thirds of the studies encouraged the patients to bring support persons (family or friend) to the educational sessions in order to foster family participation in managing diabetes.

Follow-up

The duration of follow-up ranged from 12 weeks to one year (mean ± SD: 6.6 ± 3.6 months). The median follow-up duration of the studies was 3 months. Follow-up was made by telephone interview, home or clinic visits to conduct outcome assessments.

Outcomes

Results from this meta-analysis are reported for the primary outcome of HbA1c as a reflection of glycemic control. The main results are reported as overall effects of culturally competent diabetes education on glycemic control compared to control group. In addition, the subgroups based on baseline HbA1c, settings of intervention and the time of HbA1c measurement were also reported. All results are based on random effects models.

Effect sizes (standardized mean difference) for HbA1c are depicted in Figure 1-6. Most of interventions produced a decline in HbA1c compared with controls. The pooled effect size of the 15 studies was -0.20 when measured at last follow up (Figure 1), which was statistically significant (95% CI=-0.33, -0.06). In this analysis, the summary effect size of -0.20 suggests that the average person in the intervention group is better off than 58% of the control group. However, this pooled result demonstrated significant heterogeneity (χ^2=27.83, df = 14, p = 0.015). Several factors might explain the heterogeneity in outcome: 1) intervention characteristics such as cultural relevancy, setting and duration and frequency of session; 2) patient characteristics such as biomedical and psychosocial variables.

The following subgroup analyses were performed for pooled effect size of glycemic change based on key design issues: settings of intervention, the time of HbA1c measurement, and baseline HbA1c. For participants who attended clinic or hospital based diabetes education centers (Figure 2), HbA1c values in those who attended culturally competent diabetes education was significantly improved compared to the control group (ES:-0.26, 95% CI:-0.44, -0.09). This pooled result did not demonstrate significant heterogeneity (χ^2=8.32, df = 6, p = 0.215), meaning the methods across studies were consistent. There was a significant decrease in HbA1c for the studies where participants had clinic based culturally competent diabetes education (ES:-0.26, 95% CI:-0.44, -0.09) (Figure 2) but the result for the community based setting was not statistically significant (ES:-0.25, 95% CI:-0.52, 0.03) (Figure 3). Larger declines in HbA1c compared with controls were seen at six months (ES:-0.37, 95% CI:-0.54, -0.21) as compared to three months (ES:-0.18, 95% CI: -0.38, 0.02) and 12 months (ES:-0.10, 95% CI: -0.28, 0.09) (Figure 4) and the result demonstrated that the average person in the intervention group at 6 months was better off than 64% of the control group. The standardized pooled ES differed by baseline HbA1c. Therefore, we divided the studies into two groups by the median HbA1c value, 8.5%. The ES for studies with baseline HbA1c ≤ 8.5% was -0.30 (95% CI:-0.50, -0.10) and was -0.08 for studies with HbA1c >8.5% (95% CI:-0.25, 0.10) (Figure 5), showing lower baseline HbA1c was associated with larger ES.

We included both RCT and quasi experimental studies (pre and post test intervention studies) and sensitivity analysis was performed by methodological quality. Standardized pooled effect sizes differed slightly by study quality. The ES for RCT (Figure 6) was -0.22 (CI: -0.37, -0.07, $p<0.05$) and statistically significant. However, the ES for quasi-experimental studies was -0.14 (CI: -0.51, 0.23, $p>0.05$) and it was not statistically significant.

Assessment of Publication Bias

Figure 7 presents funnel plots and results of Egger's test and Begg's test for assessing publication bias. If publication bias does not exist, the plot should reveal that the largest studies cluster around the midpoint or top of the funnel; an equal number of smaller studies should be present on both sides of the funnel. However, the funnel plot for this meta-analysis does not appear to conform to a classic funnel shape. The hole in the lower right-hand corner indicates that smaller studies showing no effect are absent. Both Egger's test and Begg's test showed consistently small p-value, which indicates evidence of publication bias.

Discussion

This meta-analysis provides evidence of the benefit of culturally competent diabetes education (CCDE) on glycemic control for ethnic minorities with type 2 diabetes. The HbA1c improves with CCDE, with a pooled ES of -0.20, when measured at last follow up. Glycemic control is an important predictor of many diabetes complications. Each 1% reduction in HbA1c over 10 years is associated with reductions in risk of 21% for any end point related to diabetes, 21% for deaths related to diabetes (Stratton et al., 2000). Lower levels of HbA1c are desirable and the small decrease found in our results may not be clinically important. A possible explanation for the small effect is that care delivered to the control groups varied greatly and the control groups also received frequent attention from the health care providers during the study periods. Since our main effect, net glycemic change is the difference between the amount of improvement in the intervention group and that of the control group, the true effect of the intervention may be underestimated because of the Hawthorne effect in the control groups, that is, the tendency for control subjects to improve when enrolled in research.

Despite the fact that a small effect was detected, this study has important implications for current clinical practice and research. The analysis shows that at least six months are needed to see a decrease of HbA1c in ethnic minority groups. The ES at 6 month was the largest (ES: -0.37, CI: -0.54, -0.21) compared to the ES at 3 months (ES: -0.18, CI: -0.38, 0.02) and 12 months (ES: -0.10, CI: -0.28, 0.09). The effect peaked at 6 months, with a decline to earlier levels after 6 months. This result is generally consistent with the previous studies of Norris et al. (2002a) and Brown et al. (1992) who found the benefit of diabetes education declines from 1-3 months (Norris et al.) to 1-6 months (Brown et al.) after the intervention ceases.

Unlike previous studies, we found that baseline HbA1c affected the HbA1c outcome. The culturally competent intervention was more effective for those with HbA1c equal to or less than 8.5% than those who had HbA1c greater than 8.5%. This is a new finding, not previously reported. In addition, this meta-analysis makes an important contribution because previous meta-analyses (Norris et al., 2002a, 2002b; Brown, 1992) did not analyze the result by ethnicity and did not include studies with culturally competent interventions. We also confirmed Brown (1992) meta-analysis finding that HbA1c was decreased more when the intervention was delivered in the clinic or hospital based diabetes education center settings than the community settings. In another study by Norris et al. (2002b), they tested the effect of diabetes education intervention in community settings (e.g. community gathering place, home, worksite and school). However, they did not include clinic or hospital settings in the analysis and thus no comparison could be made between clinic settings and community settings school.

There are several limitations to our analysis. This meta-analysis was confined to English-language articles, which could introduce selection bias. However, ethnic minority group in this analysis is considered in the relationship to the dominant ethnic group. Therefore, the population in a study reported by language other than English, who live in their own country, would not be considered as ethnic minority for this review. In addition, Moher et al. (2000) found that excluding non-English studies had little impact on overall estimates and language restricted meta-analyses overestimated treatment effect by only 2% on average, compared with language-inclusive meta-analyses.

We included only published data after searching the unpublished literature and excluding studies that did not meet the inclusion criteria. Therefore our result may be affected by the possibility of publication bias; that is, unpublished studies that were not identified in our search may have influenced our results. Many of the studies included in this analysis had methodological limitations common in undertaking research of ethnic minorities. For example, none of studies were long-term (> 12 months) and so clinically important long-term outcomes could not be analyzed. In addition, high attrition, moderate attendance, and complex multifaceted interventions made subgroup comparisons difficult to interpret with confidence.

It was difficult to analyze the data by the type of interventionist since most of studies used the combination of different providers (e.g. “nurse and dietician” or “diabetes educator and community worker”) rather than one type of provider only. We also have chosen to look only at the outcome of glycemic control, due to potential problems with pooling ES from studies where outcomes were not uniformly measured (e.g. knowledge, attitude, treatment satisfaction and adherence). None of the included studies reported blinding, although it would have been difficult to mask both intervention and control groups given the nature of the behavioral intervention.

The results of this meta-analysis are likely generalizable to African American or Hispanic women in the US because the participants of the majority studies were women and of 15 studies, 11 studies included either African American or Hispanic American.

Further research is needed to better understand how the intervention improves glycemic control among ethnic minority groups with type 2 diabetes. There is a need for long-term, multi-center RCTs that compare different ethnic minorities, different types of providers and settings. More importantly, this research should provide adequate information regarding detailed description of intervention, duration and frequency of sessions, and allocation concealment if randomization is performed. More research is needed in ethnic minorities other than African Americans and Latinos. For example, there are no published studies of culturally competent diabetes education among Native Americans and East Asians.

Conclusions

Ethnic minorities continue to grow in the US and suffer a disproportionate burden of disease from diabetes. This analysis supports benefits of culturally competent diabetes interventions in ethnic minority groups over usual care. Glycemic control was greatest when the intervention was delivered in the clinic or hospital based diabetes education center settings and had a duration of at least six months. However, the effect varied, depending on the patient's baseline HbA1c and those with higher HbA1c has least effect. Providing culturally competent diabetes intervention requires a multifaceted approach involving a multidisplinary team. More research with ethnic minority groups need to be done using rigorous RCTs that examine the effect of culturally specific diabetes education with a longer term, culturally/ethnically matched educators and more diverse ethnic minority groups.

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Table 1.

Overview of reviewed studies

Anderson, 2005 My Documents.lnk (n=239)	Aims	To evaluate the impact of a problem-based empowerment patient education program specially tailored for urban African American with type 2 diabetes
	Country	USA
	Methods	RCT
	Participants	96% African American with type 2 diabetes in urban area in Detroit Inclusion criteria: not stated Exclusion criteria: not stated
	Intervention	Intervention: two hour weekly group sessions for 6 weeks. Control group: wait-listed Setting: convenient community based location Duration of intervention: 6weeks. Duration of follow-up: 6weeks as RCT; thereafter non-RCT at 12weeks, 6months and 1year. Provider: Certified diabetes educator
	Outcome	HbA1c, lipid, BP, weight, Diabetes Care Profile (DCP) questionnaire, Diabetes empowerment Scale short-form (DES-SF), sub scale of the Diabetes Attitude scales
	Quality	3
Anderson-Loftin, 2005 (n=97)	Aims	To test effects of a culturally competent, dietary self-management intervention on physiological outcomes and dietary behaviors for African Americans with type 2 diabetes.
	Country	USA
	Methods	RCT
	Participants	Inclusion criteria: 1. African American 2. medical diagnosis of type 2 diabetes 3. aged 18 or older 4. no mental or physical limitations that would preclude participation in group activities and discussion 5. at least 1 of the following indicators of diabetes complications defined as high risk and modifiable by diet: (a) A1C >8%, (b) cholesterol >200 mg/dL, (c) triglycerides >200 mg/dL, (d) low-density lipoprotein (LDL) cholesterol >100 mg/dL, (e) weight >25 kg/m2, and (f) high-fat dietary patterns (score on the Food Habits Questionnaire [FHQ] >2.5). Exclusion criteria: not stated.
	Intervention	Intervention: 4 weekly classes in low-fat dietary strategies, 5 monthly peer-professional group discussions, and weekly telephone follow-up. Control group received referral to a local 8-hour traditional diabetes class. Setting: diabetes education center in a rural South Carolina county.

		Duration of intervention: 4weeks Duration of follow-up: 6months Provider: nurse case manager and registered dietician
	Outcome	A1C, lipids, BMI, dietary behaviors Food, Habits Questionnaire [FHQ]
	Quality	4
Agurs-Collins, 1997 (n=64)	Aims	To evaluate a weight loss and exercise program designed to improve diabetes management in older African Americans.
	Country	USA
	Methods	RCT
	Participants	African-American Inclusion criteria: 1. obese African American with type 2 diabetes 2. ≥ 55 years 3. ≥ 120% weight standard 4. HbA1c>8% 5. no contraindication for exercise Exclusion criteria: not stated
	Intervention	Intervention: weekly nutrition sessions (60min) with exercise training (30min) for three months; following three months on biweekly problem solving (90min) sessions and one individual diet counseling. Control: one class on glycemic control at three weeks from start; two letters with written information on nutrition at 3 and 6months. Setting: urban hospital clinics Duration of intervention: 6 months Duration of follow-up: at 3 and 6 months Provider: dietician and exercise physiotherapist with experience in working with African American
	Outcome	HbA1c, weight, BMI, waist/hip ratio, BP, lipid profile, physical activity, nutrition knowledge, dietary component, dietary components
	Quality	4
Brown, 2002 (n=252)	Aims	To determine the effect of a culturally competent diabetes self-management intervention in Mexican American with type 2 diabetes.
	Country	USA
	Methods	RCT
	Participants	256 Mexican American with type 2 diabetes Inclusion criteria: 1. not having participated in previous intervention 2. 35-70 years of age 3. Having type 2 diabetes from 35years of age 4. two verifiable FBG test result >or equal to 140mg/dl or taking or have taken insulin or oral

		hypoglycemic agents for one year or more in the past. Exclusion criteria: 1. pregnancy 2. medical conditions preventing changes in diet and exercise
	Intervention	Intervention: two hour weekly group educational sessions for 3 months, 6 months biweekly support sessions and thereafter two hour monthly support groups sessions for 3 months. Control: one-year wait listed group. Usual care from their private physicians or at local clinics. Setting: community based sites (schools, churches, county agricultural extension offices, adult day care center and health care clinics). Duration of intervention: 12 months. Duration of follow-up: 12 months Provider: bilingual Mexican American dietician, nurse and community health worker.
	Outcome	HbA1c, fasting blood glucose(FBG), diabetes knowledge and diabetes related health beliefs, BMI, lipids
	Quality	3
Gucciardi, 2007 (n=61)	Aims	To examine the impact of two culturally competent diabetes education methods, individual counseling and individual counseling in conjunction with group education on nutrition adherence and glycemic control.
	Country	Canada
	Methods	RCT
	Participants	Canadian Portuguese with type 2 diabetes in Toronto urban area in Canada Inclusion criteria: 1. type 2 diabetes 2. speaking Portuguese Exclusion criteria: 1. renal dialysis 2. prior attendance at a similar education program 3. diagnosis of mental illness
	Intervention	Intervention: Individual counseling of 1 initial assessment and following appointment are scheduled on a need basis per person + Group education classes (15 hours) over three consecutive weekdays. Control : Group education classes (15hours) over three consecutive weekdays Setting: hospital based diabetes education center Duration of intervention: group+ individual: 3 group meetings of 6.5 hrs each and individual meetings scheduled on a need basis per participants. Not stated the duration of the period. Duration of follow-up: 3months Provider: Portuguese speaking dietician, nurse, pharmacist, and registered physiotherapist, psychologist and social worker
	Outcome	1. TPB (Theory of Planned Behavior) scale- attitude, subjective norms, perceived behavior control,

		and intentions towards nutrition adherence 2. Self-reported nutrition adherence (Summary of Diabetes Self-care Activities Questionnaire) 3. HbA1c
	Quality	4
Hawthorne, 1997 (n=201)	Aims	To design and evaluate a structured pictorial teaching program for Parkistani Moslem patients in Manchester with type 2 diabetes.
	Country	United Kingdom
	Methods	RCT
	Participants	British Parkistani with type 2 diabetes Inclusion criteria: 1.Parkistani origin with type 2 diabetes Exclusion criteria: 1. Previous diabetes education 2. spouse receiving or received diabetes education in the past 3. planning to go abroad 4. not in good health
	Intervention	Intervention group: one session of one-to-one pictorial flash cards education (purpose of glucose monitoring, how to control blood sugar, diabetic complications, and the purpose of regular screening) with a trained link worker Control: not stated Setting: primary and secondary clinics Duration of intervention: one session. Duration of follow-up: 6months Provider: trained link worker
	Outcome	Diabetes knowledge, attitudes and self- care behaviors assessed with questionnaire, HbA1c, cholesterol level
	Quality	3
Keyserling, 2002 (n=181)	Aims	To determine whether a culturally appropriate clinic and community based intervention for African American women with type 2 diabetes will increase physical activity (PA)
	Country	USA
	Methods	RCT
	Participants	African American women with type 2 diabetes in North Carolina Inclusion criteria: 1. African-American women 2. 40 years of age or older 3. diagnosis of type 2 diabetes Exclusion criteria: not stated
	Intervention	Group A: clinic and community based intervention Group B: clinic based intervention Group C: minimal intervention

		1. Clinic based intervention: four monthly visits 2. Community based intervention: two group sessions (90min) and monthly phone calls for the first 6month; the second 6months consisted of one group sessions and monthly phone calls Minimal intervention: mailed pamphlet from the ADA. Setting: primary care practice and community center. Duration of intervention: 12months Duration of follow-up:6months and 12months Provider: clinic nurse and peer counselor
	Outcome	PA level, dietary intake, HbA1c, Lipid, weight, diabetes knowledge, diabetes health status.
	Quality	4
Melkus, 2004 (n=25)	Aims	To develop and test feasibility of culturally competent intervention and care for black women with type 2 diabetes.
	Country	USA
	Methods	One group pretest posttest quasi experimental design
	Participants	Inclusion criteria: 1. black women between 18 and 60 years of age 2. having a primary care provider 3. diagnosed with type 2 diabetes(confirmed at baseline by C-peptide levels≥ 200pmol/L) 4. English speaking Exclusion criteria: 1. receiving insulin therapy 2. pregnant or breast-feeding 3. had comorbidities 4. diabetes related complication 5. end stage renal disease or lower-extremity amputation
	Intervention	Intervention: Six week, cognitive –behavioral, culturally competent diabetes group intervention and monthly individual care visits. Setting: accessible and acceptable location central to the community. Duration of intervention: 6weeks Duration of follow-up: 3 months Provider: advanced practice registered nurse and/or certified diabetes educator, registered dietician, nurse practitioner
	Outcome	Diabetes knowledge Diabetes self-efficacy Diabetes-related psychosocial distress (Problem Areas in Diabetes) BMI Fasting blood glucose HbA1c C-peptide

	Quality	2
Middelkoop, 2001 (n=113)	Aims	To examine if culturally-specific diabetes intervention led to a decrease HbA1c level, improvement in lipid profile, or a decrease in BMI
	Country	Netherland
	Methods	RCT
	Participants	South Asian in Netherlands Inclusion criteria: 1. South Asian origin 2. type 2 diabetes 3. with no comorbidity (i.e recent myocardial infarction or dementia) Exclusion criteria: not stated
	Intervention	Intervention: approximately 4-7 intensive guidance visits for the first 3months , with less frequent subsequent visits Control: wait-list group that joined the intervention group after 6months Setting: general practices and outpatient clinic Duration of intervention: 6months Duration of follow-up: 6months for the RCT component Provider: specialist nurse and dietician trained in South Asian culture
	Outcome	HbA1c
	Quality	4
Noel, 1998 (n=596)	Aims	To examine the effects of patient choice between two education curriculums that emphasized either the standard or nutritional management of type 2 diabetes on class attendance and other outcomes among Hispanic patient.
	Country	USA
	Methods	Quasi experimental study
	Participants	Inclusion criteria: 1. 18 years of age or older 2. not attended diabetes education classes within the previous 12 months 3. received the majority of their health care at the health care system where the study took place Exclusion criteria: not stated
	Intervention	Intervention: Five weekly 2hr sessions Setting: not stated Duration of intervention: 5 weeks Duration of follow-up:6 months Provider: diabetes educator

	Outcome	Class satisfaction(modified Diabetes Treatment Satisfaction Questionnaire) Factor affecting class attendance Diabetes knowledge(Michigan Diabetes Knowledge test) Self- care behavior Importance of diabetes care HbA1c Fasting serum cholesterol, BMI
	Quality	2
O'Hare, 2004 (n=325)	Aims	To test hypothesis that enhanced diabetes care tailored to the needs of the South Asian community with type 2 diabetes, would improve risk factor for diabetic vascular complications and ultimately reduce morbidity and mortality.
	Country	United Kingdom
	Methods	RCT
	Participants	South Asian with type 2 diabetes Inclusion criteria: 1. South Asian origin 2. type 2 diabetes 3. at least one of the following risk factor: high BP, HbA1c>7%, total cholesterol>5.0mmol/L Exclusion criteria: not stated
	Intervention	Intervention: extra weekly diabetes clinic at the primary care centers Control: usual care, no further resources were provided. Setting: primary care center Duration of intervention: one year Duration of follow-up: one year Provider: diabetes nurse specialist, practice nurse, dietician, all aided by a link worker
	Outcome	BP, HbA1c, total cholesterol
	Quality	4
Rosal, 2005 (n=25)	Aims	To assess the feasibility of an self-management education in low income Spanish speaking individuals and secondly to have a preliminary data of intervention effect
	Country	USA
	Methods	RCT
	Participants	Spanish speaking individual with type 2 diabetes, >18 years of age Inclusion criteria: 1. having a health care provider 2. having a doctor confirmed diagnosis of type 2 diabetes 3. > years 18 age 4. doctor's approval to participate PA of the intervention 5. home phone 6. able to provide informed consent in English or Spanish Exclusion criteria:

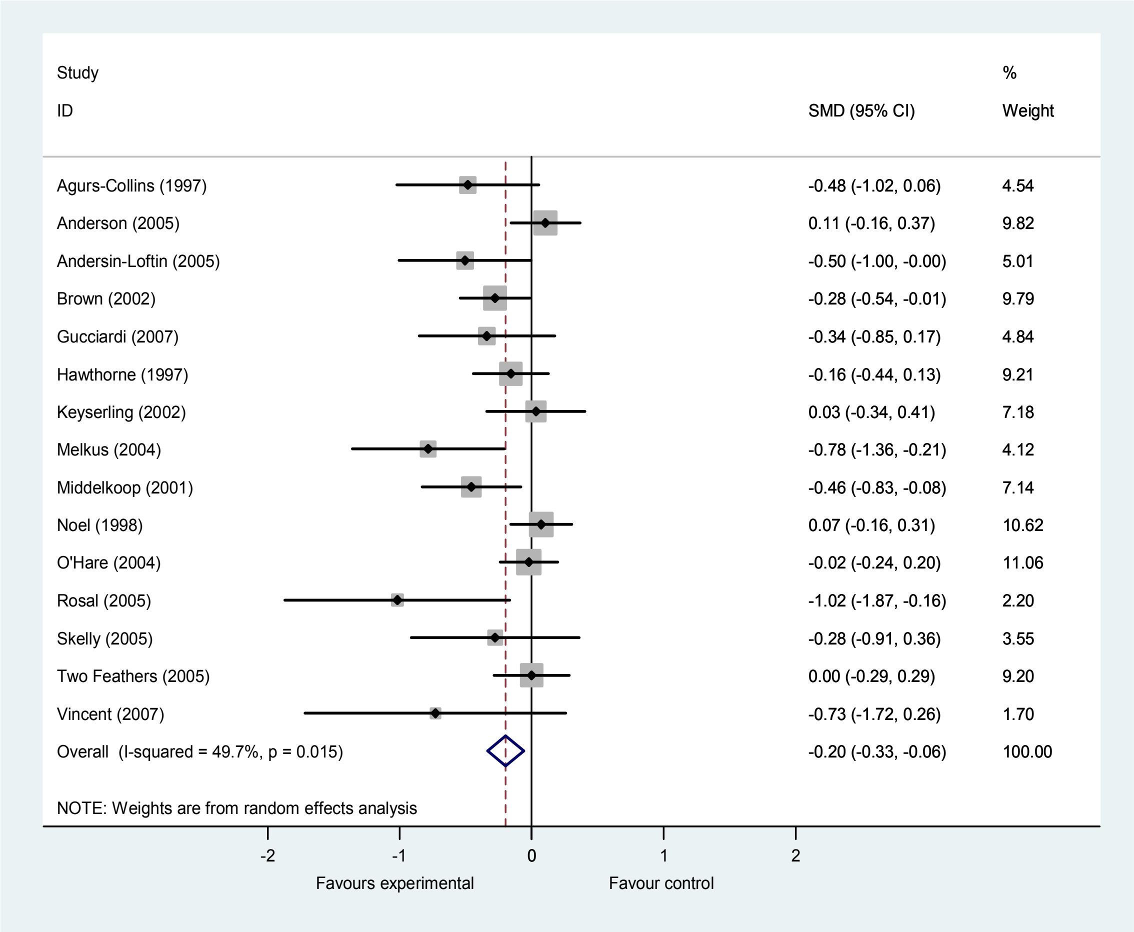
		1. history of diabetes ketoacidosis 2. current gestational diabetes 3. planning to move out of the area during study period 4. steroid use during previous year 5. having had a cardiovascular event in previous 6months
	Intervention	Intervention: One hour of initial individual sessions, followed by 2-3 hrs weekly group sessions for 10 weeks and two 15min individual sessions during the 10 week period. Primary care physicians received copies of laboratory results at each assessment point. Control: usual care and primary care physician received copies of laboratory results as intervention group did Setting: Community room Duration of intervention: 10 weeks Duration of follow-up: 6 months Provider: bilingual nutritionist, diabetes nurse and assistant
	Outcome	1. Feasibility (rate of attendance, recruitment and assessment completion) 2. HbA1c 3. Lipid profile 4. BP 5. Height 6. Weight 7. Hip waist ratio 8. Behavioral: two unannounced 24hrs dietary recall, modified version of Community Healthy Activities Model Program for Seniors PA questionnaire, 24hrs SMBG (Self-Monitoring Blood Glucose) recall. 9. Audit of Diabetes knowledge 10. Audit of Diabetes Dependent Quality of Life 11. Insulin Management Self-Efficacy Scale 12. Center for Epidemiological Studies-Depression scale
	Quality	2
Skelly, 2005 (n=39)	Aims	To test the effectiveness of an in-home, nurse-delivered symptom-focused teaching/counseling intervention with older rural African American women with type 2 diabetes.
	Country	USA
	Methods	RCT
	Participants	Older African-American women in rural in North Carolina Inclusion criteria: 1. age 50-85 2. women with type 2 diabetes 3. no cognitive, affective or functional dysfunction Exclusion criteria: 1. BDI-II score 29 2. SPMSQ error 8-109(depression or intellectual impairment)

	Intervention	Intervention: individual biweekly visits to individual's home lasting<1hr, with 4 Diabetes Symptom-Focused Management intervention modules and two preintervention visits. Total time spent with participants was 6 hours. Control: received the two pre-intervention visits during which demographic data were collected and the study instruments were administered. Controls also received a telephone call at a mid point between baseline and final evaluation details. Total time spent was 3hours and a telephone call Setting: community setting Duration of intervention: 12 weeks Duration of follow-up: 12 weeks Provider: nurse
	Outcome	Symptom distress and its effects on QoL, diabetes knowledge, HbA1c, QoL, diabetes self-care practice, patient satisfaction with intervention assessed using structured in-depth interviews
	Quality	3
Two Feathers, 2005 (n=91)	Aims	To determine the effects of a community –based, culturally tailored diabetes lifestyle intervention on risk factors for diabetes complication among African American and Latinos with type 2 diabetes.
	Country	USA
	Methods	One group before and after design
	Participants	Inclusion criteria: 1. African American and Latino men and women 2. physician diagnosed type 2 diabetes 3. had insurance or received care from a federally qualified health center 4. mentally able 5. resided in 1 of 6 REACH (Racial and Ethnic Approaches to Community Health) Detroit zip code areas. Exclusion criteria: not stated
	Intervention	Intervention: five 2hr group meetings delivered every 4 weeks by 10 FHA (Family Health Advocate) from June to October 2002. Setting: community based setting Duration of intervention: 3months Duration of follow-up:4months Provider: trained community residents
	Outcome	1. Diabetes specific quality of life (Problem Areas in Diabetes) 2. Diet and physical activity (Behavioral Risk Factor Surveillance Survey) 3. Knowledge 4. Summary of Diabetes Self-Care Activities 5. HbA1c, Bp, Lipid, weight, height
	Quality	2
Vincent, 2007 (n=17)	Aims	To test the feasibility and examine the effects of a culturally tailored intervention for Mexican American with type 2 diabetes on outcomes of self-management

	Country	USA
	Methods	RCT
	Participants	Mexican American in Tucson, Arizona Inclusion criteria: 1. self-identification as Mexican American 2. 18-75 years of age 3. fluency in Spanish 4. ability to walk without assistance Exclusion criteria: 1. pregnancy 2. medical condition(heart failure) 3. cognitive impairment 4. participated diabetes self-management program within the previous 12 months
	Intervention	Intervention: 2hr weekly group sessions for eight weeks. Control: usual care consisted of a 10-15min encounter with a physician or nurse practitioner two to four times per year Setting: community health clinic Duration of intervention: 8 weeks Duration of follow-up : 12 weeks Provider: not stated
	Outcome	Feasibility and acceptability (assessed by examining ease of recruitment and retention rate), BP, HbA1c, blood glucose, weight, BMI, diabetes knowledge, self-efficacy, self-management activity
	Quality	4

Figure 1.

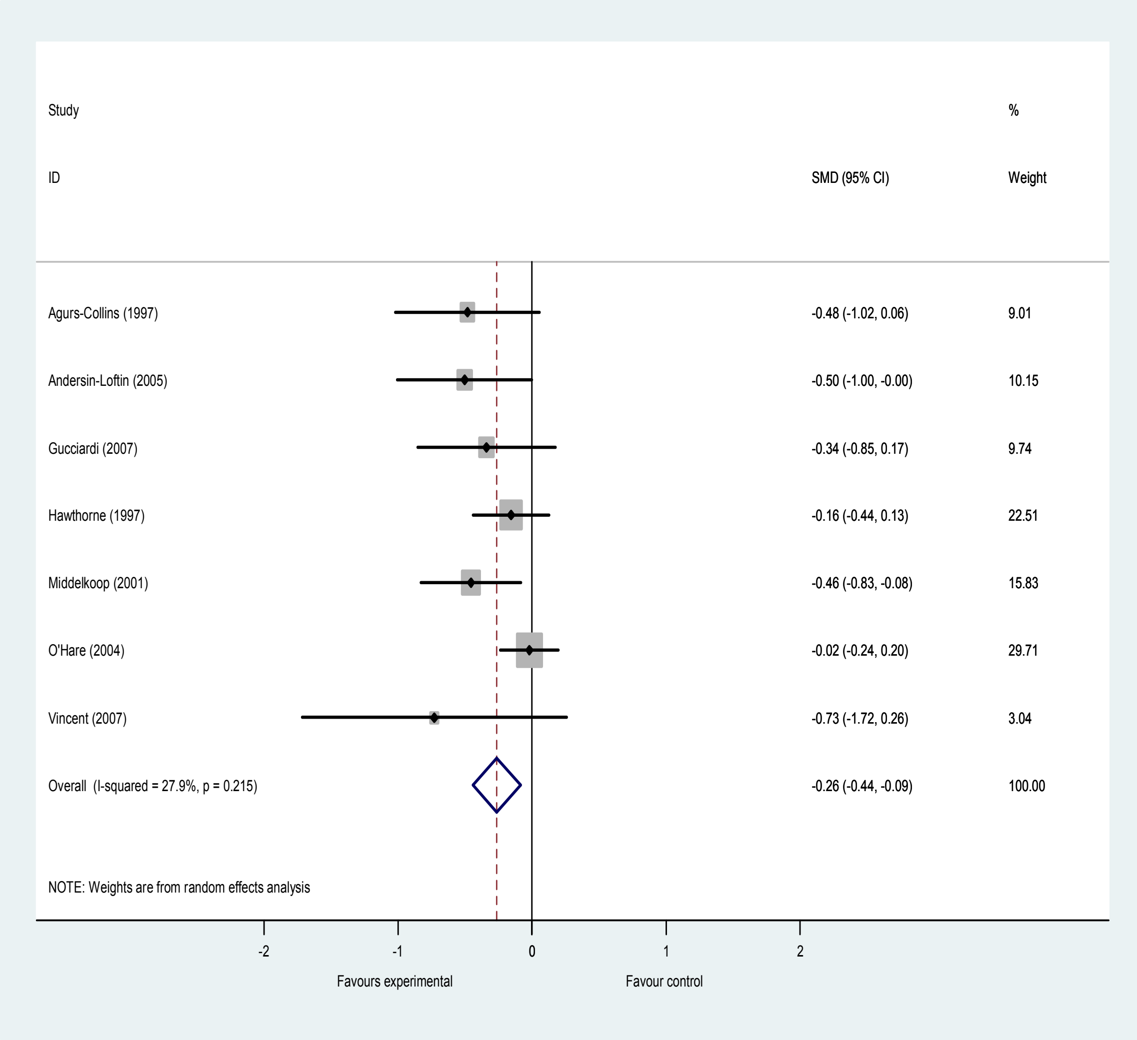
The result of meta-analysis of effect of CCDE on glycemic control in ethnic minorities with type 2 diabetes



Heterogeneity chi-squared = 27.83, (df = 14), p = 0.015

Figure 2.

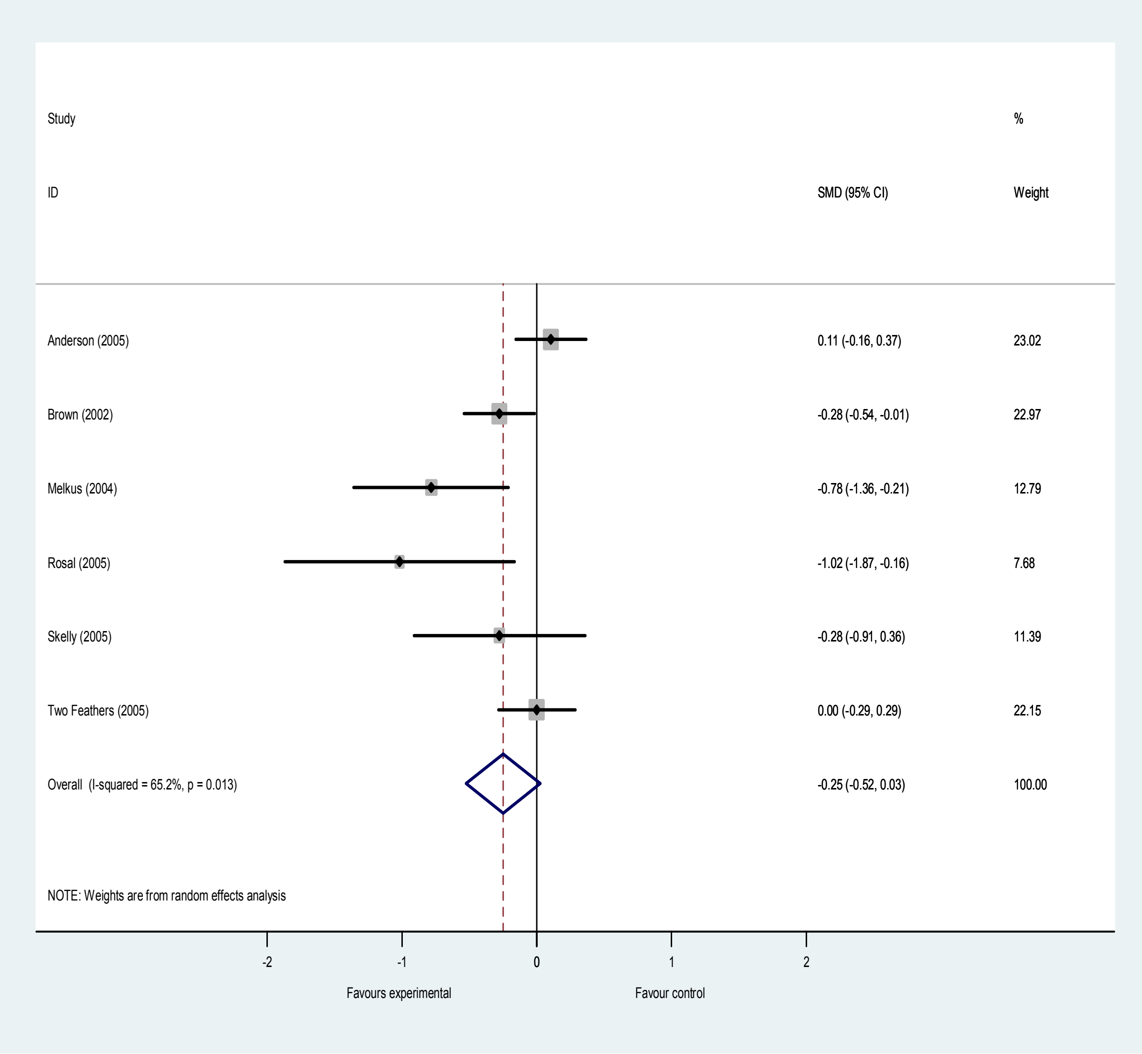
The result of meta-analysis of effect of CCDE: clinic or hospital based diabetes education center



Heterogeneity chi-squared =8.32, (df = 6), p = 0.215

Figure 3.

The result of meta-analysis of effect of CCDE: community based intervention

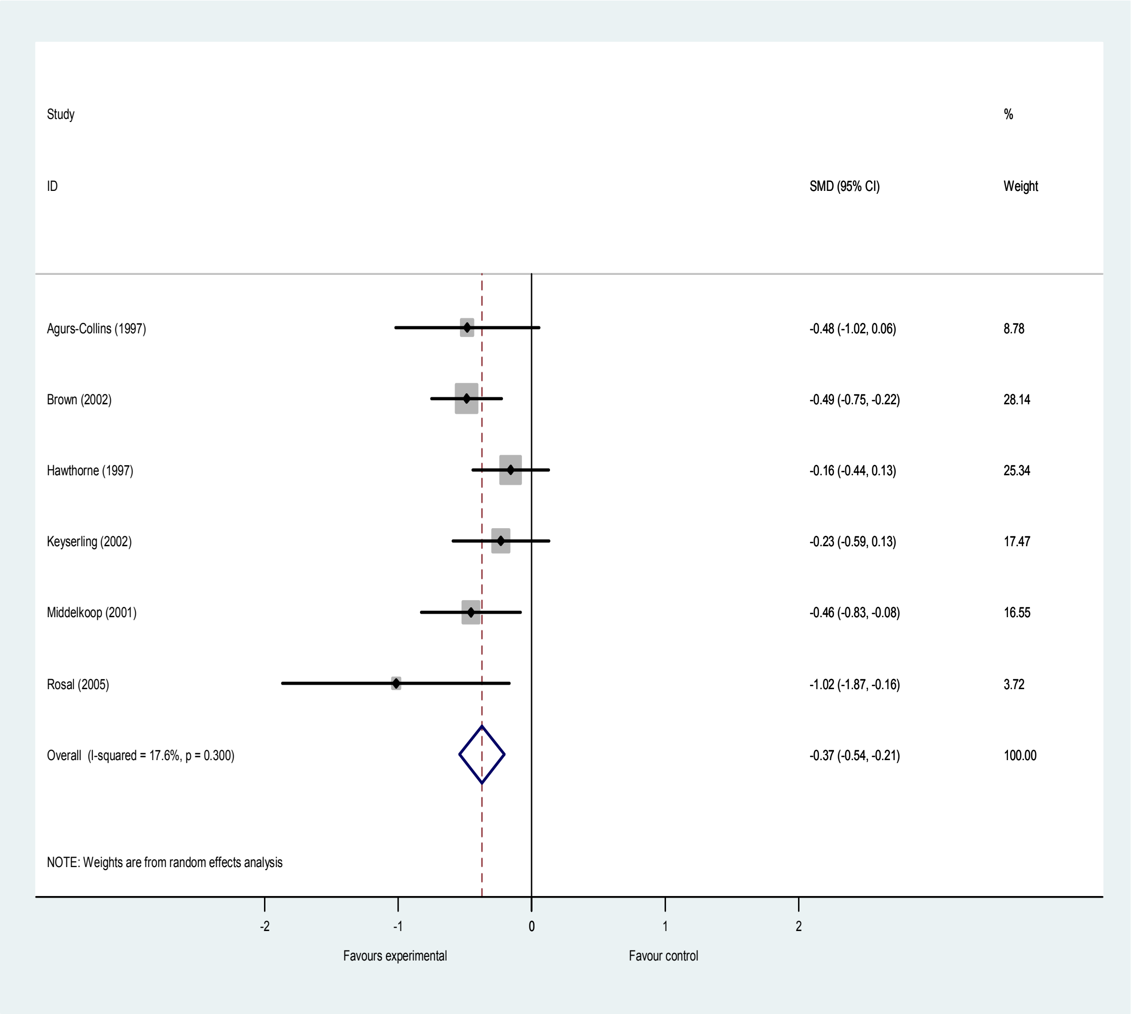


Heterogeneity chi-squared = 14.38, (df = 5), p = 0.013

Figure 4.

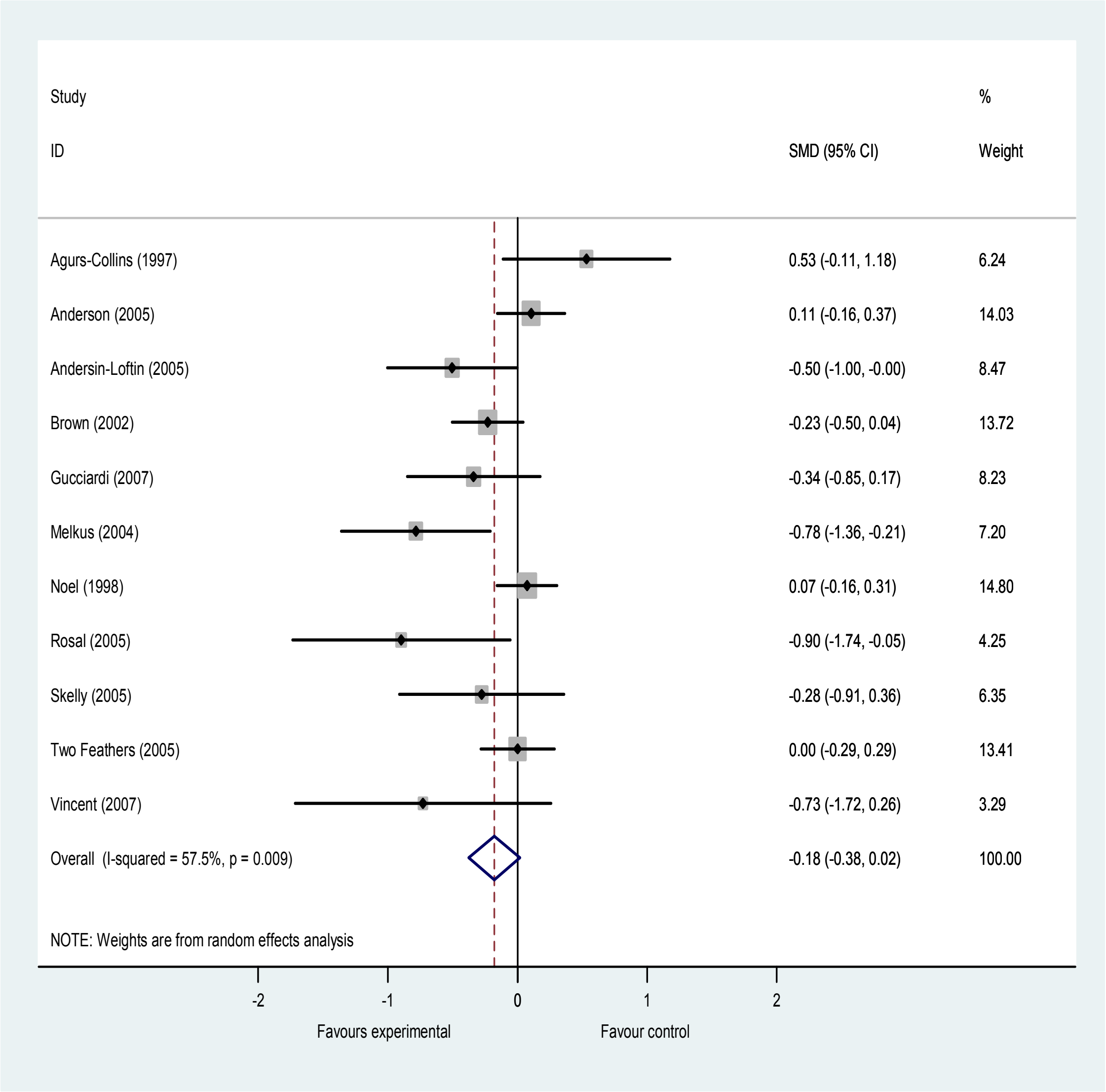
The result of meta-analysis of effect of CCDE by month

A. 6 months



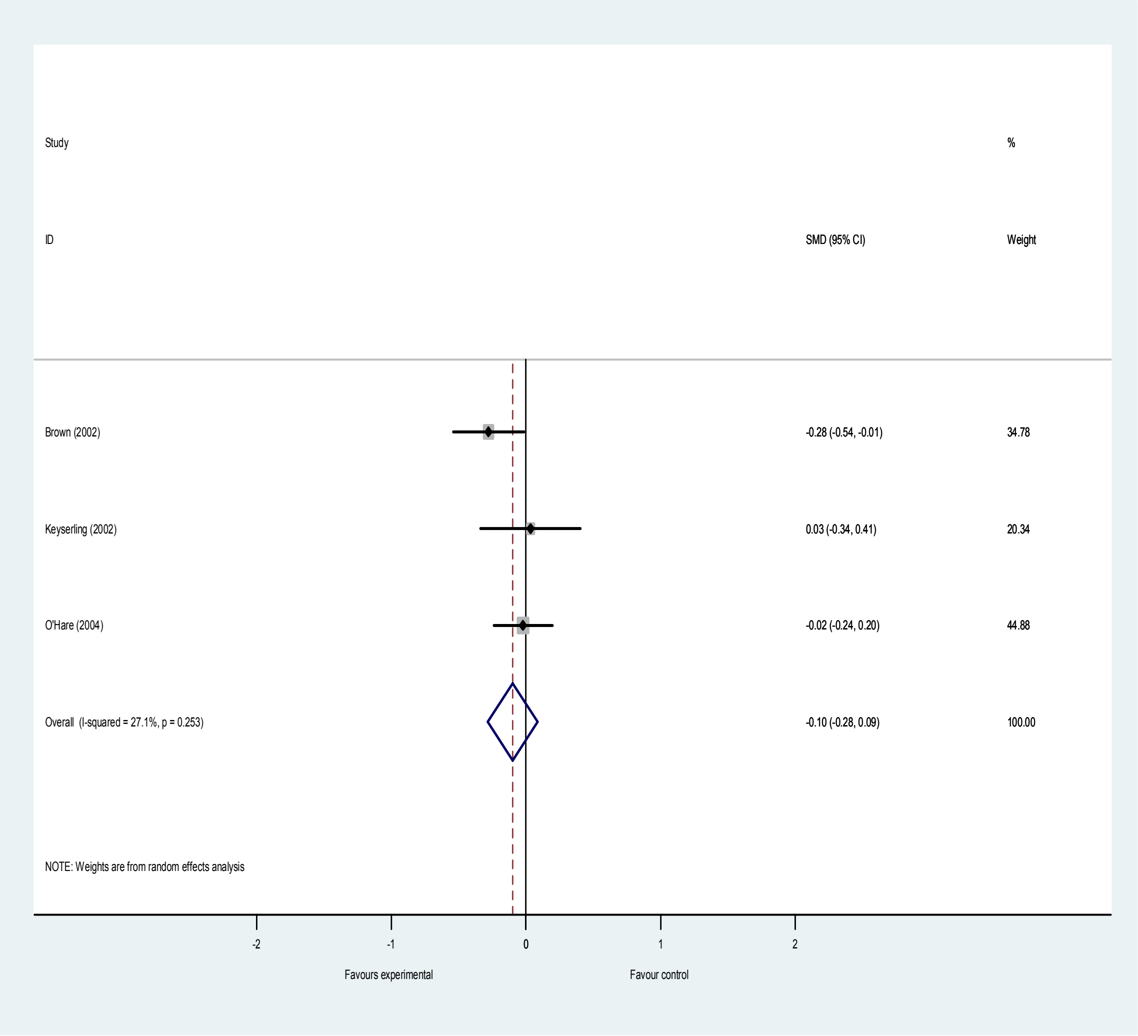
Heterogeneity chi-squared = 6.07, (df = 5), p = 0.300

B. 3 months



Heterogeneity chi-squared =23.52, (df = 10), p = 0.009

C. 12 months

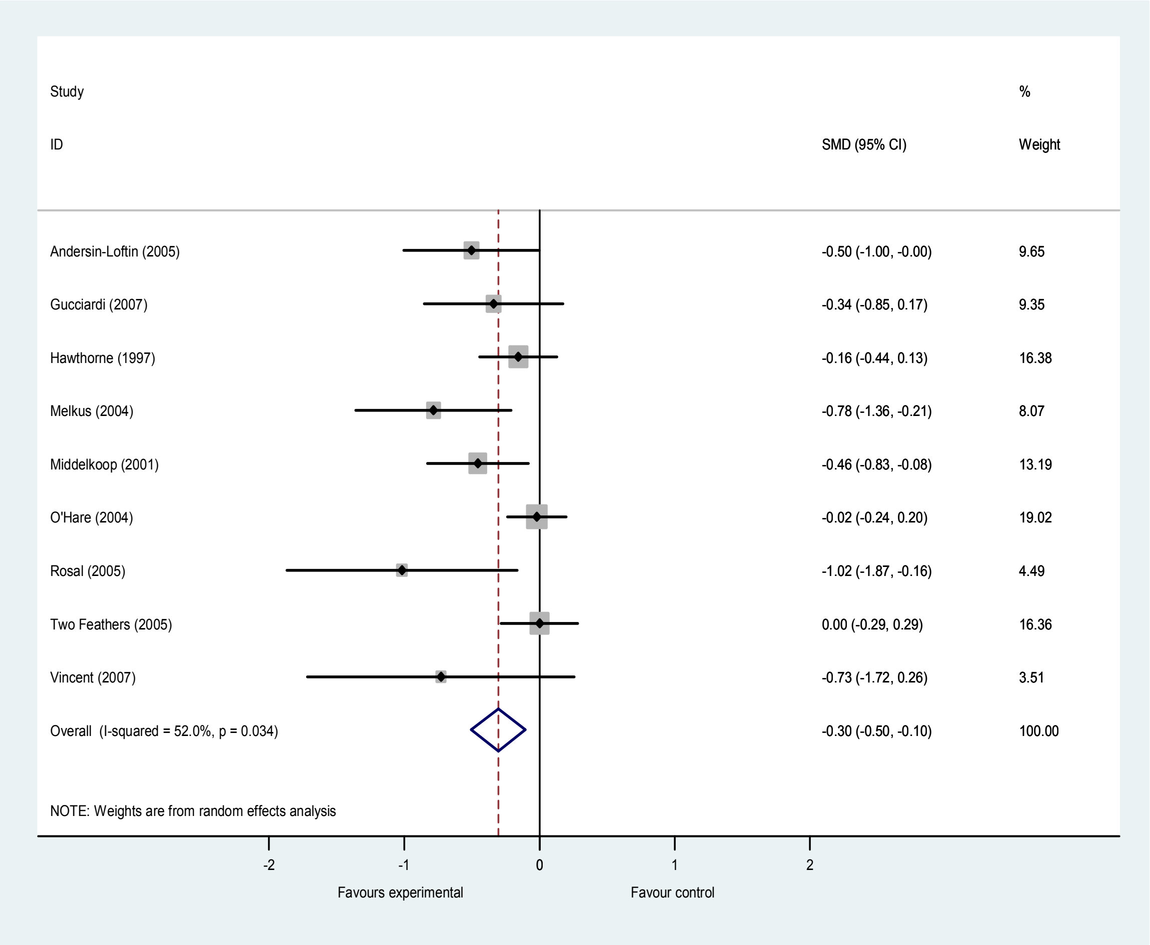


Heterogeneity chi-squared =2.75, (df = 2), p = 0.253

Figure 5.

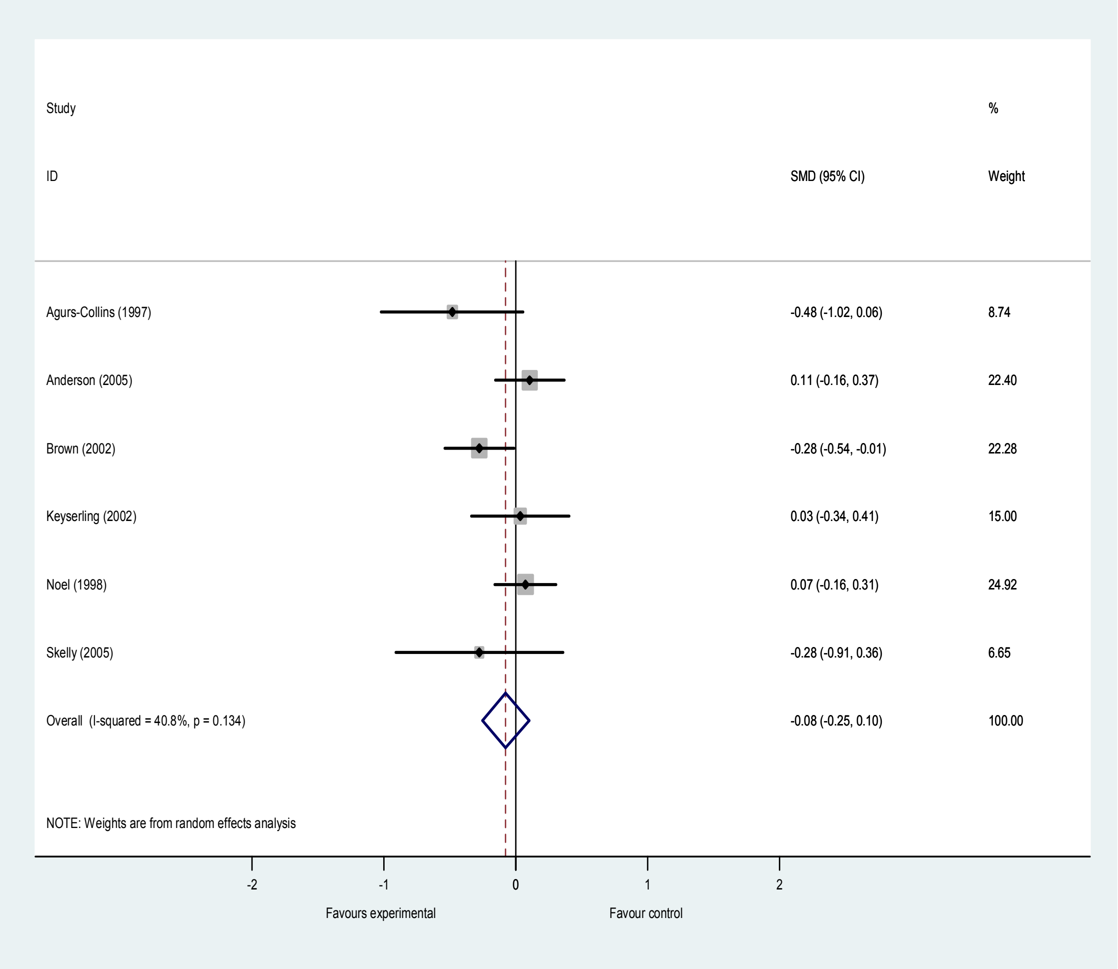
The result of meta-analysis of effect of CCDE: by baseline HbA1c

A. HbA1c ≤ 8.5



Heterogeneity chi-squared =16.66, (df = 8), p = 0.034

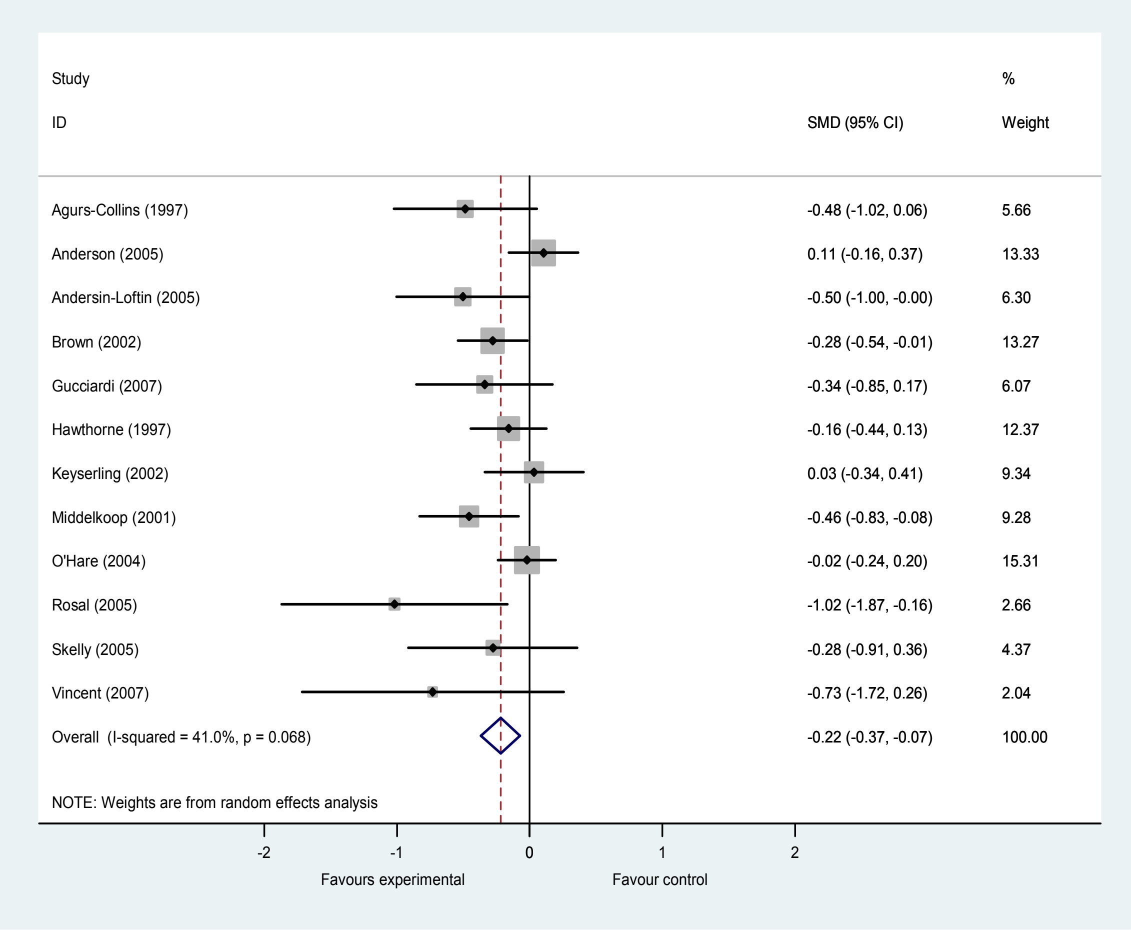
B. HbA1c > 8.5



Heterogeneity chi-squared = 8.44, (df = 5), p = 0.134

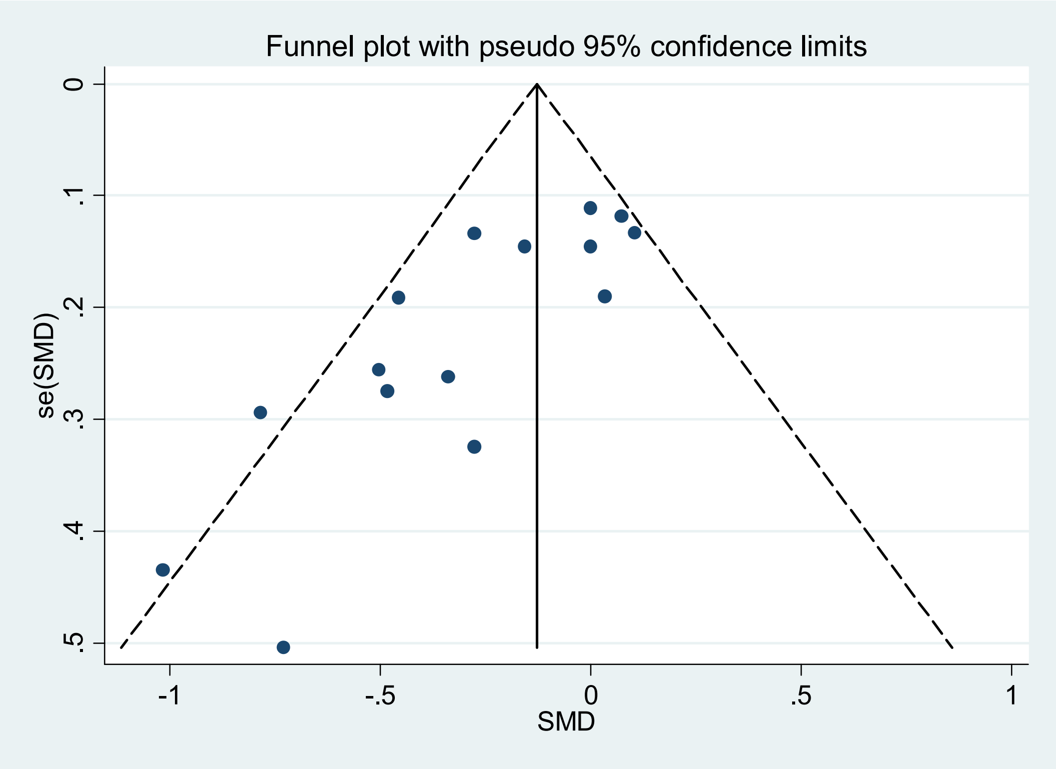
Figure 6.

The result of meta-analysis of effect of CCDE: Randomized controlled trial only



Heterogeneity chi-squared = 18.65, (df = 11), p = 0.068

Figure 7. Funnel plot



```
Egger's test for small-study effects:
Regress standard normal deviate of intervention
effect estimate against its standard error

Number of studies =15                             Root MSE = .9277
-----------------------------------------------------------------------
Std_Eff |   Coef.   Std. Err.      t    P>|t|     [95% Conf. Interval]
-----------------------------------------------------------------------
slope |   .3163328   .1083828     2.92   0.012     .0821859    .5504797
bias  |  -2.745807   .6173844    -4.45   0.001    -4.079585   -1.412029
-----------------------------------------------------------------------

Test of H0: no small-study effects          P = 0.001

Begg's test for small-study effects:
Rank correlation between standardized intervention effect and its
standard error

adj. Kendall's Score (P-Q) =     -53
          Std. Dev. of Score =   20.21
           Number of Studies =      15
                          z  =   -2.62
                    Pr > |z| =   0.009
                          z  =    2.57 (continuity corrected)
                    Pr > |z| =   0.010 (continuity corrected)
```

CHAPTER FIVE

Conclusions and Recommendations for Future Research

The prevalence of type 2 diabetes is increasing worldwide. Diabetes is a major health concern in the United States (US), with prevalence increasing in all ethnic groups. People with type 2 diabetes have an increased risk of renal disease, blindness and lower extremity amputation (Nathan, 1993), are frequently diagnosed with hypertension and/or hyperlipidemia (Hajjar & Kotchen, 2003), and have a three-fold increased risk of cardiovascular disease (Nesto, 2001). Type 2 diabetes is a chronic condition which requires continual medical care and patient self-management to prevent microvascular and macrovascular complication. Given the significant burden of diabetes, public health care systems are seeking increasingly effective means of providing diabetes care.

Despite efforts to standardize and disseminate evidence-based care guidelines, unsatisfactory diabetes outcomes continue. Less than 15% of adults with diabetes reach all goals recommended by the American Diabetes Association (ADA) (Minnesota Community Measurement, 2009). The inability to effectively translate clinical evidence into usual practice represents a significant shortcoming in diabetes care.

The review of literature (Chapter 2) indicates that there are many barriers to diabetes management for both patients and clinicians. Several patient factors that may contribute to difficulty with type 2 diabetes self-management include: adherence, beliefs, attitudes, knowledge, ethnicity/culture, language ability, financial resources, co-morbidities, and social support. Adherence to self-management, which is commonly influenced by a person’s beliefs, attitudes, and knowledge about the disease and effectiveness of the treatment regimen, positively affects glycemic control. Knowledge alone, however, does not necessarily lead to a change in health behavior. Patients’ attitudes toward diabetes and its treatment vary by ethnicity and gender. Fears and misconceptions can negatively affect adherence, particularly when patients perceive insulin therapy as evidence of personal failure. Culture is also an influential factor in diabetes care. The relationship between culture and diabetes self-management is complex and varies among different cultural groups, which suggests that it must be understood within the larger socio-cultural context. To date, no research has been done comparing cultural beliefs about diabetes self-management across different racial and ethnic groups. Therefore, future research is needed to compare cultural beliefs across different racial groups to better understand cultural factors in diabetes care and develop culture-specific diabetes intervention for the specific population. Furthermore, various socio-cultural issues related to culture should be included in the area of diabetes study.

Studies reviewed in chapter 2 also found that language discordance between clinicians and patients may impact the process of patient education and thus adversely affect glycemic control in Hispanic patients with type 2 diabetes. Co-morbidities are barriers to self-management because of competing treatment regimens. Depression decreases one’s perception of his or her ability to self-manage the illness. The presence of positive social support may serve as a mediating/modifying factor to perceived barriers of self-care, health promotion, and risk reduction.

Diabetes management is also challenging to clinicians. Clinician barriers to following treatment guidelines include beliefs, attitudes and knowledge, patient-clinician interaction and communication, and the health care system. Delays or failure in making appropriate changes in care is ascribed to competing demands during clinic visits, limited resources of practitioners, insufficient training, lack of feedback, and inadequate infrastructure and systems organization to support translation. Most randomized controlled trials (RCTs) reviewed in chapter 2 were conducted in primary care settings and research subjects were physician providers and not nurse practitioners, dieticians, pharmacist and other diabetes educators who commonly provide diabetes care. The patients in the reviewed RCTs were primarily whites and thus these factors limit generalizability of the study findings. Future research must include various practitioner and patient groups to provide more valid assessment of effective intervention strategies and to translate the information into substantial changes in care.

Insulin reluctance (IR) is one of the patient barriers to diabetes management, that may be influenced by patients' attitudes, knowledge, culture and interactions with health care providers based on these reviewed studies (Chapter 2).

The dissertation research study investigates IR in people with type 2 diabetes (Chapter 3). The findings showed that adults whose diabetes is treated by oral agents had moderate IR with a mean score of 3.1 using a six-point Likert scale. Fear of hypoglycemia was the strongest barrier (mean score: 6.38) to insulin treatment, indicating that subjects were reluctant to start insulin due to concern about hypoglycemia. The BIT subscale, expected hardship had the lowest mean values (3.34), indicating this was not a perceived barrier to starting insulin therapy compared to other factors assessed. One clinical implication for these findings is that fear of hypoglycemia is an important topic to discuss with patients. It is critical to educate patients that hypoglycemic episodes often can be avoided through adjustment of insulin and careful vigilance with self-monitoring of blood glucose levels.

Certain socio-demographic factors were associated with IR. Consistent with previous studies (Polonksy, Fisher, Guzman, Villa-Caballero, & Edelman, 2005), women were more reluctant to use insulin treatment than men. Similarly, in the studies of investigating gender disparities in diabetes and cardiovascular disease treatments, women were less likely adherent to medication than men (Chapman et al., 2005; Gouni-Berthold, Berthold, Mantzoros, Böhm, & Krone, 2008). Therefore, future studies are necessary to investigate why women are less adherent to treatment and have negative beliefs about insulin.

This dissertation research showed that ethnic minorities had greater IR than Caucasians. Asians and other non-black minority groups had significantly higher fear of injections and expected greater hardship in using insulin than whites. Future intervention research designed for providing culturally competent care to the growing ethnic minority with type 2 diabetes will be helpful in promoting greater patient satisfaction, understanding, and better compliance with insulin therapy.

The glycosylated hemoglobin (HbA1c), number of comorbidities and diabetes complications were not associated with the IR. These findings may be explained by the fact that participants in our study sample had relatively better HbA1c levels (mean±SD: 6.98 ± 0.99 %) than those found in the general diabetes population. In addition, only a small number of our participants had chronic illness comorbidities and complications associated with diabetes.

The relationship between diabetes knowledge and IR was not significant but diabetes knowledge was correlated with the patients' age, income, education and their attitude toward diabetes. Thus, knowledge itself may not be sufficient to predict IR, but knowledge is a critical factor that interacts with other demographic and psychosocial determinants in diabetes self-care.

The dissertation study revealed that beliefs about the value of tight glucose control were also an important correlate of IR. The implication for these findings is that patient education focused on benefit of optimal glucose control and progressive nature of type 2 diabetes should be emphasized.

This study also found that stronger exercise self-efficacy is associated with less IR and especially in the patients whose health care providers have a compassionate and respectful interpersonal style, the effect of their exercise self-efficacy became stronger in decreasing IR. This finding may suggest that health care providers play an important role in reducing IR and diabetes education focused on enhancing self-efficacy may be beneficial in decreasing patients' IR. Therefore, future research should be directed toward understanding and promotion of the interpersonal processes of care between patients and their health care providers. More studies are needed to develop effective interventions to help both patients and health care providers transition to insulin treatment.

Finally, this study findings also support the adapted social cognitive theory which posits that health behavior is influenced by an individual's outcome expectancy (i.e. diabetes belief/attitude) related to health outcome either directly or indirectly by interacting with self-efficacy. In addition, continuing interaction among the sociostructural factors (i.e. demographic, patient and provider interaction) and self-efficacy can in turn contribute to an individual's health behaviors.

As in this dissertation study, several studies demonstrated that ethnic minorities with type 2 diabetes have many barriers to effective diabetes management (Dagogo-Jack, Funnell, & Davidson, 2006; Kuo, Raji, Markides, et al., 2003; Lasater, Davidson, Steiner, & Mehler, 2001; Lipton, Losey, Giachello, Mendez, & Girotti, 1998).

In order to develop intervention strategies to reduce IR for the ethnic minorities with type 2 diabetes, it is important to assess whether culturally competent diabetes education (CCDE) is effective for diabetes control in the ethnic minorities with type 2 diabetes. Chapter 4 presented a meta-analysis on the effect of diabetes education in ethnic minorities with type 2 diabetes. This meta-analysis quantitatively reviewed 15 studies that evaluated the effect of CCDE on glycemic control in ethnic minorities with type 2 diabetes. This meta-analysis provides evidence of the benefit of CCDE with improvement of HbA1c. It appears that at least 6 months of educational interventions may be required to decrease HbA1c in ethnic minority groups. The CCDE intervention was more effective for those with HbA1c equal to or less than 8.5% than those who have HbA1c greater than 8.5%. The result showed that HbA1c was decreased more when the intervention was delivered in the clinic or hospital based diabetes education center settings than the community settings. An important implication from this meta-analysis is that CCDE program should consider carefully the setting of intervention as well as the duration of intervention and provide tailored interventions based on patients' baseline HbA1c. More importantly, future research should focus on what content in diabetes education is critical in improving glycemic control for ethnic minorities with type 2 diabetes and how to help health care providers develop and deliver effective intervention by considering the content for ethnic minority groups.

In summary, the dissertation provided significant insight into the concept of IR and its associated factors. To our knowledge, this is the first study to examine relationships between IR and its potential predictors. Our findings have clinical implications for developing interventions to reduce barriers to insulin treatment. The meta-analysis and review of literature on barriers to diabetes self-management will also serve as groundwork for future research and clinical arena. What types of education strategies produce which benefits for which types of patients should be addressed by conducting more sophisticated data analyses of the interactions between patients and provider factors in the future.

More efforts in diabetes self-management research will lead to improvements in diabetes clinical care. Specifically, it is imperative to include racially diverse samples in future studies and provide culture-specific interventions, appropriately matched intervention providers, and attention to barriers to diabetes management for the specific population.

In addition, future research needs to continue exploration of IR and its relationship with other potential variables that were not included in this dissertation to better explain IR and mechanism of relationship among the variables. For example, duration of diabetes, family history of diabetes, and patient experience with diabetes education may influence the degree of IR. To assess psychosocial variables by using instruments written in non-English languages for monolingual, non-English speaking subjects will be helpful to understand the impact of culture and language on diabetes management. Furthermore, replication of the original research presented in this dissertation with a larger sample and inclusion of patients with poor glycemic control and more diabetes complications should be done to identify key determinants of IR and design effective intervention strategies.

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