SELF-MANAGEMENT FOR SOUTH ASIANS WITH TYPE 2 DIABETES

CULTURALLY TAILORED SELF-MANAGEMENT INTERVENTIONS FOR SOUTH ASIANS WITH TYPE 2 DIABETES: A SYSTEMATIC REVIEW

By

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Lay Abstract

South Asians are the largest visible ethnic minority group in Canada and are at high risk of developing type 2 diabetes (T2DM). This research project aims to understand how diabetes self-management education (DSME) and support (DSMS) is delivered to South Asians with T2DM and how these practices are culturally tailored. The scientific literature was searched using electronic databases to find 1259 research studies, of which four examined the effectiveness of DSME/DSMS provided to migrant South Asians with T2DM. Only one study showed significant improvements in blood glucose control. All of the four studies contained several DSME/DSMS components and they all failed to address differences in gender roles and responsibilities in relation to South Asian culture. Thus, there is a need for future studies to design DSME/DSMS interventions that are culturally tailored to improve blood glucose control and thus, improve the health and well-being of South Asians with T2DM.

Abstract

Introduction: As the prevalence of diabetes continues to rise in Canada, South Asians, as the largest visible minority group in Canada, are at higher risk for developing diabetes than the general population. Although diabetes self-management education (DSME) interventions for South Asians with type 2 diabetes (T2DM) have been researched, these interventions have not been assessed for their cultural congruency. *Methods:* This systematic review examined the effectiveness of DSME interventions for South Asians with T2DM. Electronic databases (MEDLINE, EMBASE, Cochrane CENTRAL and CINAHL) were searched since inception, along with relevant reviews and guidelines. Title and abstract and full text screening were conducted independently by two reviewers; data extraction was done by one reviewer and confirmed by another. Quality assessment of the included studies was completed using the Cochrane Risk of Bias tool; cultural congruency was assessed using Leininger's Sunrise Model. All results were synthesized narratively. *Results:* A total of 1259 studies were found in the search, of which only four randomized controlled trials (RCT) met the inclusion criteria. All studies were consistent in showing a reduction in A1C following the intervention; however only one study reported statistically significant reductions in A1C. Interventions were conducted in person, with follow-up periods ranging from six months to two years, with the use of South Asian community link workers in most interventions. Bias was identified across all studies for sequence generation, allocation concealment and blinding. All

studies had limited evidence of cultural congruency, particularly for gender roles and responsibilities. *Conclusions:* This review found limited effectiveness of culturally specific DSME interventions for South Asians with T2DM. Furthermore, the interventions were scant in their description of cultural congruency. Future research ought to begin with designing interventions for cultural congruency and improved methodologies for DSME research to improve internal and external validity.

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List of all Abbreviations

A1C:	Glycated hemoglobin
CDA:	Canadian Diabetes Association
DSM:	Diabetes self-management
DSME:	Diabetes self-management education
DSMS:	Diabetes self-management support
IDF:	International Diabetes Federation
PHAC:	Public Health Agency of Canada
RCT:	Randomized controlled trial
RNAO:	Registered Nurses' Association of Ontario
T2DM:	Type 2 diabetes mellitus
TIDieR	Template for Intervention Description and Replication
UK:	United Kingdom
UKPDS:	United Kingdom Prospective Diabetes Study
WHO:	World Health Organization

Declaration of Academic Achievement

I, Nevin Navodia, declare that this work is my own.

December 2, 2016

Nevin Navodia

Chapter 1: Introduction

The Global Status Report (2014) on noncommunicable diseases published by the World Health Organization (WHO) reported that deaths from noncommunicable diseases are projected to increase globally from 38 million in 2012 to 52 million by 2030. Of these noncommunicable diseases, cardiovascular disease, cancer, chronic respiratory diseases and diabetes made up the four major categories, comprising 82% of noncommunicable disease deaths in 2012. Although diabetes accounted for 4% of these noncommunicable disease deaths as per the WHO report, it is nonetheless a cause of great concern because the incidence and prevalence rates of diabetes are on the rise in Canada and worldwide. This calls for increased resources dedicated to chronic disease management, particularly diabetes self-management (DSM), across all levels of healthcare (Canadian Diabetes Association [CDA], 2013).

The Chronic Care Model has been used in the Canadian context as an approach to structure diabetes care and quality improvement strategies. It contains six elements (health systems, community linkages, self-management support, delivery system design, decision support, and clinical information systems) which work to foster collaboration and interactions between the health care provider and the patient, with the ultimate goal of improving clinical outcomes (Wagner et al., 2001). In this model, self-management support, together with self-management education forms the foundation upon which diabetes care interventions are developed within the chronic care model.

The significance of providing client-centered self-management education and support for diabetes is particularly important now, given that the incidence and prevalence rates of diabetes are on the rise. By collaborating with the client and the interprofessional team to achieve self-management goals, lifelong self-management efforts can be supported (Registered Nurses' Association of Ontario [RNAO], 2015). This is crucial in the context of diabetes, which requires the patient to be an active agent in the management of their condition.

As Canada fosters a multicultural and pluralistic society with immigrants from many countries around the world, it becomes even more important to conceptualize DSM in the context of client-centered care. There has been research conducted to demonstrate the effectiveness of such client-centered DSM interventions, particularly in the context of the South Asian community, who represent a high risk population for developing diabetes in Canada. However, one major gap across this research is the lack of assessment of how culturally tailored these DSM interventions are among the South Asian population. Thus, the purpose of this thesis research is to: a) conduct a systematic review to determine the effectiveness of DSM interventions used among South Asians with type 2 diabetes, and b) examine the cultural congruency of these DSM interventions with the South Asian population, using Leininger's Sunrise Model. Here, the term culturally congruent care refers to "the use of culturally based care knowledge that is used in assistive, facilitative, sensitive, creative, safe and meaningful ways to individuals or groups for beneficial and satisfying health and well-being"

(Leininger & McFarland, 2002, p. 128). This chapter presents context regarding diabetes, the population of interest (South Asians), and cultural implications and barriers in relation to DSM that are important to consider when engaging with this population.

1.1 Diabetes Mellitus

Diabetes mellitus, usually referred to as diabetes, is a chronic disease characterized by chronic hyperglycemia, which results from decreased secretion of insulin or impairment of insulin action within the body (CDA, 2013; International Diabetes Federation [IDF], 2015a). Insulin is a hormone secreted by the beta cells in the pancreas which the body uses for glucose metabolism. With the absence of insulin secretion, decreased insulin secretion or impaired insulin action, the glucose concentration in the blood rises and the cells are not able to convert glucose to energy (IDF, 2015a). The chronic high concentration of glucose in the blood, referred to as hyperglycemia leads to the diagnosis of diabetes.

According to the CDA (2013) clinical practice guidelines for the prevention and management of diabetes in Canada, diabetes is diagnosed if the following clinical values are achieved: a fasting plasma glucose concentration of ≥7.0 mmol/L, a glycated hemoglobin (A1C) of ≥6.5% in adults, a two hour plasma glucose in a 75g oral glucose tolerance test of ≥11.1 mmol/L, or a random plasma glucose concentration of ≥11.1 mmol/L. If any one of the previously listed values is achieved in the presence of symptomatic hyperglycemia, then a diabetes

diagnosis is confirmed. In the absence of hyperglycemic symptoms or in the presence of a single elevated random glucose plasma test, a repeat confirmatory laboratory test needs to be done on another day to confirm the diabetes diagnosis (this should be done with either a fasting plasma glucose, A1C or a two hour plasma glucose in a 75g oral glucose tolerance test). There are three main types of diabetes: type 1 diabetes mellitus, type 2 diabetes mellitus (T2DM) and gestational diabetes mellitus. T2DM will be discussed below, since that is the focus of this thesis.

1.1.1 Type 2 Diabetes Mellitus

T2DM is characterized by varying degrees of insulin resistance, along with decreased insulin secretion. This leads to the body not being able to use the insulin effectively, thereby resulting in hyperglycemia (CDA, 2013). The symptoms of T2DM include polyuria (frequent urination), polydipsia (increased thirst), weight loss, fatigue, and vision changes/blurred vision (IDF, 2015c; WHO, 2016). T2DM accounts for approximately 90% of all diagnosed cases of diabetes worldwide, and usually occurs later in life (CDA, 2016c; IDF, 2015c).

Screening for T2DM is recommended in individuals who are at high risk of developing T2DM. Screening in high risk individuals is recommended every three to five years with an A1C, regardless of the age of that individual (these risk factors are outlined in Section 1.6). Those individuals who are at a very high risk of T2DM due to multiple risk factors should be screened annually with an A1C (Canadian Task Force on Preventative Health Care, 2012). These risk factors for

T2DM will be discussed later in this chapter. Since T2DM develops gradually over time, symptoms of hyperglycemia are not always present, and thus, it is estimated that about half of all people with diabetes go undiagnosed (IDF, 2015c). This is potentially why patients often present with diabetes-related complications at the time of diagnosis of T2DM. Thus, screening for diabetes-related complications should also occur at the time of T2DM diagnosis so that if they are detected, they can be managed in time by appropriate pharmacologic treatment (CDA, 2013; IDF 2015c). T2DM requires significant self-management to prevent the onset and severity of diabetes-related complications. DSM will be discussed later in this chapter.

1.2 Prevalence of Diabetes

The IDF is a global organization comprised of over 230 national diabetes associations in 170 countries and territories around the world, which advocates for the global diabetes community, including those living with the disease and those at risk. Every two years, the IDF publishes a report called the *IDF Diabetes Atlas*. This report is produced in collaboration with multinational experts from around the world such as the United Nations, the WHO and experts from the diabetes community worldwide. Sources of data include official reports from the United Nations and WHO, peer-reviewed literature from electronic databases, ministry of health websites as well as data from health surveys conducted nationally and regionally. The final report consists of data on a global, national and regional level, outlining prevalence, mortality and health expenditure related to diabetes.

The *IDF* (2015c) *Diabetes Atlas* reported a global diabetes prevalence of 8.8% in 2015, which is equivalent to one in 11 adults having diabetes worldwide (age 20-79 years). By the year 2040, this prevalence is estimated to increase to 10.4%, which is equivalent to one in 10 adults. Nearly half (46.5%) of all adults diagnosed with diabetes did not know that they had the disease, as the symptoms are not always overtly present (IDF, 2015c).

Of all diagnosed cases globally in 2015, about three quarters live in low and middle income countries (IDF, 2015c). This includes China, which is ranked first in the top 10 countries and territories worldwide for the number of people diagnosed with diabetes at 109.6 million in 2015 (age 20-79 years); in the same category, India is ranked second at 69.2 million people. Projections of these estimates to the year 2040 reveal China to be ranked first at an estimated 150.7 million and India to be ranked second with 123.5 million. Other countries in the South Asian region including Bangladesh, ranked at 10 in the year 2015, having 7.1 million people diagnosed with diabetes. Estimated projections to the year 2040 reveal Bangladesh to be ranked ninth at 13.6 million people having diabetes and Pakistan to be ranked eighth at 14.4 million diagnosed cases of diabetes (IDF, 2015c).

In order to provide a regional breakdown of the data, the *IDF Diabetes Atlas* has divided the global map into seven regions: North America and Caribbean, Middle East and North Africa, South and Central America, Western Pacific, South-East Asia, Europe and Africa. Amongst these seven regions, the

North America and Caribbean region has the highest diabetes age-adjusted comparative prevalence at 11.5% in 2015 and this is estimated to increase to 12.0% by the year 2040 (IDF, 2015c). This region includes the United States of America, Mexico, Canada and 25 Caribbean countries and territories. Looking at diabetes prevalence rates specific to Canada, the CDA (2016b) has estimated the prevalence rate to be 9.3% in the year 2015, with projections for an estimated increase to 12.1% by the year 2025. This represents an estimated diabetes prevalence increase of 44% from 2015-2025.

Epidemiological data on diabetes in Canada is provided by the Public Health Agency of Canada's (PHAC) latest surveillance report on diabetes in Canada. This report utilizes data from the Canadian Chronic Disease Surveillance System, which gathers population-based administrative data, as well as data from population surveys from every Canadian province and territory. This data is in turn used to determine the burden, health services and health outcomes of chronic diseases (including diabetes) across the country. This report revealed that 50% of all Canadians that have been diagnosed with diabetes were of working age (25-64 years). In addition, 20% of diabetes cases remain undiagnosed in the country (Public Health Agency of Canada [PHAC], 2011).

Furthermore, data from the recent Canadian Community Health Survey, which is an annual cross-sectional survey conducted across Canada to collect information related to the population's health status, service utilization and determinants of health, revealed important province-specific prevalence data. For

those aged 12 and older, the highest prevalence of diabetes across Canada was at 9.0% in Newfoundland and Labrador, followed by 8.4% in New Brunswick and 8.2% in Nova Scotia. Ontario's diabetes prevalence was at 7.4%, followed by Manitoba, British Columbia and Alberta at 5.6%, 5.5% and 5.0% respectively. This province-specific prevalence data across Canada can provide important information which can be used for the planning and delivery of important health services for diabetes care, based on the needs of the population (Statistics Canada, 2015a).

1.3 Complications of Diabetes

Those who are diagnosed with diabetes, have a high risk of developing microvascular and macrovascular complications as a result of chronic hyperglycemia. Microvascular complications affect the blood vessels in the eyes, kidneys, and nerves, leading to retinopathy, macular degeneration, blindness, nephropathy, end-stage renal disease, and neuropathy. Macrovascular complications take the shape of cardiovascular and cerebrovascular diseases such as coronary artery disease, myocardial infarction and stroke (CDA, 2013; IDF, 2015b). According to the CDA (2016b), an estimated one in 10 deaths in Canada is due to these diabetes complications. Moreover, hospitalizations due to cardiovascular disease are two to four times more likely in people with diabetes (PHAC, 2011). Likewise, hospitalizations for end-stage renal disease are 12 times more likely and hospitalizations for non-traumatic lower limb amputations are

over 20 times more likely in those with diabetes, compared to the general population (PHAC, 2011; CDA, 2016b).

One well known, high quality randomized controlled trial (RCT) has drawn important findings in the relationship between the level of diabetes control and the development of diabetes-related complications. The United Kingdom Prospective Diabetes Study (UKPDS) focused on participants with newly diagnosed T2DM and aimed to ascertain the effects of intensive therapy on the development of microvascular and macrovascular complications of diabetes. Here, intensive therapy was referred to as achieving and maintaining fasting plasma glucose less than 6 mmol/L, with the addition of insulin-treated participants to achieve pre-meal glucose concentrations between 4 to 7 mmol/L (United Kingdom Prospective Diabetes Study [UKPDS] Group, 1998). This group was followed every three to four months in clinic, with additional follow-ups in between as necessary to maintain the specified blood glucose targets. The conventional therapy group was to maintain their fasting plasma glucose below 15 mmol/L with the absence of symptomatic hyperglycemia, which was usual care at that time; participants in this group were followed up every three to four months in clinic (UKPDS Group, 1998).

The study population in the UKPDS consisted of participants with T2DM, with the mean age of participants being 53 years in both intensive and conventional therapy groups. The majority of participants were of Caucasian ethnicity. The participants in the UKPDS were stratified into non-overweight and

overweight cohorts (UKPDS Group, 1998). The non-overweight participants were randomized to intensive therapy with insulin, intensive therapy with sulphonylureas, or to conventional therapy with diet. The overweight participants were randomized to intensive therapy with insulin, intensive therapy with sulphonylureas, intensive therapy with Metformin, or to conventional therapy with diet. A total of 5102 participants were recruited and 4209 were randomized. Of these, 58% of them were males. All participants were followed up for ten years (UKPDS Group, 1998).

The results of the UKPDS revealed a statistically significant reduction in median A1C ($p < 0.00$) in the intensive therapy groups at 7.0% (range: 6.2 to 8.2) compared to the conventional therapy group at 7.9% (range: 6.9 to 8.8) over ten years. Furthermore, there was a 25% risk reduction in microvascular endpoints ($p = 0.01$) in participants in the intensive therapy compared to conventional therapy groups. There was also a statistically significant risk reduction of 12% ($p = 0.03$) in diabetes-related endpoints (95% CI 1 to 21) in the intensive therapy group compared to the conventional therapy group (UKPDS Group, 1998).

The results of the UKPDS demonstrate the importance of maintaining blood glucose concentrations in as close to a normal range as possible, in order to prevent the development and progression of microvascular complications of diabetes (UKPDS Group, 1998). Common adverse events as a result of keeping blood glucose in a near-normal range were severe hypoglycemia and weight gain in the intensive therapy groups in the UKPDS. Since macrovascular complications

of diabetes take a long time to manifest, more longitudinal studies are needed so that the impact of intensive therapy on the development and progression of these complications in diabetes can be studied (UKPDS, 1998).

1.4 Costs of Diabetes

Diabetes contributes significant costs to the economy, both nationally and globally. Total economic costs associated with diabetes are divided into two categories: direct and indirect costs (CDA, 2009a; PHAC, 2011). Direct costs include those where services and materials are paid for by the public or private health insurances, as well as by the person and family living with diabetes. These costs include, but are not limited to: direct hospitalization costs related to procedures such as amputation and dialysis, and cardiovascular disease hospitalization costs, general practitioner costs, specialist costs and costs related to diabetes medications (CDA, 2009a; PHAC, 2011). Indirect costs lie outside the healthcare system, whereby they affect individual and economic productivity as a result of having diabetes. They may result due to ill health, disability or premature death related to diabetes and/or diabetes-related complications, and are often very difficult to measure accurately (CDA, 2009; PHAC, 2011).

The most recent data related to estimates of diabetes-related costs are presented by the *IDF Diabetes Atlas* (2015c). The R=2 estimate at calculating health expenditure takes a conservative approach in calculating diabetes-related costs as it assumes that healthcare costs are twice as high in people diagnosed with diabetes compared to those who do not have diabetes (IDF, 2015c).

According to the *R*=2 estimate, the IDF (2015c) has estimated Canada's diabetes-related costs to be 17 billion US dollars in 2015; these costs are estimated to increase further to 22 billion US dollars by the year 2040.

Furthermore, the cost of out-of-pocket expenses to effectively manage diabetes, such as glucose testing meters, test strips, lancets, insulin and/or diabetes-related medications, can be extensive. These out-of-pocket expenses for a majority of people can account for greater than 3% of their income or greater than 1500 dollars (CDA, 2011). For individuals and families living on a low-income, it can be costly to purchase these necessary supplies and medications to effectively manage their diabetes. This can in turn jeopardize one's DSM, which can further increase the risk for developing diabetes-related complications (CDA, 2011).

1.5 Diabetes Self-Management

As has been mentioned previously, diabetes is a chronic disease which requires considerable self-management to prevent or delay the progression of diabetes-related complications. Self-management in the context of diabetes is broadly categorized under two categories: diabetes self-management education (DSME) and diabetes self-management support (DSMS). The next sections will discuss these two types of self-management in further detail.

1.5.1 Diabetes Self-Management Education and Support Definitions

Diabetes Self-Management Education. DSME is defined as a process which facilitates the knowledge, skill, and ability needed for diabetes self-care

using evidence-based standards and guidelines (Haas et al., 2012; Powers et al., 2015). DSME is delivered by healthcare professionals as part of an interdisciplinary team, with the objective to support: informed decision making, self-care behaviours, problem solving, active patient participation and collaboration with the health care team (Haas et al., 2012; Powers et al., 2015).

Traditionally, education was delivered via didactic teaching methods, however in recent years there has been a shift towards developing and implementing comprehensive interventions targeting various educational, psychological and behavioural components using the empowerment approach (CDA, 2009b, 2013). These educational, psychological and behavioural components which comprise DSME, are conducted in a variety of formats, ranging from a combination of didactic to interactive sessions delivered individually and/or in group settings (CDA, 2009b, 2013). Ultimately, the goal of DSME is to improve the health status of individuals with diabetes by improving clinical outcomes and overall quality of life (Haas et al., 2012).

Diabetes Self-Management Support. To complement DSME, DSMS is defined as the activities that help to implement and sustain self-management behaviours on an ongoing basis in persons with diabetes (Haas et al., 2012). Similar to DSME, DSMS can take the form of educational, behavioural and psychosocial interventions. It can be provided via healthcare providers, as well as trained peers, community health workers, community-based programs, information technology, and education support groups, in addition to diabetes

management programs (Haas et al., 2012). DSMS interventions can include reminder systems for follow-up care and medical tests, as well as connecting clients with community resources to help sustain their DSM behaviours (CDA, 2013; Haas et al., 2012). DSMS can be targeted at both the individual with diabetes, as well as their caregivers, with the goal of providing ongoing support in achieving healthy behaviour-change and self-care strategies (CDA, 2013; Powers et al., 2015).

1.5.2 Diabetes Self-Management Education and Support Interventions

DSME and DSMS interventions can be subdivided into two categories: interventions targeting knowledge and skill development and cognitive-behavioural interventions (CDA, 2013). Interventions targeting knowledge and skill development include education and support for nutrition therapy, physical activity, pharmacological management of diabetes, self-monitoring of blood glucose, including treatment and management of hypoglycemia, and treatment and management of diabetes-related complications (CDA, 2009b, 2013; American Association of Diabetes Educators, 2016).

In addition to interventions targeting knowledge and skill development, cognitive-behavioural interventions are equally important in successfully educating and supporting the patient with diabetes. Such cognitive-behavioural interventions can include education and support about goal setting, problem solving, stress management and cognitive-behavioural therapy (CDA, 2009b, 2013; American Association of Diabetes Educators, 2016).

Healthcare professionals delivering DSME and DSMS interventions and programs often utilize the empowerment approach to guide their intervention development. The concept of empowerment refers to the idea that individuals are more likely to maintain and sustain changes in their behaviour, if those behaviour changes are personally meaningful to them and are chosen out of their own free will (Funnell et al., 1991). Patient-selected self-management goals motivate initial and sustained behavioural changes. Furthermore, it facilitates a collaborative approach between the client and the healthcare provider to work together to facilitate and implement the behaviour change process. The empowerment approach, combined with DSME and DSMS in turn facilitate knowledge and skill development for self-monitoring, problem-solving, and shared decision-making between the client and the healthcare provider; all of these components go hand-in-hand when it comes to implementing and evaluating the success of DSME and DSMS interventions (CDA, 2009b, 2013; Anderson & Funnell, 2010; Funnell et al., 1991).

It is often difficult to separate DSME interventions from DSMS interventions due to the extensive overlap between them, however both DSME and DSMS interventions collectively (often referred to as DSM interventions) have yielded both clinically important and statistically significant outcomes such as lowering the risk of diabetes-related complications, reductions in hospitalizations and improving quality of life (Powers et al., 2015). In fact, a meta-analysis of DSM interventions for patients with T2DM conducted by Minet,

Moller, Vach, Wagner and Henriksen (2010), found these interventions to be associated with statistically significant improvements in glycemic control by demonstrating a modest 0.36% (95% CI 0.21 to 0.51) reduction in A1C. Another meta-analysis that examined the effectiveness of DSME interventions for adults with T2DM also showed statistically significant reductions in A1C by 0.76% (95% CI 0.34 to 1.18) at immediate follow-up and by 0.26% (95% CI 0.05 to 0.48) at greater than or equal to four months of follow-up (Norris, Lau, Smith, Schmid, & Engelgau, 2002). Results showed the most improvement in glycemic control in the short term period (less than six months) compared to follow-up durations that were greater than six months. Also, interventions were more effective when they provided regular reinforcement over a longer duration of time, and that collaboration between the client and the healthcare provider resulted in improvements in glycemic control (Norris, Engelgau, & Venkat Narayan, 2001).

1.6 Diabetes in South Asians

The CDA (2013) clinical practice guidelines have identified a set of risk factors for the development of T2DM, such as being from a high risk population (e.g. Aboriginal, African, Asian, Hispanic, and South Asian descent). Additional risk factors include: age greater than or equal to 40 years, first degree relative with T2DM, history of prediabetes, history of gestational diabetes, history of delivering a macrosomic infant, presence of end organ damage associated with diabetes (i.e., microvascular or macrovascular complications) and the presence of vascular risk

factors (i.e., low high-density lipoprotein cholesterol, elevated triglycerides, hypertension, being overweight, abdominal obesity). The nature of T2DM in the South Asian population will be discussed in subsequent sections, as that is the focus of this thesis research.

1.6.1 Canadian Immigration – Facts and Figures

Canada is a country known for its multicultural diversity as it fosters the immigration and integration of people from many different cultural backgrounds (Government of Canada, 2012). As immigrants continue to arrive in Canada, population surveys provide important information regarding the distribution and make up of these populations, so as to guide the development of social, economic and health care resources. The National Household Survey is a cross-sectional survey which collects important demographic, social and economic information from residents across Canada. The National Household Survey conducted in 2011 provided important information regarding immigrant populations and ethnocultural diversity within the country.

According to the 2011 National Household Survey, one out of five people living in Canada is: a) foreign-born (20.6%); and b) is classified as belonging to a visible minority group (19.1%). These groups include: South Asian, Chinese, Black, Filipino, Latin American, Arab, Southeast Asian, West Asian, Korean and Japanese (Statistics Canada, 2015b). South Asians, Chinese and Blacks together were the three largest visible minority groups in Canada, and together, they made up 61.3% of the visible minority population in Canada. Of these three groups,

South Asians were the largest group, comprising 25% of the total visible minority population in the country. Most of these visible minority groups (95.2%) resided in Ontario, British Columbia, Quebec and Alberta (Statistics Canada, 2015b).

1.6.2 Diabetes among South Asians

As mentioned previously, T2DM is more prevalent among people of South Asian descent (CDA, 2013). This community is three to five times more likely to develop T2DM and that too, develop it five to ten years earlier than their European counterparts (Gholap, Davies, Patel, Sattar, & Khunti, 2011; Sohal, 2008). In addition to the increased risk of developing T2DM, South Asians can also present with diabetes-related complications at the time of diabetes diagnosis. This is thought to be attributed to the prolonged period of undiagnosed diabetes where elevated blood glucose concentrations over a long period of time lead to the manifestation and development of diabetes-related complications (Sohal, 2008). These complications most commonly include cardiovascular and renal diseases at the time of diabetes diagnosis (Gholap et al., 2011; Sohal, 2008).

A combination of biological and lifestyle factors predispose South Asians to their increased risk of developing T2DM. From a biological standpoint, insulin resistance is one of the predisposing factors to the early diagnosis and onset of T2DM among South Asians (Shah & Kanaya, 2014). People of South Asian descent are reported to have higher levels of subcutaneous fat and visceral fat, both of which contribute to an increased percentage of overall body fat. It is the higher level of visceral fat in particular which contributes to central abdominal

obesity and adiposity and can in turn lead to the development of insulin resistance. Insulin resistance is a precursor to the development of T2DM, and hence, leads to the increased prevalence of T2DM within this population (Gholap et al., 2011; Shah & Kanaya, 2014).

The increased percentage of overall body fat among South Asians is reflective in the comparison of body mass index between South Asians and Caucasians. For a given identical body mass index calculated in both of these populations, South Asians will have a significantly increased percentage of body fat that is primarily situated in the abdominal area (Gholap et al., 2011; Shah & Kanaya, 2014). For this reason, the WHO (2008) has identified specific cut-off points for what is considered to be "normal" waist circumference and waist-to-hip ratio within the South Asian population, to account for their increased risk.

Pancreatic beta cell dysfunction is another predisposing factor for the increased risk of T2DM development among South Asians (Shah & Kanaya, 2014). This cellular dysfunction leads to hyperglycemia and insulin resistance, which then leads to the diagnosis of T2DM. In combination with all these biological risk factors, lifestyle risk factors also put the immigrant South Asian community living in North America at even greater risk of developing T2DM. These lifestyle factors of the immigrant South Asian population will be discussed in subsequent sections below.

1.6.3 South Asian Culture

The term culture is defined as "the lifeways of a particular group with its values, beliefs, norms, patterns, and practices that are learned, shared, and transmitted intergenerationally" (Leininger, 1996, p. 73). Although South Asians are identified as one cultural group, there is ethnic diversity present in terms of geographical, religious, and linguistic variability amongst this group. South Asian refers to individuals who come primarily from India, Pakistan, Sri Lanka and Bangladesh. During British colonial times, some individuals from these countries left to settle communities in East and South Africa, Guyana, Trinidad and Tobago, Fiji and Mauritius (Buchignani, 2015). As such, the South Asian population in Canada are either immigrants or descendents of immigrants from all of these countries (Buchignani, 2015; Statistics Canada, 2015b).

According to the 2011 National Household Survey, the majority of South Asian immigrants in Canada came from India (nearly two-thirds), Pakistan (9.3%) and Sri Lanka (8.5%). The majority of all visible minority populations, including South Asians, live in Ontario, British Columbia, Quebec and Alberta. Of these four provinces, Ontario is home to 52.3% of the visible minority population (Statistics Canada, 2015b).

Despite the diversity across South Asians from different geographical and linguistic backgrounds, one common similarity that most share is a strong sense of kinship and family belonging. Family households usually comprise of parents, children and other relatives such as grandparents (Buchignani, 2015;

Tran, Kaddatz & Allard, 2005). The family thus becomes a medium through which cultural values, languages and religious customs and traditions are passed down between generations. (Buchignani, 2015).

Religious diversity among South Asians takes the form of three major religions which are practiced by this population: Islam, Hinduism and Sikhism. According to the 2011 National Household Survey, Islam was practiced by over one million people across Canada, representing 3.2% of the total population. The majority of people identified themselves as Muslim and came from Pakistan. Hinduism was practiced by 498,000 people and Sikhism was practiced by 455,000 people, each representing 1.5% and 1.4% respectively of the total Canadian population. Of these, the majority of Hindus (73.6%) and Muslims (55.2%) resided in the province of Ontario (Statistics Canada, 2015b).

1.6.4 Barriers to Diabetes Self-Management

Diabetes is a chronic disease that requires significant self-management by the patient on a routine basis. Culture can play a significant role, particularly in DSM. A person's values and beliefs related to lifestyle changes, including diet and physical activity, substantially influence self-management practices and patterns. Also, the ways in which the diabetes disease process is understood and perceived is important to consider when examining DSM in the South Asian culture (Shaw, Huebner, Armin, Orzech & Vivian, 2009).

As has been discussed previously, Canada is home to people who come from many different countries worldwide. Immigration laws ensure that people

who immigrate to Canada are generally in a good state of health when they arrive in the country. This is further explained by the concept known as the healthy immigrant effect (Lesser, Gasevic, & Lear, 2014; Sanou et al., 2014). This concept explains that immigrants are generally in a better state of health than the general population of their new country when they first migrate; however, as immigrants live and settle in their new country, dietary acculturation, along with the socioeconomic, and lifestyle factors within the new country, all interact and may contribute to deterioration in their health status (Lesser et al., 2014; Sanou et al., 2014).

When examining diabetes within the South Asian population residing in Western countries, dietary acculturation plays an important role in potentially diminishing the healthy immigrant effect. Dietary acculturation refers to the process whereby immigrants transition to and adopt the dietary practices of their new country (Sanou et al, 2014). Among South Asian immigrants to western countries, dietary acculturation takes the shape of increased consumption of sugar-sweetened beverages, processed foods and convenience foods that contain increased fat and sodium content (Lesser et al., 2014; Sanou et al., 2014; Shah & Kanaya, 2014). This transition away from traditional foods is attributed to a lack of time in preparing traditional meals, lack of availability and affordability of traditional foods and ingredients, as well as other factors such as financial insecurity related to settling in a new country (Lesser et al., 2014; Sanou et al., 2014). All of these factors in turn contribute to weight gain and obesity, which in

turn translates to an increased risk of prediabetes and T2DM as discussed previously.

In addition to dietary acculturation, a lack of physical activity is another barrier to successful DSM within the South Asian population. Influencing factors include a lack of motivation to engage in physical activity and misconceptions related to physical activity on the part of South Asians within this population (Sohal, 2008; Sohal, Sohal, King-Shier & Khan, 2015). Furthermore, barriers related to language and resultant poor communication with health care providers, fatalistic views towards disease and illness, low levels of literacy and health literacy, including a lack of knowledge about the diabetes disease process and its successful self-management, all impede optimal management of the disease in this population (Hill, 2006; Sanou et al., 2014; Shah & Kanaya, 2014; Shaw et al., 2009; Sohal, 2008; Sohal et al., 2015).

1.7 Published Systematic Reviews in the Literature

There are systematic reviews that have explored the effectiveness of culturally appropriate health education and support interventions for ethnic minority groups (including South Asians) with T2DM. One such high quality Cochrane systematic review examined culturally appropriate health education interventions among ethnic minority groups in upper-middle and high-income countries (Attridge, Creamer, Ramsden, Cannings-John & Hawthorne, 2014). Likewise, a second moderate quality systematic review also assessed the impact of culturally competent diabetes care interventions in ethnic minority groups (Zeh,

Sandhu, Cannaby & Sturt, 2012). Finally, a third moderate quality systematic review conducted by Khunti, Camosso-Stefinovic, Carey, Davis and Stone (2008) examined the effectiveness of DSME interventions specifically for the migrant South Asian population with T2DM residing in western countries.

Of the three systematic reviews mentioned above, only the Cochrane review provided results of a meta-analysis (Attridge et al., 2014). Of the 33 randomized control trials included in this review, five were focused on the South Asian population. The meta-analysis from this review demonstrated statistically significant reductions in A1C as a result of culturally appropriate DSME interventions at three months MD -0.4% (95% CI -0.5 to -0.2), six months MD -0.5% (95% CI -0.7 to -0.4), 12 months MD -0.2% (95% CI -0.3 to -0.04), and 24 months MD -0.3% (95% CI -0.6 to -0.1). These reductions in A1C are also clinically important as they demonstrate improved glycemic control which is important in delaying the onset and severity of diabetes-related complications. It is important to note that not all studies containing the South Asian population were included in the meta-analysis; a large number of studies included in the meta-analysis included data from African-American and Hispanic populations. Thus, despite the review's high internal validity, there are gaps where the external validity is concerned as there is insufficient synthesis of the evidence to make any conclusions regarding the effectiveness of culturally appropriate DSM interventions among South Asians (Attridge et al., 2014).

The other two systematic reviews by Zeh et al. (2012) and Khunti et al. (2008), each provided narrative summaries of their results. Like the Cochrane review, the systematic review conducted by Zeh et al. (2012) also included varying ethnic minority populations. Although all three systematic reviews, including the Cochrane review by Attridge et al. (2014), examined the impact of culturally appropriate DSM interventions in ethnically diverse populations with T2DM, only one of these reviews has assessed what qualifies these interventions to be culturally appropriate. Zeh et al. (2012) developed the culturally competent assessment tool which they used to assess cultural competence of the study interventions. However, a major limitation here was that there was no discussion of the psychometric properties of this tool such as its validity and reliability, nor any details reported pertaining to the content of this tool. It is important to note that the review conducted by Khunti et al., (2008) was the only review which solely focused on the South Asian population. Like the Cochrane review, Khunti et al. (2008) also lacked an analysis to describe how the study interventions were culturally appropriate through the use of a similar tool.

1.8 Leininger's Sunrise Model

Madeleine Leininger (2002) is known as the founder of the field of transcultural nursing and the developer of the theory of Culture Care Diversity and Universality, and the resultant Sunrise Model. The Sunrise Model presents a guide for healthcare providers to assess the cultural and social dimensions that shape health, illness, care and well-being of clients belonging to a given culture.

The model identifies the following categories which influence human care: *technological factors*; *religious and philosophical factors*; *kinship and social factors*; *cultural values, beliefs and lifeways*; *political and legal factors*; *economic factors*; and *educational factors* (Leininger, 1996; Leininger & McFarland, 2002). Data gathered from these categories provides the healthcare provider with meaningful information about the client's *environmental context, language and ethnohistory*. This information, along with the healthcare provider's professional knowledge, lead to the development of a care plan via one of three transcultural care decisions and actions nodes: *culture care preservation/maintenance*; *culture care accommodation/negotiation*; and *culture care repatterning/restructuring*. This decision making process involves co-participation between the client and the healthcare provider, so as to achieve culturally congruent care for the health and well-being of the client (Leininger, 1996; Leininger & McFarland, 2002).

The broad scope of this model assists in its applicability in a number of research, educational and clinical settings. To date, there have been over 80 different cultures and subcultures studied using Leininger's model, theory and ethnonursing research method (Leininger, 1996). The findings published from these studies have been used not only by nurses, but also by other health care professionals to guide the delivery of health services. Administrators and nurse educators have also used the model and theory to understand workplace culture and practices and have used these findings to guide decision making and planning. In addition, the model and theory have been used in the educational setting to

guide development of transcultural nursing curricula in nursing schools across the United States. To date, the Sunrise Model has not been used in the context of diabetes and DSM.

Leininger's Sunrise Model was chosen to assess the cultural congruency of DSME and DSMS interventions with the migrant South Asian population living with T2DM for this thesis project. Fawcett's and DeSanto-Madeya's (2013) framework was used to evaluate several transcultural nursing models, after which Leininger's model was chosen (see Appendix A). Although the Sunrise Model performed better than some of the other transcultural nursing models in the transcultural model evaluation, it still has some limitations. For instance, the categories in the model which influence human care such as *technological factors*; *religious and philosophical factors*; *kinship and social factors*; *cultural values, beliefs and lifeways*; *political and legal factors*; *economic factors*; and *educational factors*, are very vague. Although this can be a strength because it does not restrict the model in its application to a wide variety of settings and scenarios, it does leave the reader with his or her personal interpretation as to the actual definitions of those categories. This is because Leininger has not provided actual definitions for these concepts. Another limitation is that the model has not been evaluated for its psychometric properties. In spite of these limitations, Leininger's Sunrise Model fared better in comparison to the other models evaluated in Appendix A, and hence, it was chosen as the model of choice to use in this thesis.

1.9 Summary

In summary, T2DM is a chronic disease that requires considerable self-management. South Asians are at a greater risk for developing T2DM at an early age and thus can develop diabetes-related complications earlier in life compared to their European counterparts. Thus, DSM is very important as it can help in preventing and delaying the onset and progression of diabetes-related complications. DSM can be particularly challenging in the context of ethnic minority groups, such as South Asians, who represent a very diverse cultural group. This can often times present barriers which make effective DSM a challenge.

The impact of DSME and DSMS interventions on A1C has been addressed in the current literature for many ethnic minority groups. However, there is a major gap in the literature where this evidence is not assessed from a cultural perspective using a theoretical framework. This makes it difficult to determine whether these DSME and DSMS interventions are truly culturally congruent, particularly in the context of the South Asian population.

One of the components of this systematic review is to fill that gap by evaluating these interventions for cultural congruency using Leininger's Sunrise Model. With a growing South Asian population in Canada, the need for culturally tailored DSME and DSMS interventions is highly warranted at this time so that improved health outcomes can be sustained and the risk of diabetes-related complications reduced.

Chapter 2: Methods

This chapter will discuss the methodological process to answer the research questions which are outlined in Section 2.1 below. The research questions were answered by conducting a systematic review and a cultural assessment of the interventions in the included studies. A systematic review allows the implementation of a structured methodological approach to identify, appraise and synthesize the current research evidence surrounding a particular topic of interest (Higgins & Green, 2008). Through this systematic review process, knowledge is identified and will contribute to further study of DSM among South Asians.

2.1 Research Questions

In addition to determining the effect of the study interventions on A1C, this systematic review has also assessed the cultural congruency of these DSME and DSMS interventions (collectively referred to as DSM interventions) used with the migrant South Asian population. The following research questions have guided this systematic review:

1. What is the effectiveness of self-management education and support interventions used among South Asians with type 2 diabetes, who are 18 years of age and older, and residing in Western or European countries, on their haemoglobin A1C?
2. How are these diabetes self-management education and support interventions culturally tailored to the South Asian population?

2.1.1 Population

The target population for this systematic review is migrant South Asians living in Western or European countries. Therefore, the included studies in this review consisted of people of South Asian descent who were living outside their country of origin. Where studies included a mixed sample of people from different ethnicities, only studies where the authors provided separate results for each ethnic group were included in this review. The inclusion criteria regarding the study population for this review was as follows: South Asian adults who were 18 years of age or older with T2DM, and who were residents (immigrants) in Western or European countries [for example Canada, United States of America, United Kingdom (UK), Australia, New Zealand].

In this review, the term 'South Asian' included individuals who were of South Asian descent from the following countries: India, Pakistan, Sri Lanka and Bangladesh (CDA, 2016a). Studies that took place within South Asian countries (India, Pakistan, Sri Lanka and Bangladesh) with participants who were residing in these countries were excluded from this review. This exclusion was based on the objective to assess how the DSME and DSMS interventions were culturally tailored to the migrant South Asian population with T2DM. Studies that included participants who were already residents living in their native country of origin are likely to employ DSME and DSMS interventions that are already culturally tailored as patients and their healthcare providers belong to the same culture.

Studies that included participants with prediabetes (as determined by glucose levels above normal range, but not high enough to diagnose with diabetes), type 1 diabetes and gestational diabetes, and participants who were younger than 18 years of age were also excluded from this review.

2.1.2 Intervention

This systematic review examined the effectiveness of DSME and DSMS interventions. Both DSME and DSMS interventions were educational (targeting knowledge and skills development including healthy eating, physical activity and self-monitoring of blood glucose), behavioural and/or psychological interventions (i.e., cognitive-behavioural interventions including cognitive behavioural therapy, stress management, goal setting, problem solving). These interventions could be conducted in a variety of formats such as on an individual basis, dyads, and triads or in group settings (CDA, 2009b, 2013; Haas et al., 2012; Powers et al., 2015). To be included in this review, the interventions must have had a healthcare provider who was involved at some point in the intervention design, development and/or delivery of any one or more aspects of the intervention (i.e., education component or support component or both). The interventions could be delivered face-to-face or via technological means (for instance via telecommunication technologies).

2.1.3 Comparator/Control

Studies selected to be included in this systematic review contained a control group for comparison with the intervention group. Control groups should

have received usual standard care, which refers to standard usual care that is provided to patients within that healthcare system. In brief, standard care is not adjusted to suit the needs of the specific population, setting or any other context.

2.1.4 Outcome

The sole outcome of this systematic review is the effect of DSME and DSMS interventions on A1C, which is the gold standard for assessing glycemic control of individuals with diabetes over the past two to four months (CDA, 2013). An A1C level may be reported using the National Glycohaemoglobin Standardization Program units, measured as a percentage (%), or using the International Federation of Clinical Chemistry and Laboratory Medicine SI units (mmol/mol). Studies included in this review must have reported A1C change expressed as a continuous outcome (mean or median). Study authors who reported the A1C as a dichotomous outcome would be contacted to obtain A1C change as a continuous outcome. No secondary outcomes were investigated within this review.

2.2 Search Strategy

The search strategy for this systematic review was developed in conjunction with and reviewed by a McMaster University medical librarian and consisted of searching electronic databases including MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, and CINAHL. These databases were searched from their dates of inception to June 26, 2015. Peer-reviewed published studies that met the following inclusion criteria were included in this

review: studies published in the English language; and RCTs or non-randomized studies that contained a control group. Due to uncertainty about how many studies would meet the eligibility criteria, the search was left open to include non-randomized studies containing a control group. It was planned that if there were RCTs derived from the search that met the inclusion criteria of this systematic review, then only RCTs would be included in the final data synthesis and analysis due to their rigorous study methodology.

Studies that were excluded from the review comprised of: qualitative studies, commentaries, editorials, and grey literature. Here, the term grey literature refers to "that which is produced on all levels of government, academics, business and industry in print and electronic formats, but which is not controlled by commercial publishers" (Grey Literature Report, n.d., "What is Grey Literature," para. 1). Sources of grey literature include reports, dissertations/theses, conference proceedings and government reports, and all of these were excluded from this review. Search terms, including mesh terms were adapted for each database. Reference lists of systematic reviews, meta-analysis, and clinical practice guidelines that were identified through the reference lists of the included studies were also examined for relevance. These resources were hand searched for title and abstract according to the inclusion criteria of the population, intervention and outcome. The search strategy for this systematic review is outlined in Appendix B in Tables B1 to B4.

2.3 Screening and Selection Criteria

Using the Cochrane handbook as a guide, the screening of studies involved two independent reviewers to ensure rigor. Any discrepancies that occurred were resolved with a third review to reach consensus. As such, the screening process involving *Phase 1* and *Phase 2* within this review was conducted by two independent reviewers (NN and KS). Any discrepancies that occurred within this review process were resolved via discussion and consensus with a third review author (DS) (Higgins & Deeks, 2008). The screening process was undertaken using an online data management software, Distiller SR (Evidence Partners, 2015).

2.3.1 Title and Abstract Screening (Phase 1)

Phase 1 of the review process consisted of title and abstract screening. Predetermined criteria on an electronic screening form assisted the reviewers in screening for all the studies obtained from the search (see Appendix C). This form consisted of high-level questions for screening to rule out studies that were not published in the English language and not about T2DM or the target population (members of South Asian descent); studies that did not contain a control group were also removed at this stage. As such, all studies that were marked as "No" for any of the questions outlined in the screening form for title and abstract (Appendix C) were excluded at this stage and did not proceed towards the full text screening stage. All those studies that met all the inclusion criteria, as well as

those studies that were marked as "Unclear" on the electronic screening form, proceeded to *Phase 2*, the full text screening stage.

2.3.2 Full Text Screening (Phase 2)

Phase 2 of the screening process began upon conclusion of the *Phase 1* screening process. *Phase 2* screening involved obtaining and screening the full-text of the studies that remained at the end of *Phase 1*. Again, predetermined criteria on an electronic screening form in Distiller SR assisted the reviewers in screening for all the studies in this phase (see Appendix D). This electronic screening form consisted of questions to identify the population of interest (South Asian adults with T2DM residing in Western countries), the intervention (DSME and/or DSMS intervention with involvement from a healthcare provider), the outcome (A1C as a continuous outcome) and the study design. All studies that were marked as "No" for any of the questions outlined on the screening form in Appendix D were excluded from the review. All studies remaining at the end of the *Phase 2* screening process proceeded to the data extraction phase.

2.4 Data Extraction

For the data extraction phase, the Cochrane handbook was used as a guide, however with some minor modifications. Data was extracted from the included studies using one review author, instead of two independent authors. To ensure rigor was maintained in this process, the data extraction forms were reviewed by a second reviewer, and any discrepancies that occurred during this process were resolved via discussion with a third review author to reach consensus. In this

phase, data was extracted individually by one review author (NN) and confirmed by a second reviewer (DS). Any discrepancies that occurred within the data extraction process were resolved via discussion and consensus between NN and DS (Higgins & Altman, 2008; Higgins & Deeks, 2008).

2.4.1 Study Characteristics

A standardized data extraction form was used to extract the necessary data from the included studies within this systematic review (see Appendix E). The following data were extracted from the included studies: Study ID from Distiller SR; year; citation; study design; study duration; setting; age of participants allocated to each group (intervention and control); sample size (at the beginning of the study and at the end of the study and within each intervention and control group at the start and end of the study period); estimate of the treatment effect (p-values, confidence intervals, means, standard deviations); conclusion of the study findings; funding source; and reason for exclusion if the study was excluded at this stage (Higgins & Deeks, 2008). Missing data from the studies pertaining only to the outcome for A1C was obtained by contacting the study authors to request the missing information. If the missing information remained unavailable after contacting the study authors, the study was excluded from this review.

2.4.2 Leininger's Sunrise Model

In order to address the second research question to assess culturally tailored DSME and DSMS interventions used among South Asian adults with T2DM, data was examined to determine whether the interventions in the final

included studies within this review were culturally tailored to the study population. Leininger's Sunrise Model was used as a guide to determine the cultural congruency of the interventions used within the studies in this review (Leininger & McFarland, 2002). As per Leininger's Sunrise Model, data was reported for the following categories pertaining to the study intervention: technological factors; religious and philosophical factors; kinship and social factors; cultural values, beliefs and lifeways; political and legal factors; economic factors; and educational factors (Leininger & McFarland, 2002). See Appendix F for the data extraction form for Leininger's Sunrise Model.

2.4.3 Risk of Bias Assessment

A risk of bias assessment was conducted to determine the methodological quality of the included studies in this review. The risk of bias assessment was conducted using the standardized Cochrane Risk of Bias tool (Higgins & Altman, 2008). Data was collected for the following categories to assess risk of bias within the included studies: sequence generation; allocation concealment; blinding of participants, personnel and outcome assessors; incomplete outcome data; and selective outcome reporting that may have been present (Higgins & Altman, 2008). See Appendix G for the risk of bias assessment tool.

2.5 Data Synthesis & Analysis

The decision to conduct a meta-analysis was based on assessing the clinical heterogeneity across the included studies and the quality of the included studies. Clinical heterogeneity was assessed by examining the differences in the

population of study participants and the differences across DSME and DSMS interventions that were present across the included studies. There were noteworthy differences present across the migrant South Asian population across the included studies (discussed in Chapter 3). Furthermore, the DSME and DSMS interventions in this review were also quite variable when assessed according to the Template for Intervention Description and Replication (TIDieR) checklist as has been discussed in Chapter 3. Due to these noteworthy differences present in the study population and the interventions, conducting a meta-analysis was not an appropriate option.

The decision to not conduct a meta-analysis was further supported by conducting a quality assessment of the included studies. This process included consultation with a statistician to discuss the risk of bias assessment and the results in demonstrating a treatment effect of the DSME and DSMS interventions on A1C of the target population. Due to the lack of demonstrating a statistically significant reduction in A1C in the target population across a majority of the studies in this review, accompanied by the presence of bias across the studies in this review (as discussed in Chapter 3), a meta-analysis was not appropriate to conduct. Hence, a narrative (descriptive) synthesis was conducted as described below.

The narrative (descriptive) synthesis for this systematic review reported on the effectiveness of DSME and DSMS interventions for migrant South Asians with T2DM across the included studies. This narrative synthesis describes the

characteristics of the study populations within the included studies, as well as descriptions of the interventions used in the included studies, along with their comparators. The items from the TIDieR checklist were used as a guide to describe the study interventions, with descriptions about the following: what materials were used in the interventions and the process of delivery; who provided the interventions; how the interventions were delivered; where the interventions were delivered; the intensity, dose and frequency of the interventions; and how well the interventions were tailored and adapted to the needs of the study population (Hoffmann et al., 2014).

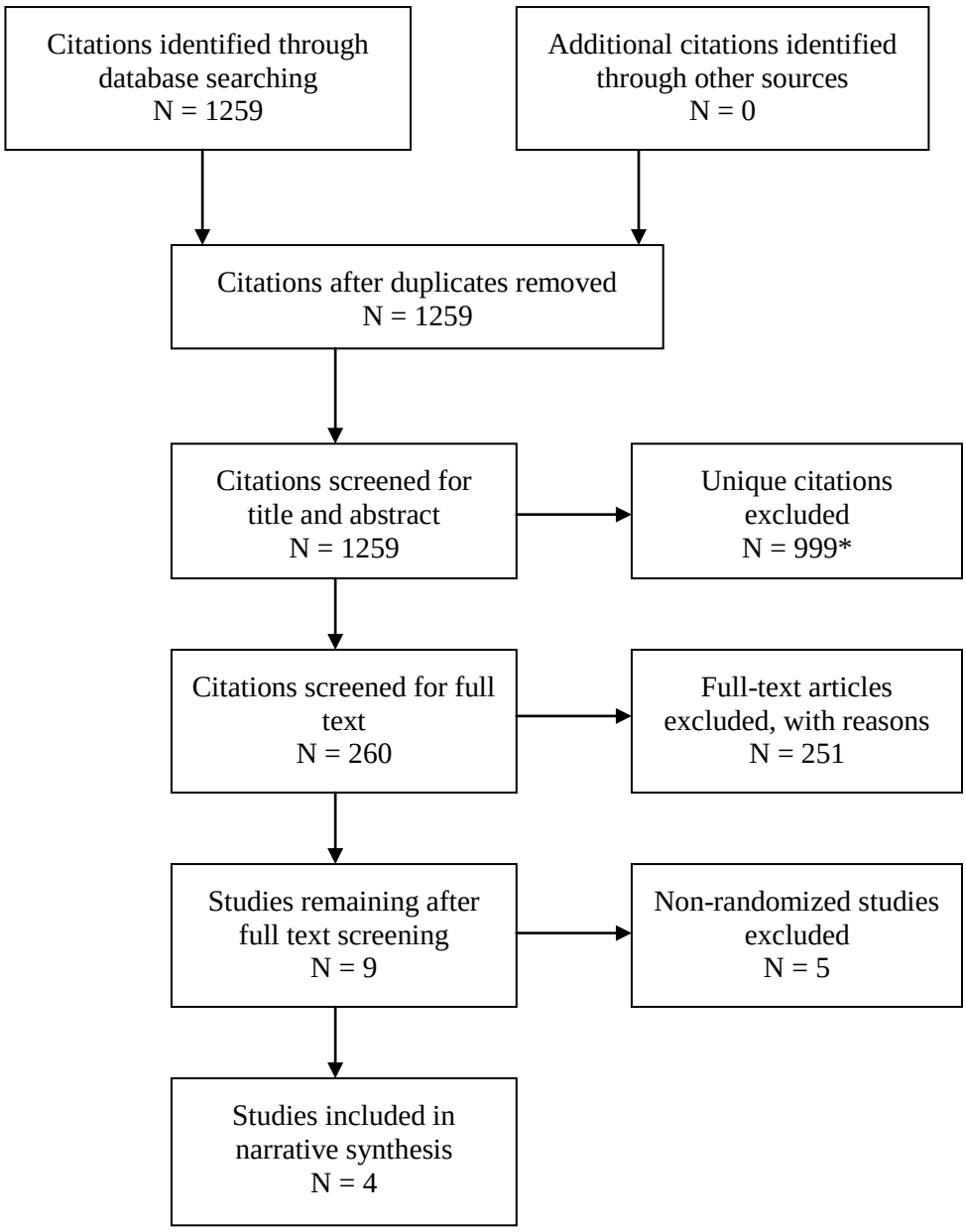
Furthermore, the interventions in the included studies were also synthesized for their cultural congruency, using the *Cultural & Social Structure Dimensions* of Leininger's Sunrise Model (technological factors; religious and philosophical factors; kinship and social factors; cultural values, beliefs and lifeways; political and legal factors; economic factors; and educational factors) (Leininger & McFarland, 2002). The narrative synthesis also included an assessment of the risk of bias across the included studies in this review, as well as an analysis and a discussion of some of the confounders that were apparent across the included studies and how they may have impacted the study intervention and the reported outcome. Data to search for further information about the interventions would be searched using the reference lists of the included studies and these companion papers would subsequently be searched to extract any missing data.

Chapter 3: Results

This chapter will describe the results of this systematic review. There were a total of 1259 records identified through searching the electronic databases and hand-searching of relevant references. These were screened for title and abstract against the criteria outlined in Appendix C. At the conclusion of the title and abstract screening process, 999 unique citations were excluded as they did not include the population of interest, and did not use an included study design, thereby leaving 260 studies to be eligible for full text screening. As a result of full text screening, 251 additional studies were excluded because they did not include migrant South Asian adults with T2DM. Finally, nine studies remained at the end of the full-text screening stage. As four of the included citations at this stage represented RCTs, only citations with the RCT study design were included in the review, for which data was extracted and synthesized (see Figure 1). Reference lists of these four included studies were searched to identify any companion papers to further assess the study interventions as per the TIDieR criteria and Leininger's Sunrise Model. However, no companion papers were found. The following sections will describe the characteristics of the studies included in this review, along with a discussion of the interventions used and the methodological quality of these included studies.

The results of this systematic review will be described narratively. As previously described in the Methods section in Chapter 2, in consultation with a statistician, it was decided that conducting a meta-analysis would not be a feasible

option. This was due to the fact that only one RCT showed a statistically significant reduction in A1C after data in this study was adjusted for confounders (Middelkoop, Geelhoed-Duijvestijn, & van der Wal, 2001). Since three out of the four studies did not show a significant reduction in A1C, these findings limit confidence in our ability to combine the data across all four studies. Furthermore, the interventions across all the four studies included in this review were very complex and heterogeneous with regards to the study population and the make-up of DSME and DSMS interventions, as will be discussed in subsequent sections in this chapter. Thus, in light of the statistical and clinical heterogeneity that was presented in the four studies included in this review, it was deemed inappropriate to conduct a meta-analysis.



*studies were excluded for more than one reason at the title and abstract level (excluded for incorrect population and study design).

Figure 1. PRISMA flow diagram outlining the identification and screening of literature search results. Adapted from "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement," by D. Moher, A. Liberati, J. Tetzlaff, D. G. Altman, and The PRISMA Group, 2009, *PLoS Med*, *6*(6), doi:10.1371/journal.pmed1000097. Copyright 2009 by Evidence Partners.

3.1 Study Characteristics

All four studies included in the review were RCTs, two of which were cluster RCTs. Three of the four studies were conducted in the UK, specifically in Coventry, Birmingham and Manchester (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; O'Hare et al., 2004). The study by Bellary et al. (2008) was a cluster RCT, which included a sample of 1486 participants. O'Hare et al. (2004) also conducted a cluster RCT, having a sample of 361 participants. The RCT by Hawthorne and Tomlinson (1997) contained 201 participants. The fourth study was conducted in The Hague in the Netherlands and it contained a sample of 113 participants (Middelkoop et al., 2001). The studies were conducted in a mix of outpatient diabetes clinics and community general practices, with follow-up periods ranging from six months to two years. Table 1 describes the study characteristics of the included studies.

Baseline characteristics of the study population in all the RCTs consisted of adults solely of South Asian descent. There was an even split between males and females in all the studies, with a majority of participants being over the age of 50 years. Length of diabetes duration was reported by only two studies, both of which reported the smallest percentage of participants were those who had T2DM for 20 years or more (Bellary et al., 2008; O'Hare et al., 2004). Likewise, type of diabetes treatment was also reported by only two studies, with the majority of participants being treated with oral hypoglycemic agents (Bellary et al., 2008; O'Hare et al., 2004). The mean baseline A1C of participants across all the

included studies ranged from 7.8% to 8.4% in the intervention groups and 8.1% to 8.6% in the control groups (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; Middelkoop et al., 2001; O'Hare et al., 2004).

Table 1

Study Characteristics of Included Studies

Authors (Year)	Country & Setting	Study Design & Follow-up	Population	Intervention	Key Findings
Bellary et al., (2008)	UK – 7 general practices in Coventry and 14 in Birmingham *n* = 1486	Cluster RCT Follow-up: 2 years	Adults of South Asian origin with T2DM	Four hours a week of additional time by a practice nurse who was supported by link workers and a community nurse specializing in diabetes	Significant reductions in A1C noted based on non-adjusted data [-0.18% (95% CI -0.34 to -0.01)], (*p* = 0.037). Data adjusted for confounding and confounding plus clustering showed no significant reduction in A1C after 2 years of follow up
Hawthorne & Tomlinson (1997)	UK – Manchester Diabetes Centre and 10 neighbouring general practices *n* = 201	RCT Follow-up: 6 months	Pakistani patients with T2DM	Ten pictorial flashcards (content developed by a dietitian and link worker) were used in conjunction with an education package by a link worker to deliver diabetes education	There was a mean difference in reduction of A1C after 6 months after the intervention, however this was not statistically significant [-0.34% (95% CI -0.81 to 0.13)]

Middelkoop et al., (2001)	The Hague, Netherlands – 3 general practices and 1 outpatient clinic *n* = 113	RCT Follow-up: 6 months	Surinam South Asians patients with T2DM	Diabetes education delivered via an audio cassette recorded in the Surinam-Hindi language, two booklets containing nutrition-specific information related to South Asian cuisine and frequent meetings with dietitians and nurses	Significant reductions in A1C noted based on non-adjusted data (p = 0.02), as well as after controlling for differences in age, sex and initial A1C (p = 0.004)
O'Hare et al., (2004)	UK – 4 general practices in Foleshill Coventry and 2 in East Birmingham *n* = 361	Cluster RCT Follow-up: 1 year	Adults of South Asian ethnicity (Indian, Pakistani and Bangladeshi) with T2DM	Weekly research clinics facilitated by an additional practice nurse, with additional educational and clinical support provided by a community diabetes specialist nurse. Asian link workers provided educational support to patients and healthcare providers throughout the intervention	More patients in the intervention group were started on insulin and had the dose and/or number of oral hypoglycemic agents increased. However, no significant reductions in A1C were noted following 1-year post-intervention [-0.03% (95% CI -0.36 to 0.3)], p = 0.866

3.2 Intervention Characteristics

The following sections will describe the intervention characteristics of studies included in this review. The interventions were assessed as per the TIDieR checklist. Study interventions were also assessed to determine how culturally tailored they were to the study population according to the Leininger's Sunrise Model.

3.2.1 Interventions Assessed as per TIDieR Criteria

Intervention assessment as per the TIDieR criteria is summarized in Table 2. As has been mentioned previously, all of the four included studies were conducted in primary care general practices, and two studies were conducted in outpatient diabetes clinics (Hawthorne & Tomlinson, 1997; Middelkoop et al., 2001). Except for one study by Middelkoop et al. (2001) which was conducted in The Hague in the Netherlands, the remainder of the three studies took place in the UK, specifically in Coventry, Birmingham and Manchester (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; O'Hare et al., 2004). Three of the included studies involved face-to-face in-person delivery of the study interventions (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; O'Hare, 2004). However, Middelkoop et al. (2001) did not specify how their intervention was delivered (i.e., face-to-face, in-person, in groups). Furthermore, all of the four studies failed to provide additional details about the delivery of their study interventions (i.e., delivered individually, with family members, in groups).

The two cluster RCTs by Bellary et al. (2008) and O'Hare et al. (2004) involved weekly clinic visits, where practice nurses and link workers met with participants to deliver DSME and DSMS. Participants were followed every two months in clinic in the study by Bellary et al. (2008) however, O'Hare et al. (2004) did not report the intensity or frequency of follow-up of their study participants in their clinics. Among the two RCTs, participants had four to seven visits with the diabetes nurse and dietitian for the first three months, after which visits were less frequent in the study by Middelkoop et al. (2001). In the RCT conducted by Hawthorne and Tomlinson (1997), there was no information reported as to the intensity, dose and frequency of follow-up of their study participants during the course of the study intervention.

Two out of the four included studies in this systematic review used educational materials to aid in the delivery of their interventions. Hawthorne and Tomlinson (1997) used an educational package containing information about diet, blood glucose monitoring and diabetes-related complications. They also developed colour photographs (flashcards) depicting Asian individuals, utensils and food, which were used to supplement the diabetes education content of their interventions. Likewise, Middelkoop et al. (2001) developed educational booklets containing general nutritional information and a carbohydrate variation list based on South Asian cooking practices. In addition, they also provided participants with an audio-cassette containing diabetes education recorded in the Surinam-Hindi language.

Except for the study by Middelkoop et al. (2001), the studies relied on link workers for the delivery of their interventions. Typically, these link workers were lay members of the South Asian community, who assisted healthcare providers in delivering language-specific diabetes education to the study participants. They worked collaboratively with healthcare providers including practice nurses, diabetes specialist nurses and dietitians to deliver diabetes education and support to the study participants (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; O'Hare, 2004).

All of the interventions across the four studies involved the healthcare provider at some point in the design and/or delivery of the intervention. Both of the cluster RCTs presented with similar interventions, where a community diabetes specialist nurse, in addition to practice nurses and link workers, facilitated the delivery of diabetes education within the study interventions (Bellary et al., 2008; O'Hare et al., 2004). Likewise, in Middelkoop et al. (2001), diabetes specialist nurses and dietitians delivered DSME and DSMS to study participants. Finally, Hawthorne and Tomlinson (1997) utilized a dietitian, link worker and a professional photographer to design the pictorial flashcards in their study.

Table 2

Intervention Characteristics According to TIDieR Criteria

	Materials used	Process of delivery	Who delivered	How was it delivered	Where was it delivered	Intensity, dose and frequency
Bellary et al., (2008)	None	Clinic visits facilitated by practice nurses and community diabetes specialist nurse in conjunction with primary care physicians to achieve glycemic, BP and lipid targets. Link workers provided language-specific interpretation to encourage/improve lifestyle changes.	Practice nurses trained in diabetes, community diabetes-specialist nurse and link workers	Face-to-face clinic appoint-ments	Primary care practices in Coventry and Birmin-gham, UK	Clinics held weekly by practice nurses and link workers; participants followed every two months in clinic, supported by community diabetes-specialist nurse visit every six to eight weeks
Hawthorne & Tomlinson (1997)	-10 pictorial flashcards -Educational package	Pictorial flashcards were developed in conjunction with a dietitian, link worker and photographer containing educational topics related to Asian cuisine. These were used	Link worker	One-to-one, in-person interview	Interviews and education conducted in participant's home,	Not specified

		by the link worker with an educational package to deliver diabetes education about diet, blood glucose monitoring and diabetes-related complications.			hospital clinic or GP office as per preference	
Middelkoop et al., (2001)	- Audio-cassette with translated diabetes information (in the Surinam-Hindi language) - Educational booklets	Diabetes education delivered in clinic visits using an audio-cassette (recorded in the Surinam-Hindi language) and booklets containing general nutritional information and a carbohydrate variation list based on South Asian cooking practices.	Diabetes specialist nurse and dietitian trained in South Asian culture	Not specified	Three general practices and one outpatient clinic in the Hague, Netherlands	Four to seven visits with the nurse and dietitian for the first three months, with decreasing frequency of visits thereafter (not specified)
O'Hare et al., (2004)	None	Clinic visits facilitated by practice nurses and community diabetes specialist nurse in conjunction with primary care physicians to achieve protocol targets. Link workers provided language-specific	Practice nurse, community diabetes nurse and Asian link workers	Face-to-face clinic appoint-ments	Four general practices in Foleshill Coventry and two in East Birmin-gham, UK	Weekly clinics held by practice nurses and supported by Asian link workers with additional educational and clinical input from a community diabetes specialist

	education to encourage/improve adherence to lifestyle changes.	nurse

3.2.2 Interventions Assessed as per Leininger's Sunrise Model

The interventions in the four studies were also assessed according to the seven factors that comprise the *Environmental Context, Language & Ethnohistory* component of Leininger's Sunrise Model (see Table 3). The use of *technological factors* was only demonstrated by one study whereby Middelkoop et al. (2001) recorded and provided the intervention group participants with an audio-cassette containing general diabetes information in the Surinam-Hindi language. However, the study authors did not discuss how they addressed *educational factors* related to the study participants within their interventions. Across all studies, all of the interventions provided diabetes education to study participants in their preferred language; this language preference was used in the development of education materials given to participants, as well as during interviews (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; Middelkoop et al., 2001; O'Hare et al., 2004). *Political factors* and *economic factors* however, were not addressed by any of the interventions in the included studies.

Furthermore, there was a lack of information about how *religious and philosophical factors* and *kinship and social factors* were addressed in the interventions in all four studies. *Cultural values, beliefs and lifeways* were addressed by two studies, however there was a lack of clarity in how this was addressed in their interventions. Specifically, Hawthorne and Tomlinson (1997) incorporated cultural concepts in the flashcards that they developed by depicting pictorial representations of South Asian individuals, utensils and food.

Middelkoop et al. (2001) developed diabetes educational booklets which contained general nutritional information and a carbohydrate variation list based on South Asian cooking practices. Unfortunately, there was lack of clarity in both studies regarding the specific details about what the flashcards contained or the precise content of the educational booklets (Hawthorne & Tomlinson, 1997; Middelkoop et al., 2001).

Table 3

Intervention Characteristics According to Leininger's Sunrise Model

	Bellary et al., (2008)	**Hawthorne & Tomlinson (1997)**	**Middelkoop et al., (2001)**	**O'Hare et al., (2004)**
Technological Factors	No info provided	No info provided	The use of an audio-cassette containing language-specific general diabetes information	No info provided
Religious & Philosophical Factors	Link workers provided language-specific education/interpretation. No details about religious considerations provided	Link worker provided language-specific education on an individual basis at participant's preferred place. No details about religious considerations provided	No info provided	Link workers provided language-specific education, however no details about religious considerations provided
Kinship & Social Factors	No info provided	Interviews were conducted on a one-to-one basis in the participant's preferred language and location by the link worker. No	No details provided about the nature of the clinic visits (i.e., one-to-one, group sessions, coed). No specific details provided about	No info provided

		specific details provided about gender roles and how they were addressed	gender roles and how they were addressed	
Cultural Values, Beliefs & Lifeways	Link workers provided language-specific education/interpretation. No further details about cultural considerations provided	Pictorial flashcards depicted photographs containing Asian models, utensils and food	Details about content of the two educational booklets on South Asian cooking not described. Unable to determine how cultural considerations were addressed	Link workers provided language-specific education, however no details about cultural considerations provided
Political & Legal Factors	No info provided	No info provided	No info provided	No info provided
Economic Factors	No info provided	No info provided	No info provided	No info provided
Educational Factors	Language-specific education delivered via the link worker	Interviews conducted in participant's preferred language	Language-specific education recorded on the audio-cassette	Language-specific education delivered via the link worker

3.3 Risk of Bias Assessment

Risk of bias across all included studies was assessed using the Cochrane Risk of Bias tool and findings have been summarized in Table 4. All of the four RCTs were free of selective outcome reporting as they all reported data for the outcome of A1C following their interventions (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; Middelkoop et al., 2001; O'Hare et al., 2004). All of the studies, except for one, adequately addressed incomplete outcome data (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; O'Hare et al., 2004). Middelkoop et al. (2001) did not provide any information of attrition during their study, nor any information about the participants lost to follow-up. They also failed to provide any information about how they handled missing data (Middelkoop et al., 2001).

There was a lack of clarity about allocation concealment and blinding of participants, personnel and outcome assessors across all the studies (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; Middelkoop et al., 2001; O'Hare et al., 2004). Three out of the four studies provided no information about how they concealed the allocation of participants within their studies (Bellary et al., 2008; Middelkoop et al., 2001; O'Hare et al., 2004). One study described the use of presealed envelopes to allocate their study participants to their respective groups; however, they did not provide sufficient descriptive information about those presealed envelopes as to whether or not they were opaque to ensure complete concealment of allocation (Hawthorne & Tomlinson, 1997). Likewise, none of the included studies discussed their processes for blinding of participants, study

personnel or outcome assessors (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; Middelkoop et al., 2001; O'Hare et al., 2004).

Sequence generation was adequately conducted in only one study by the generation of random number tables (Hawthorne & Tomlinson, 1997). Middelkoop et al. (2001) did not generate the allocation sequence adequately because they used the participants' date of birth as the medium of allocation (odd numbers allocated to the intervention group and even numbers to a wait-list control group). The remainder of the studies lacked clarity in addressing the allocation sequence within their studies. Bellary et al. (2008) mentioned the use of simple randomization, but failed to provide any further details. O'Hare et al. (2004) provided no information about how the allocation sequence was generated in their study.

Further assessment of risk of bias in this review revealed that contamination was not reported by any of the studies. As such, it is possible that participants between the intervention and control groups in the studies may have interacted with each other within individual practices or across practices as in the case of cluster RCTs. This may in turn expose the control group participants to the study intervention, which can in turn reduce the effect of the interventions of the included studies (DiCenso, Guyatt & Ciliska, 2005).

Furthermore, the presence of confounding variables may have also impacted the study results across the included studies. As mentioned previously under Study Characteristics, only two out of four studies provided baseline data

about length of diabetes duration and type of diabetes treatment among its participants (Bellary et al., 2008; O'Hare et al., 2004). The participant's education level was another potential confounding variable that was not addressed across all the included studies. These variables have the potential to affect the degree of A1C change following any given DSME and/or DSMS intervention, and are thus important to consider.

Table 4

Risk of Bias Assessment across Included Studies

	Sequence Generation	Allocation Concealment	Blinding of participants, personnel, and outcome assessors	Incomplete outcome data	Selective Outcome Reporting	Other sources of bias
Bellary et al., (2008)	Unclear	Unclear	Unclear	Yes	Yes	Unclear
Hawthorne & Tomlinson (1997)	Yes	Unclear	Unclear	Yes	Yes	Unclear
Middelkoop et al., (2001)	No	Unclear	Unclear	Unclear	Yes	Unclear
O'Hare et al., (2004)	Unclear	Unclear	Unclear	Yes	Yes	Unclear

Chapter 4: Discussion

This chapter will present a discussion to summarize the key findings of the results of this systematic review. First, the population characteristics of the included studies, the methodological quality of the included studies, and the implications of culture related to the design of study interventions used for South Asians with T2DM will be discussed. Second, the implications of these findings for policy, clinical practice and education, and research will be discussed.

4.1 Summary of Key Findings

This systematic review included four RCTs, all of which took place in Europe, in the UK and the Netherlands (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; Middelkoop et al., 2001; O'Hare et al., 2004). All study participants were adults with T2DM and were migrants of South Asian descent. Only one out of the four included studies showed a statistically significant reduction in A1C following the intervention (Middelkoop et al., 2001).

The interventions across all the four studies were complex, involving multiple components. Materials used across the interventions included educational booklets, audio-cassettes recorded in the participants' preferred language and pictorial flashcards (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; Middelkoop et al., 2001; O'Hare et al., 2004). Three out of the four interventions made use of link workers who delivered DSME and DSMS interventions to study participants. Link workers are also known as community health workers; they are lay members of the community who bridge the link between the healthcare

provider and the patient (Garcia & Grant, 2015; Shah, Kaselitz & Heisler, 2013; Witmer, Seifer, Finocchio, Leslie & O'Neil, 1995). These link workers provided language support to healthcare providers who delivered DSME and DSMS as part of the intervention across the three studies that utilized them (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; O'Hare et al., 2004). A cultural assessment of these interventions according to Leininger's Sunrise Model revealed that the interventions across all the studies failed to provide culturally tailored care to the South Asian population across all the included studies. This was due to a lack of information provided for the categories of *religious and philosophical factors* and *kinship and social factors*, and insufficient details and lack of clarity provided for the implementation of *cultural values, beliefs and lifeways* within the interventions (Bellary et al.; Hawthorne & Tomlinson, 1997; Leininger & McFarland, 2002; Middelkoop et al., 2001; O'Hare et al., 2004).

The methodological quality of the included RCTs presented with limitations as well. According to the risk of bias assessment, the included studies in this review were weak studies because they were unclear about their process for sequence generation, allocation concealment of their study participants, and blinding of study participants, personnel and outcome assessors (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; Middelkoop et al., 2001; O'Hare et al., 2004). Only one study demonstrated a statistically significant reduction in A1C following the intervention, however this finding cannot be taken with confidence,

as this too was a very study as demonstrated by the risk of bias assessment (Middelkoop et al., 2001).

4.1.1 Population Characteristics

Although the study population in all the four included studies was classified as being adults of South Asian descent, it is important to note the variability that was present between the populations of the four RCTs. Although the term South Asian signifies one ethnic group, there is considerable diversity present among South Asians with regards to language, dietary practices and religion. This diversity presents a challenge in designing culturally-tailored DSME and DSMS interventions for this high risk population, as will be discussed in the following paragraphs.

The study population in the RCT by Middelkoop et al. (2001) included South Asians who had immigrated to The Hague from Surinam. Surinam was a former Dutch colony located in South America (Middelkoop, Kesarlal-Sadhoeram, Ramsaransing & Struben, 1999; Middelkoop & van der Wal, 2004). The ancestors of the South Asian population living in The Hague came to Surinam from the Indian sub-continent as labourers. Due to political difficulties in Surinam, many of these South Asians subsequently came to the Netherlands, and settled in The Hague. Approximately 75% of Surinamese inhabitants of The Hague are of South Asian descent (Middelkoop et al., 1999; Middelkoop & van der Wal, 2004).

The South Asian study population in the remainder of the three RCTs came from different parts of the UK. The RCT by Hawthorne and Tomlinson (1997) consisted of Pakistani patients which were recruited from Manchester. The last two remaining cluster RCTs consisted of South Asian patients recruited from Birmingham and Coventry (Bellary et al., 2008; O'Hare et al., 2004). One of these cluster RCTs further specified that study participants were recruited from the Foleshill area of Coventry and the eastern region of Birmingham for their study (O'Hare et al., 2004).

Although all RCTs recruited their study participants from the UK, it is important to examine the regions from where these participants were recruited from, as that speaks to the characteristics of the South Asian population represented in each study. According to the 2011 UK census, the majority of South Asians living in Manchester (8.5%) are of Pakistani descent (Office for National Statistics, 2013a). The remainder of the South Asian population residing in Manchester identifies themselves as coming from Indian and Bangladeshi descent, and represents a smaller minority at 2.3% and 1.3% respectively (Office for National Statistics, 2013a). Likewise, the majority of South Asians living in Birmingham are also of Pakistani descent (13.5%), with a smaller proportion from Indian (6.0%) and Bangladeshi (3.0%) descent (Office for National Statistics, 2013b). In Coventry however, the majority of South Asians identified themselves as being of Indian descent (8.8%), followed by a smaller proportion who identify

themselves as coming from Pakistani (3.0%) and Bangladeshi (0.9%) descent (Ohandjanian, 2015).

Although the term 'South Asian' signifies one ethnic group, there is considerable heterogeneity amongst this group, depending on the country of origin. As has been discussed previously in Chapter 1, this heterogeneity stems from varying religious beliefs and cultural values that are present among South Asians (Basuray, 2002; Buchignani, 2015). Based on the 2011 UK census data on the South Asian population residing in Manchester and Birmingham presented previously, it is possible that a large majority of the study participants recruited from these two areas were of Pakistani descent. Having said that, it is also possible that a majority of the study participants recruited from Birmingham and Manchester were Muslims because Islam is the official dominant religion in Pakistan (Ziring & Burki, 2016). The 2011 UK census data further reports that 21.8% of the Birmingham population follows Islam, followed by 3.0% of Sikh followers and 2.1% following Hinduism (Office for National Statistics, 2013c).

Furthermore, South Asians of Indian descent ranked second after the Pakistanis in Manchester and Birmingham, and were the largest proportion of South Asians residing in the city of Coventry according to the 2011 UK census. Although Hinduism is the dominant religion in India, Islam, Sikhism and Christianity are amongst the other religions practiced by people of Indian descent (Basuray, 2002). One of the cluster RCTs did specify that participants were recruited from the Foleshill area of Coventry (O'Hare et al., 2004). According to

the 2011 UK census, about 50.1% of the population in this ward is made up of South Asians (The Corporate Research Team, 2011). The same data set reveals that about 38.6% of the Foleshill population is Muslim, followed by 8.7% of the population being Sikh, and 6.3% of the population being Hindu (The Corporate Research Team, 2011).

As can be seen with the aforementioned statistics, there is considerable variability across Birmingham, Manchester and Coventry (and the ward of Foleshill) with regards to the makeup of South Asians residing in these areas. This variability stems from their country of origin, as well as their religious backgrounds and beliefs. The two cluster RCTs included in this review recruited participants from different locations: Coventry and Birmingham; and Foleshill, Coventry and Birmingham (Bellary et al., 2008; O'Hare et al., 2004). In light of this, it becomes difficult to know the characteristics of South Asian participants recruited into each of these studies, unless this data is collected and reported by the study authors. Thus, in light of this geographical, linguistic and religious heterogeneity in the South Asian population in the UK and globally at large, it makes it difficult to design and deliver one intervention to such a large and diverse group. Perhaps what is required is some rethinking of the broad term "South Asian," and recognizing this diversity that encompasses this entire population when considering the design and delivery of a culturally tailored DSM intervention.

Furthermore, religion is important to consider among the South Asian population because dietary practices are influenced by the follower's religious beliefs. Muslims for example fast during the month of Ramadan where they abstain from eating and drinking from sunrise to sunset (Sivia, 2011). This practice of fasting during the month of Ramadan is mandatory for most Muslims, except for certain groups of people such as pre-pubertal children, pregnant women, the elderly and individuals with chronic diseases. Similarly, fasting is also practiced among Hindus during religious events, whereas Sikhs do not usually observe fasts. In addition to fasting, there are varying dietary practices among Muslims, Hindus and Sikhs, which are in accordance with their religious and cultural beliefs (Sivia, 2011).

Again, all of this demonstrates the diversity that is present among people categorized under one ethnic group: South Asians. For a population that is so heterogeneous in terms of its geographical descent, language and religious customs and beliefs, it can be understood why three out of the four interventions presented in the included studies in this review failed to show a statistically significant reduction in A1C. This heterogeneity in the study population is not identified, nor accounted for by the study authors. For a population that is foundationally flawed in the way it is being labelled as one ethnic group due to its considerable diversity, it can definitely pose challenges for researchers and healthcare providers when it comes to designing culturally tailored DSM interventions that show effectiveness.

Apart from the religious diversity that is present amongst South Asians, it is important to note the potential variation that may be present among the participants in the included RCTs from a socio-demographic perspective. Data about baseline characteristics of the study participants across all the four RCTs lacked information about the educational level of the study participants. This missing information is important to consider because education and literacy are considered social determinants of health (Braveman, Egerter & Mockenhaupt, 2011; Raphael, 2009). Education for instance, is related to income; a higher education can lead to increased prospects of attaining high-paying employment. Increased income and wealth can subsequently lead to economic security, which can in turn lead to the ability of families to pay for necessities like health insurance premiums to access healthcare services, medicines, and purchase healthier nutritious foods (Braveman et al., 2011). Consequently, a lower education status can have the opposite effect, leading to lower income due to employment instability. This can in turn lead to poor access to nutritious foods, and affordability of healthcare services and medications, as in the case of resources needed for successful DSM (Braveman et al., 2011).

Like education, literacy can also affect health. By definition, literacy refers to, "the ability to understand and use reading, writing, speaking and other forms of communication as ways to participate in society and achieve one's goals and potential" (Rootman & Gordon-El-Bihbety, 2008, p. 10). Health literacy on the other hand, refers to "the ability to access, understand, evaluate and communicate

information as a way to promote, maintain and improve health in a variety of settings across the life-course" (Rootman & Gordon-El-Bihbety, 2008, p. 11). In this regard, those individuals who have low literacy and health literacy can face challenges in acquiring knowledge and understanding about medical conditions, self-management behaviours related to lifestyle practices (i.e., healthy eating, physical activity) and medication taking behaviours (Raphael, 2009).

Although all the RCTs included in this review did not provide any information about the educational level or any other socio-demographic baseline characteristics of their study participants, the Index of Multiple Deprivation measured in 2015 can provide some useful information in this regard. The Index of Multiple Deprivation is an overall measure of deprivation measured across seven different domains for neighbourhoods across England (Department for Communities and Local Government, 2015). These seven domains include: income deprivation; employment deprivation; education, skills and training deprivation; health deprivation and disability; crime; barriers to housing and services; and living environment deprivation. All the neighbourhoods are in turn ranked relative to each other, based on the Index of Multiple Deprivation, with neighbourhoods that are ranked higher up, constitute as being part of the most deprived 10% of neighbourhoods across England (Department for Communities and Local Government, 2015).

According to the 2015 Index of Multiple Deprivation measure, Manchester ranked fifth, containing one of the largest proportions of highly

deprived neighbourhoods in England, followed closely by Birmingham, which ranked sixth (Department for Communities and Local Government, 2015). Coventry, on the other hand, ranked 46th on the 2015 Index of Multiple Deprivation measure (Coventry City Council's Insight Team, 2015). It should be noted however, that although Manchester and Birmingham are ranked higher on the 2015 Index of Multiple Deprivation measure, it is possible that they also contain some neighbourhoods which are affluent. Similarly, although Coventry is ranked lower down on the 2015 Index of Multiple Deprivation measure, it is possible that it contains neighbourhoods which are highly deprived (Department for Communities and Local Government, 2015). Foleshill for instance, is a ward in the city of Coventry and it is one of 36 neighbourhoods in the city which is considered to be part of the most deprived 10% of neighbourhoods across England (Coventry City Council's Insight Team, 2015).

It is important to note that of the seven domains used to calculate the Index of Multiple Deprivation, two domains carry the greatest weight: income deprivation and employment deprivation. It is anticipated that scores for these two domains would be similar because employment insecurity will ultimately translate into income deprivation (Department for Communities and Local Government, 2015).

It is known that both of the cluster RCTs recruited participants from Birmingham as one of their sites of recruitment (Bellary et al., 2008; O'Hare et al., 2004). The RCT by Hawthorne and Tomlinson (1997) recruited their study

participants from Manchester. The authors of these studies do not provide names of specific neighbourhoods in Birmingham and Manchester from where their study participants were recruited. O'Hare et al. (2004) do specify that they recruited their study participants from the Foleshill ward in the city of Coventry. Since Foleshill is one of the highly deprived neighbourhoods in Coventry, it is possible that participants that were recruited from that area belonged to a lower socio-economic class. None of the authors across all the RCTs included in this review provided baseline data of their study participants with regards to their education level, occupation or employment. This makes it difficult to determine how the health of these individuals was at baseline and the kind of healthcare resources that they had access to, in order to manage their diabetes and comorbidities, if any were present.

4.1.2 Study Quality

As stated previously, all of the four studies that were included in this review were RCTs and cluster RCTs, all of which were of weak quality. RCTs are known for their scientific rigour due to randomization and blinding of involved parties. In cases where these characteristics are absent, it could render the findings of the studies to be biased or less rigorous.

One of the key characteristics of an RCT study design is randomization of study participants (Hulley, Cummings, Browner, Grady & Newman, 2013; Higgins & Altman, 2008; O'Connor, Green & Higgins, 2008). Randomization ensures that all baseline variables of study participants, both measured and

unmeasured, are evenly distributed between the intervention and control groups at the start of the study. This guarantees that any variation that may be present between the participants, across the study groups, will be due to chance alone and not due to the influence of confounding variables (Hulley et al., 2013). To meet this criterion of an RCT, a study should employ appropriate sequence generation and allocation concealment methods (Higgins & Altman, 2008).

Hawthorne and Tomlinson (1997) were the only authors who reported adequate sequence generation using random number tables. In another study by Middelkoop et al. (2001), participants were also randomized, however, this allocation was based on whether the dates of birth of the subjects were even or odd numbered. Such a means of sequence generation is inadequate because it is not based on a random or a chance process (Higgins & Altman, 2008). This could mean that participants in this study were unbalanced between the intervention and control groups with regards to their baseline characteristics. In such a case, the intervention group could have disproportionally contained participants with elevated A1Cs compared to the control group. A higher A1C at baseline has been shown to result in a greater reduction in A1C following the intervention (Sherifali, Nerenberg, Pullenayegum, Cheng & Gerstein, 2010). This could be potentially why this study showed a statistically significant reduction in A1C, despite this limitation in its internal validity (Middelkoop et al., 2001). The remainder of the two studies provided no information as to how the participants in their studies

were randomized. This questions the rigour and internal validity of these studies due to this lack of reported information (Bellary et al., 2008; O'Hare et al., 2004).

The second characteristic of an RCT, allocation concealment, ensures that strict randomization has been implemented without informing the participant or the investigator of the participants' group assignment (Schulz & Grimes, 2002). Similar to sequence generation, only one of the included studies reported adequate implementation of the allocation concealment process. This study reported the use of presealed envelopes; however, this reported information was insufficient as the authors had not reported on the opacity of these envelopes (Hawthorne & Tomlinson, 1997). A translucent envelope when placed under a light source could easily reveal the written/typed allocation group of the participant to the study investigator or any member of the research team (Schulz & Grimes, 2002). This incomplete concealment of group allocation in the aforementioned study could have lead to over- or underestimation of the effect of DSM interventions on the participants' A1C as members of the research team could have already been aware of the allocation status of the study participants.

Another key characteristic of all RCTs is the concept of blinding of participants, study personnel and outcome assessors (Hulley et al., 2013; Higgins & Altman, 2008; O'Connor et al., 2008). Blinding ensures that biases are minimized post-randomization, including biased outcome ascertainment and adjudication (Hulley et al., 2013). Blinding also ensures that participants are treated equally in both groups, without any special treatment of participants in

either group (Higgins & Altman, 2008; Hulley et al., 2013). Similar to allocation concealment, none of the included studies reported any information about implementing blinding protocols in their study methodology. Potential lack of blinding, as in the case of the included studies in this review, could have led to differential treatment of study participants by members of the research team (Karanicolas, Farrokhyar & Bhandari, 2010). This could inherently lead to biased outcomes and compromise the internal validity of the studies.

For educational interventions such as those used to deliver DSME and DSMS, it can become difficult to blind study participants in the intervention and control groups. This is because the control group participants would be aware of not receiving any intervention versus the intervention group, who would be aware of the intervention beforehand as evidenced by the educational support that is being delivered to them. However, it can still be possible to blind study personnel and outcome assessors with regards to the allocation status of participants to their respective groups (Hulley et al., 2013). This ensures that biased outcome ascertainment and adjudication are minimized such that members of the research team are not inclined to look more vigilantly for outcomes in the control group.

In an RCT study design, it is possible that contamination can occur between participants from the intervention and the control group. In other words, participants in the control group may get unintentional access to the intervention during the study (DiCenso et al., 2005). Contamination could therefore lead to an inaccurate comparison between the control and the treatment groups producing

biased results. Furthermore, co-interventions can also affect determination of an accurate outcome of interest (Hulley et al., 2013). For example, if participants across any of the study sites were exposed to other diabetes self-management programs in their communities during their participation in the RCTs, then it becomes difficult to determine if the outcome of A1C measured at the end of the study period was truly attributed to the effect of the intervention under investigation (Hulley et al., 2013). None of the authors of RCTs included in this review acknowledged the possibility of contamination and/or co-intervention amongst their study participants. Practically speaking, such scenarios are very likely and may be difficult to control. In the case of the cluster RCT study design, however, this contamination may be limited to some degree as participants from the general practice setting would also be randomized collectively to the same study group, as was done in the two cluster RCTs that were included in this review (Higgins, Deeks & Altman, 2008).

A cluster RCT study also has one major drawback in terms of obtaining unbiased results. Cluster RCTs may lead to false-positive findings by demonstrating that the intervention was effective when it may not be so. This is likely in a scenario where researchers do not account for this clustering statistically (Higgins et al., 2008). This was evident in one of the cluster RCTs by Bellary et al. (2008), whereby the data showed a statistically significant reduction in A1C among the participants in the intervention group. The authors in this study however, failed to account for the clustering factor in their data analysis, which

means that the statistically significant reduction in A1C was based on data that was not adjusted for clustering (Bellary et al., 2008). This leads to reduced confidence in the study's findings as this may not demonstrate the true effect of the intervention.

In the end, there was only one RCT which showed a statistically significant reduction in A1C in the intervention group following the intervention, with a 0.42% reduction in A1C ($p = 0.02$) for non-adjusted data, and a 0.5% reduction in A1C ($p = 0.004$) following data that was adjusted (Middelkoop et al., 2001). However, due to the lack of reporting of crucial information and weak internal validity of this study (due to a lack of reported information about allocation concealment, blinding, contamination and inadequate methods of randomization), these findings should be interpreted with caution.

4.1.3 Intervention Characteristics for Diabetes in South Asians

The study interventions across all of the four studies included in this review comprised of multiple components. Such interventions can be characterized as complex interventions. Complex interventions are those which consist of various components that may act independently or interdependently to lead to the treatment effect of the intervention (Campbell et al., 2000; Medical Research Council, 2000). For instance, DSME and DSMS in the two cluster RCTs was primarily delivered by practice nurses and the community diabetes specialist nurse. These two studies also made use of link workers who provided language-

specific interpretation to study participants in an effort to encourage lifestyle changes in the management of diabetes (Bellary et al., 2008; O'Hare et al., 2004). Likewise, the remainder of the two RCTs also utilized multiple components that made up their respective interventions. Middelkoop et al. (2001) used diabetes specialist nurses and dietitians who met with study participants to deliver DSME and DSMS. This education and support was complimented by two educational booklets and an audio-cassette containing language-specific DSME and DSMS for the study participants. Finally, the RCT by Hawthorne and Tomlinson (1997) used pictorial flashcards and an educational package, which was used by link workers to deliver DSME and DSMS to the study participants.

In all the interventions described previously, it becomes difficult to determine which aspect(s) of the intervention contributed to the treatment effect. In the case of the two cluster RCTs, it could have been that the DSME and DSMS delivered by the community diabetes specialist nurse lead to a reduction in A1C, or that the reduction was due to the impact of the link workers who reinforced the education. Similarly, in the remainder of the two studies, it may have been the materials used in the interventions that lead to a mean difference reduction in A1C, or the impact of the diabetes specialist nurses and dietitians and the link workers that contributed to the treatment effect. The treatment effect might also be explained by the frequency of interactions between the study participants and the healthcare providers and link workers, or the use of face-to-face interactions between them.

Although only one study in this review showed a statistically significant reduction in A1C, it still presents a challenge when it comes to identifying the active ingredients within the intervention that lead to the treatment effect (Medical Research Council, 2000). This challenge is further exacerbated with the lack of adequate reporting, particularly in the context of such complex interventions, which makes reproducibility of these interventions difficult (Craig et al., 2008).

A cultural assessment of the interventions across the four included studies in this review was conducted using Leininger's Sunrise Model. As has been mentioned previously, three out of the four included studies in this review made use of link workers as one component of their interventions (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; O'Hare et al., 2004). Since link workers belong to the same cultural group as that of patients, it enables them to reduce cultural barriers between the healthcare provider and the patient. They also assist in overcoming language barriers and can strengthen communication between the healthcare providers and patients (Garcia & Grant, 2015, Shah et al., 2013; Witmer et al., 1995).

Although link workers were incorporated as part of the intervention in most studies in this review, it remains unknown as to how they provided culturally congruent care to take into account the participants' religious, kinship and social factors. It is known that the link workers in these studies were members of the South Asian community from which participants were recruited. However, their baseline characteristics such as specific cultural and religious backgrounds,

gender, age, and education level were not reported by the authors in any of these studies.

There was considerable heterogeneity in the South Asian population recruited in these studies. Likewise, this heterogeneity can equally be applicable to the link workers as well because they too were members belonging to the South Asian community from which study participants were recruited. With such heterogeneity present among the study participants, and potentially among the link workers as well, it remains unknown whether the link workers truly 'matched' the study participants on the grounds of religious, cultural beliefs, and age. If cultural and religious beliefs differed between the link workers and study participants, it becomes difficult to determine how this culturally-sensitive care was delivered by the link workers, and subsequently received by the study participants. Such a clash of differences on these factors between link workers and the participants might lead to non-significant results in terms of a reduction in A1C in the intervention groups in these studies.

A systematic review of RCTs examined the effects of community health worker-led interventions on the A1C of the Latino population in the United States (Little, Wang, Castro, Jimenez & Rosal, 2014). There were 12 RCTs included in this descriptive review; however, only six of these studies reported the training that community health workers went through to deliver their roles in the respective studies (Little et al., 2014). This finding resonates with the studies included in this systematic review, where the authors provided no information

about the training that link workers went through in order to deliver DSME and DSMS to the migrant South Asian study population (Bellary et al., 2008; Hawthorne & Tomlinson, 1997; O'Hare, et al., 2004). This creates ambiguity and uncertainty into the qualifications of the link workers used in the studies with regards to their ability to deliver accurate DSME and DSMS to the study participants. This also questions the effectiveness of the delivery of the interventions overall, which can in turn be one of the contributing factors as to why the interventions did not result in a statistically significant reduction in A1C.

Furthermore, the findings of this current review also resonate with the findings of a similar systematic review where the authors assessed the impact of diabetes management interventions for South Asians with T2DM (Bhurji, Javer, Gasevic & Khan, 2016). The participants of the studies in this latter review contained South Asian participants from around the world, including from India. The studies included in this review consisted of RCTs and prospective pre-post observational studies. A total of 23 studies were included in the review, of which 16 were conducted in India and seven were conducted in the West (Bhurji et al., 2016).

Similar to the review conducted for this thesis, Bhurji et al. (2016) also noted that the interventions were very heterogeneous and that statistically significant reductions in A1C were only noted in studies that were conducted in India (studies conducted in the West did not show significant reductions in A1C). Both of the aforementioned systematic reviews pose strong recommendations to

ensure cultural tailoring of DSM interventions to show effectiveness in glycemic control. Bhurji et al. (2016) suggest that such novel culturally tailored interventions in the West should consider evaluation of using traditional dance or yoga for example, in addition to the use of simply educational-based interventions, as this may engage participation of participants in terms of healthy behaviour change practices.

4.1.4 Summary of Evidence

In summary, the four RCTs included in this review examined the effectiveness of DSME and DSMS interventions on the A1C of the migrant South Asian population with T2DM residing in European countries. Based on data available from the 2011 UK census, it is evident that although the participants across the included studies were classified as one homogeneous group as 'South Asians,' there is considerable heterogeneity in this population, with regards to diverse beliefs related to culture, religion and languages. Such diversity among South Asians presents challenges in terms of providing culturally congruent care to this high risk ethnic minority group.

The interventions across the four RCTs attempted to provide culturally tailored care to this population. There were however clear gaps with regards to the reporting of these complex interventions as per the TIDieR criteria, which makes reproducibility of these interventions (or parts of these interventions) a challenge. From a methodological perspective, the studies were compromised on their internal validity due to inappropriate randomization (sequence generation and

allocation concealment) and blinding of study personnel and outcome assessors. Since only one RCT resulted in a statistically significant reduction in A1C, there is limited confidence to be able to generalize these findings to migrant South Asians at large residing in western countries.

4.2 Implications of Findings

The DSME and DSMS interventions in this review have failed to demonstrate statistically significant reductions in the outcome of A1C among migrant South Asians with T2DM. This finding can be reflective of various limitations presented in the included studies in this review, including the heterogeneity of the study population, the methodological quality of the included studies and the lack of reporting of intervention characteristics. These limitations make it difficult to determine whether DSME and/or DSMS interventions are truly effective in improving glycemic control among the migrant South Asian adult population with T2DM. However, as mentioned previously in Chapter 1, there is high quality evidence that DSM interventions in the general population have shown statistically significant effects in terms of A1C reductions, and also clinically significant effects in terms of delaying the onset and severity of diabetes-related complications in those afflicted with this disease. As such, it can be safely said that DSM interventions, both DSME and DSMS should still be implemented for everyone with T2DM, including the migrant South Asian community with T2DM.

The following sections will present recommendations for policy, clinical practice and education, and research. These recommendations stem from the evidence synthesized in this systematic review, as well as what is known from other literature sources about the population (South Asian adults with T2DM), interventions (DSME and DSMS), and the subsequent impact on clinical outcomes (A1C).

4.2.1 Policy

As discussed previously, DSME and DSMS interventions have shown to improve clinical outcomes by lowering A1C and subsequently decreasing the risk of developing diabetes-related complications, reducing hospitalizations and ultimately, improving the quality of life of people living with T2DM (Minet et al., 2010; Norris et al., 2001; Norris et al., 2002; Powers et al., 2015). Routine diabetes self-care and self-management requires skills such as critical thinking, goal setting and problem solving. Receiving structured diabetes education from healthcare providers who have expertise in the treatment and management of diabetes, enables individuals with diabetes to be equipped with the skills necessary to self-manage this disease. (Anderson & Funnell, 2010; CDA & Diabetes Educator Section, 2014; Haas et al., 2012; Powers et al., 2015).

The Health and Social Care Information Centre, Healthcare Quality Improvement Partnership and Diabetes UK (2016) published a recent report on the results of the National Diabetes Audit. The National Diabetes Audit provides data on the delivery of diabetes care in England and Wales. For the years 2014 to

2015, around 4,700 general practices and 99 specialist services participated in the audit, and collected information on 1.9 million people living with diabetes. The results indicated that 78% of people living with T2DM were offered structured education for diabetes however, only 5.3% of people actually attended a structured diabetes education program (The Health and Social Care Information Centre, Healthcare Quality Improvement Partnership and Diabetes UK, 2016).

Furthermore, a cohort study conducted in Ontario, Canada found similar results as the National Diabetes Audit in the UK. This population-based cohort study collected data from healthcare administrative databases on adults (18 years of age and older) living in Ontario, Canada, who were diagnosed with diabetes between January and June 2006, according to the Ontario Diabetes Database (Cauch-Dudek, Victor, Sigmond & Shah, 2013). The results indicated that only 20.6% of the cohort attended a DSME program within six months of their diabetes diagnosis. Unfortunately, this data was not solely accountable for adults with T2DM as the Ontario Diabetes Database does not distinguish between the different types of diabetes (Cauch-Dudek et al., 2013).

Nonetheless, the findings presented above, stress the urgent need for policy to support the consistent and comprehensive provision of structured DSME for all individuals and their caregivers upon diabetes diagnosis, along with continued self-management support provided thereafter (Anderson & Funnell, 2010; CDA, 2016d; CDA & Diabetes Educator Section, 2014). In the context of the migrant South Asian population living with T2DM in the West, some of the

common barriers identified to receiving structured DSME included language barriers, cold climate, transportation difficulties, and a lack of culturally-specific care towards DSM (Sohal et al., 2015). In such a scenario, one policy recommendation would be to engage the use of link workers, or community health workers to ensure the increased uptake of DSME and DSMS among the South Asian population.

Link workers or community health workers were used as part of the interventions in most studies included in this review; however their role was not described in detail, other than to provide language-specific education to the study participants. Language-specific education does not necessarily mean that the educational content is culturally tailored. Culturally tailored care can be delivered with collaboration between patients, family members, community health workers and healthcare providers using a needs assessment. This assessment can be undertaken by collecting qualitative data using focus groups and one-to-one interviews carried out with migrant South Asians with T2DM to understand their culture, and subsequently, their perspectives on health, illness (particularly T2DM) and quality of life.

In conjunction with the data collected from the needs assessment, and in keeping with tenets of Leininger's Sunrise Model of co-participation between the patient and the healthcare provider, a collaborative effort can help to address some of the barriers to receiving structured DSME and DSMS as outlined previously. Link workers or community health workers can be used to reach out to the

migrant South Asian population to provide the much needed education and support to coach effective DSM. In terms of the migrant South Asian population, these community health workers can be harnessed from different faith communities. By liaising these community health workers with local diabetes education centers of that region, these community health workers can receive structured education about diabetes and its management, along with education about principles of empowerment and motivational interviewing which can be used to assist in behaviour change and improve the lifestyle management of the disease.

The impact of using peer support on achieving target glycemic control has been studied in the literature and has shown positive findings. One such systematic review and meta-analysis of RCTs assessed the effectiveness of peer support on glycemic control in patients with T2DM (Qi et al., 2015). The results of this meta-analysis demonstrated a significant reduction in A1C with a MD -0.57 (95% CI -0.78 to -0.36), in favour of the intervention. The results were significant for those patients whose A1C was greater than ≥ 8.5%, with MD -0.78 (95% CI -1.06 to -0.51), as well as those whose A1C was between 7.5% and 8.5%, with a MD -0.76 (95% CI -1.05 to -0.47). Patients who received high (each patient received more than two contacts per month) or moderate (each patient received one to two contacts per month) frequency of contact also demonstrated a significant reduction in A1C with MD -0.52 (95% CI -0.6 to -0.44) and MD -0.75 (95% CI -1.21 to -0.29) respectively (Qi et al., 2015).

An added advantage of recruiting community health workers from different faith communities is that these individuals would belong to the same cultural and religious background as the population of interest, and would be better able to tailor DSME and DSMS to the cultural values and beliefs of that population. This would help to overcome the barriers of a lack of delivery of culturally congruent care, as outlined by Sohal and colleagues (2015), and would also help to mitigate barriers related to language. Transportation barriers can also be minimized and access to DSME and DSMS can be improved if such DSME and DSMS sessions are held at common places of religious and community gathering where the population frequently gathers for religious and social events. Not to mention the rising prevalence rates of diabetes both nationally and internationally, such utilization of community health workers would help to decrease the burden on the healthcare system, particularly on Canada's publically funded health care system, and contribute to cost-effectiveness in terms of reducing hospitalizations and costs-related to diabetes-related complications (CPG, 2013; IDF, 2015b; UKPDS Group, 1998).

. 4.2.2 Clinical Practice and Education

A previous systematic review of qualitative studies by Sohal et al. (2015) assessed barriers and facilitators of DSM among the South Asian population living with T2DM. From their review, it was determined that South Asians residing in the West expressed the need for DSME and DSMS to be culturally tailored to their values and beliefs so that the health advice they received from

healthcare providers could be operationalized. However, similar to the lack of culturally specific chronic care modification identified by Sohal and colleagues (2015), the lack of clarity in intervention description within the included studies in this review makes it difficult to ascertain whether the interventions were truly culturally congruent with the study population.

Although it is evident that all the DSME and DSMS interventions included in this current systematic review involved the healthcare provider in the design of these interventions, it is unclear if members of the designated population were also involved in the intervention design process. Patients are key stakeholders for healthcare interventions that are targeted towards them, such as the DSME and DSMS interventions across the studies in this review (Graham et al., 2006). As the cultural assessment of these interventions using Leininger's Sunrise Model has revealed, religious, kinship and cultural factors lacked clarity in how they were addressed across the four studies. One possible solution to this limitation would be to consider involving patients themselves in the design and conceptualization of these healthcare interventions by collecting qualitative data such as one-to-one interviews and focus groups, to collect data about their culture and perspectives on DSM. This would ensure that such interventions are truly culturally tailored to meet the needs of the population for which they are designed. This may in turn contribute to the effect of the intervention on outcomes such as A1C, as in the case for South Asians with T2DM.

The results of this systematic review also reinforces the need for nurses and members of the interdisciplinary team to implement care that is culturally congruent, so as to extend the greatest clinical benefit towards the health and well-being of the patient (Andrews & Boyle, 2016; Leininger & McFarland, 2002; Purnell & Paulanka, 2003). One strategy for providing care that is culturally congruent with the patient's values and beliefs is to perform a thorough assessment of the patient's health and psychosocial status (RNAO, 2015). Leininger's Sunrise Model provides a very useful guide to aid the nurse or any other healthcare provider to conduct this assessment. It enables the healthcare provider to gather information about the patient's religious and philosophical factors, kinship and social factors, cultural values, beliefs and lifeways, and other factors related to the patient such as economic factors and educational factors (Leininger & McFarland, 2002). Information gathered for all of these factors, in addition to the patient's medical history and overall health, enables the healthcare provider to know and understand the patient holistically. This can in turn allow the healthcare provider to tailor health interventions according to the patient's needs, resulting in culturally-congruent care that will be effective in improving health outcomes (RNAO, 2015).

Nurses, educators, physicians and members of the healthcare team can implement the assessment strategy described above in their initial and continued interactions with patients and their families during their clinical encounters. Concepts of Leininger's Sunrise Model such as *religious and philosophical*

factors, kinship and social factors, cultural values, beliefs and lifeways, and others such as *economic factors* and *educational factors* can be incorporated in standard documentation practices as part of flow-sheets to ensure that this data is collected about the patient's culture. Recognizing these factors about patients in the clinical setting can be the first step in beginning to understand the patient's culture and subsequently using that information to collaboratively problem-solve solutions to implementing culturally-congruent care.

After gathering data and completing a comprehensive assessment of the patient, the healthcare provider can then work in partnership with the patient to develop their plan of care (RNAO, 2015). As an active member of the healthcare team, the involvement of the patient in healthcare decision making can facilitate implementation of care practices that are in line with the patient's cultural values and beliefs. This concept also resonates with Leininger's Sunrise Model where she emphasizes the concept of co-participation between the patient and the healthcare team to facilitate the delivery of culturally congruent care (Leininger & McFarland, 2002).

One important aspect to keep in mind is that the concept of cultural competence begins with oneself. Continuous self-reflection of one's values, beliefs and thoughts can enable nurses to recognize their own inherent biases and personal value systems, which may or may not be similar to that of their patient's (RNAO, 2007). Self-reflection thus provides an opportunity for nurses, and healthcare providers alike to develop self-awareness about themselves and the

similarities and differences that they share with the patients to whom they deliver care (RNAO, 2007). This acknowledgement of one's own values and belief systems acquired through self-reflective practices can strengthen the nursing practice role and can be the first step in recognizing the cultural diversity that exists amongst the patients which they care for (RNAO, 2007).

One solution to ensuring that nurses and healthcare providers alike practice self-awareness and self-reflection in their professional practice is to design educational programs that address the concepts of culture and culturally-congruent care. The notion of developing the skill to recognize cultural diversity, and subsequently the idea of delivering culturally-congruent care should be inherent in the educational programs used to prepare nurses, physicians and other members of the health care team. Designing educational curricula that address this concept of cultural-competence ensures that healthcare providers are properly educated and equipped with the knowledge, skill and understanding of the concept of culture and its impact on the way care is delivered to patients, and their resulting health outcomes (RNAO, 2007).

4.2.3 Research

From a research perspective, the methodological limitations that were present in the included studies in this systematic review warrant the need for researchers to adequately implement and report rigorous methodologies concerning the design of their RCTs. Evidence from the risk of bias assessment in this review found a lack of adequate reporting about sequence generation,

allocation concealment and blinding in the included studies. A lack of implementation and reporting of these constructs compromises the internal validity of the RCT study design, which in turn compromises external validity and generalizability of these findings to the population at large.

To preserve methodological rigour and maintain internal validity of RCTs, the CONSORT 2010 statement presents guidance for researchers to ensure the adequate reporting of RCTs (Moher et al., 2010; Schulz, Altman & Moher, 2010). The CONSORT statement was first presented in 1996, with subsequent revisions published in 2001 and 2010. The most current version of the CONSORT 2010 statement was developed by the CONSORT 2010 Group, which was comprised of 31 international members including clinical trialists, statisticians, epidemiologists and biomedical editors. The final 25-item checklist was agreed upon after seven revisions, based on the evidence synthesized for each checklist item of interest (Moher et al., 2010; Schulz et al., 2010). This list contains the minimum number of items that need to be reported in RCTs, beginning from title and abstract, introduction, methods, results, and discussion. The methods section in particular highlights the reporting of information about study participants, interventions, outcomes, sample size, randomization, allocation concealment, and blinding (Moher et al., 2010; Schulz et al., 2010). The adequate reporting of these items as per the CONSORT 2010 checklist ensures clarity and transparency in the conduct of RCTs. It can also provide guidance to researchers in the design of an RCT, to

ensure that the relevant items are addressed in their study design, which will ultimately reduce bias and strengthen the internal validity of the study.

Just as the studies included in this review lacked adequate reporting of their study methodology, they also lacked clarity in the adequate reporting of their study interventions. The TIDieR criteria were used as a means to assess the interventions across the included studies in this review. Like the CONSORT 2010 checklist, the TIDieR checklist presents guidance to researchers to assist in the design of study interventions, and the subsequent reporting of these interventions to ensure clarity and transparency (Hoffmann et al., 2014). This checklist was developed by the TIDieR steering group in collaboration with the CONSORT steering group. Like the CONSORT 2010 checklist, the development of the TIDieR checklist consisted of a synthesis of the literature and items were agreed upon by consensus of 125 experts and stakeholders, including researchers, clinicians, clinical trialists, methodologists, statisticians and authors of existing reporting guidelines (Hoffmann et al., 2014).

The DSME and DSMS interventions in this review failed to demonstrate statistically significant reductions in the outcome of A1C among migrant South Asians with T2DM. However, there are a number of reasons that could have potentially contributed to this, such as the heterogeneity in the study populations, lack of rigorous study methodology, and the lack of clarity in the reporting of contents of the study interventions including the cultural-tailoring of these interventions (all of which have been discussed previously). Had this review

contained RCTs with rigorous methodologies, which demonstrated statistically significant reductions in the outcome of A1C, then it might be worth considering the replication of such interventions to apply them in clinical practice for the benefit of the larger population. In such a scenario, the reproducibility and replication of these interventions would be of great importance. Such reproducibility and replication of interventions can only be possible with their adequate reporting, and the TIDieR checklist provides the appropriate breakdown of what needs to be reported (Hoffmann et al., 2014).

Furthermore, this review has also demonstrated challenges in determining whether the interventions in the included studies are truly culturally congruent. Given the importance of implementing culturally-congruent interventions, as has been discussed previously, qualitative research methods can be useful in helping to address research questions about the involvement of patients as key stakeholders in the design of DSME and DSMS interventions. Using purposive sampling techniques, a sub-sample of migrant South Asian adults with T2DM (for instance, participants from the Punjabi Sikh community or participants from the Tamil community) can be recruited from a given setting for researchers and others to learn about the barriers that this population encounters related to effective DSM (Graham et al., 2006; Patton, 2015; Thompson, 1999). Researchers should keep in mind however, the heterogeneity that is present among the South Asian population, as has been discussed previously. This heterogeneity can reflect

differences encountered in terms of perceived barriers, and the resultant solutions to overcome those barriers.

Assessments of perceived barriers can be conducted by gathering data via focus groups, which allows for data collection from multiple individuals at the same time (CDA & Diabetes Educator Section, 2014). Focus groups conducted using six to 12 participants allow enough people to represent diversity in terms of ideas, thoughts and feelings shared, while at the same time, ensuring a comfortable environment where participants can share their views (Onwuegbuzie, Dickinson, Leech & Zoran, 2009). Data from focus groups and one-to-one interviews alike can be collected until data saturation has reached (Onwuegbuzie, Dickinson, Leech & Zoran, 2009). This data can in turn be used by healthcare providers and participants alike to inform and generate solutions to overcome these barriers to effective DSM. This collaboration between the healthcare provider and the participants (who are also patients), is synonymous with the concept of co-participation as postulated by Leininger in the Sunrise Model. Co-participation between the healthcare provider and the patient can ensure a mutual exchange of ideas and solutions to problems, which can in turn result in care that is culturally meaningful and effective (Leininger & McFarland, 2002). Once such culturally-tailored interventions have been designed and delivered in such a collaborative manner, it would be helpful to assess the patients' and their caregivers' perspectives on how these culturally-tailored DSM interventions impacted their DSM practices. In addition to assessing for outcomes such as A1C,

patient reported outcomes can also be assessed as to how this intervention impacted patients' and their caregivers' quality of life.

4.3 Conclusion

This systematic review has examined the effectiveness of DSME and DSMS interventions on the A1C of migrant South Asian adults residing in the West with T2DM. One key gap that this review aimed to fill was to explore the cultural congruency of these study interventions based on the concepts of Leininger's Sunrise Model. Four RCTs matched the eligibility criteria and were included in the review, however only one of these studies demonstrated a statistically significant reduction in A1C following the intervention. All of the studies included in this review were weak from a methodological perspective, rendering low confidence in the acceptance of these findings.

Further exploration into the interventions across the four RCTs revealed poor reporting of the intervention components, with lack of clarity related to the process of delivery of the interventions, as well as poor reporting of study methodology. The population, although termed as 'South Asian' presented a very heterogeneous mix of individuals coming from different geographical, linguistic, religious and cultural backgrounds, making tailoring of interventions an immense challenge.

Three out of the four RCTs included in this review made use of link workers, or community health workers. Looking ahead at the rising prevalence rates of diabetes both nationally in Canada, as well as across the globe,

community health workers would be a very feasible and appropriate solution to deliver DSME and DSMS. To assess feasibility, a pilot project using community health workers that are matched to their specific sub-population of migrant South Asians with T2DM, would be the first step to their integration as part of policy to bring DSM to this high risk population. They would provide a means of delivering care surrounding DSM that is not only culturally tailored to the South Asian population, but is also very cost-effective, if they are given appropriate structured training.

It is also important to recognize that only four RCTs were found to have studied the effects of DSME and DSMS interventions on migrant South Asian adults with T2DM. This speaks to the urgent need to study DSM behaviours in this high-risk population, along with employing correct methodological rigorous procedures of adequate reporting to ensure validity of the results. As South Asians are the largest visible ethnic minority population in Canada, and also at high risk for developing diabetes, further research in the West needs to open its doors and explore the vast diversity of this population in relation to developing, testing and implementing effective and feasible options to deliver DSME and DSMS to this much needed population.

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Appendix A

Evaluation of Transcultural Nursing Models Using Fawcett's Framework

Table A1

Fawcett's criteria for evaluating models (Fawcett & DeSanto-Madeya, 2013)

Explication of Origins	- Are the philosophical claims on which the nursing model is based explicit? - Are the scholars who influenced the thinking of the model author acknowledged, and are bibliographical citations given?
Comprehensiveness of Content	- Does the nursing model provide adequate descriptions of all four concepts of the nursing metaparadigm? - Do the relational propositions of the nursing model completely link the four metaparadigm concepts? - Is the practitioner given sufficient direction to be able to make pertinent observations, decide that an actual or potential need for nursing exists, and prescribe and execute a course of action that achieves the goal specified in a variety of practice situations? - Is the researcher given sufficient direction about what questions to ask and what methodology to use? - Does the educator have sufficient guidelines to construct a curriculum? - Does the administrator have sufficient guidelines to organize and deliver nursing services?
Logical Congruence	- Does the model reflect more than one world view? - Does the model reflect characteristics of more than one category of nursing knowledge? - Do the components of the model consistently reflect logical translation or reformulation of diverse perspectives? - Is the model logically congruent?
Generation of Theory	- What theories have been generated from the nursing model?

Legitimacy of the Nursing Model	- Is the nursing model a useful guide for nursing activities? - Does evaluation of the use of the nursing model reveal that the content of the nursing model is sound and believable? - Are education and special skill training required before applying the nursing model in nursing practice? - Is it feasible to implement practice protocols derived from the nursing model and related theories? - To what extent is the nursing model actually used to guide nursing practice, research, education and administration? - Does the nursing model lead to nursing activities that meet the expectations of the public and health-care professionals of various cultures and in diverse geographic regions? - Does application of the nursing model, when linked with relevant theories and appropriate empirical indicators, make important differences in the health conditions of the public?
Contribution to Nursing Knowledge and the Discipline of Nursing	- What is the overall contribution of the nursing model to advancement of nursing knowledge the discipline of nursing?

Table A2

Leininger's Sunrise Model (Leininger & McFarland, 2002)

Explication of Origins	- The philosophical claims on which the model is based are explicit: a) human beings exist in diverse cultures; b) nursing as a profession has a moral responsibility to discover and use culturally-based care when interacting with clients of diverse cultures. - The Sunrise Model was founded by Leininger (founder of transcultural nursing). Her personal experiences leading to the development of the model are discussed. Her work does not stem from any previous scholar or theorist, so no citations and references to acknowledge influencing authors are mentioned.
Comprehensiveness of Content	- Adequate descriptions are provided for ***human beings*** (belonging to diverse cultures presenting some universal attributes), ***environment*** (physical, geographical, and sociocultural), ***health*** (state of well-being/restorative state

	that is culturally structured by individuals/groups in order to function in daily life), and <u>*transcultural nursing*</u> (focusing on humanistic and scientific knowledge/practices focused on holistic culture care). - The relational propositions of the model link the four metaparadigm concepts as depicted by bidirectional arrows which show how human beings are influenced by cultural and social dimensions in the environment and how those factors in turn influence the health of clients and nursing care. - The researcher is given sufficient direction about the types of questions to ask and what skills and attributes the nurse should possess in asking those assessment questions that lead to clients openly sharing their stories. - The administrator of the model has guidelines to base his/her decision making using three action/decision modes.
Logical Congruence	- The model reflects an interpretivist worldview by emphasizing the co-participation between the healthcare provider and the client to determine the culturally tailored care. - Logical congruency noted between the philosophical assumptions, the concepts, and the linkages between these concepts. Some lack of clarity present as the factors that influence the cultural and social dimensions are not defined and left up to the interpretation of the author (for instance, technological factors).
Generation of Theory	- The model has been generated from the Theory of Culture Care Diversity and Universality.
Legitimacy of the Nursing Model	- The model is a useful guide for nursing activities as it presents a holistic view by presenting cultural and social dimensions that can influence care practices within a culture. These influencers can be *kinship and social factors, economic factors, political factors* and so on, that can all influence the care of individuals, families and communities of a given culture. The co-participation between the healthcare provider and the individual/family/community ensures that health decision making is culturally-tailored. The three action/decision modes guide the decision making process. - The model is quite broad in scope, thus, can be applied in diverse settings. When linked with the Culture Care Theory, this model has the potential to make health care interventions and care practices more sustainable among clients due to the emphasis on its co-participation element and the involvement of clients/families in their health care decision making. - Healthcare providers may require education in the area of transcultural nursing in order to apply the model.
Contribution to Nursing Knowledge and the Discipline of Nursing	- The model contributes greatly to advancement of nursing knowledge and the discipline of nursing in the context of nursing in Western countries where immigration has lead to great diversity of individuals. Such a model can guide the fundamentals of health assessment so that care planning is culturally sensitive and health outcomes can be improved.

Table A3

Purnell's Model for Cultural Competence (Purnell, 2002, 2005)

Explication of Origins	- 21 assumptions for culture are listed, forming the basis of the model. One assumption mentions the concept of co-participation between clients and healthcare providers, but this lacks clarity. - The scholars who influenced the thinking of the model author are not acknowledged, nor are bibliographical citations given.
Comprehensiveness of Content	- Adequate descriptions of ***health*** and ***human beings*** are provided which discuss the person, family and health. The metaparadigm concept of ***environment*** is partly described in the definitions provided under the model concepts of *Community* and *Global Society*, however the author does not discuss things like access to resources (accessibility) that may also constitute as being part of the environment. The metaparadigm of ***nursing*** is not discussed and is absent from the model. - The relational propositions link the concepts of ***human beings*** and ***health***; however it is unclear how the metaparadigm concept of ***environment*** links with the other concepts, based on how it is pictorially represented in the model (solid circular lines seem to make it a separate entity, rather than being interconnected). - The model provides a good assessment tool to guide data collection from persons/groups from a cultural perspective however, it does not provide directions to execute a course of action. - Lack of clarity as to why there are concepts like *Death Rituals*, *Pregnancy* and *Workforce Issues* as these domains tie into the overarching broader domains such as *Overview/Heritage*, *Health-care Practices* and *Spirituality* (creates unnecessary overlap between the domains and crowds the model). Also, solid lines in the outer circles between *Global Society*, *Community*, *Family* and *Person* convey that each of these paradigms are separate, however a person may belong within a family, which may belong in the community, which is in the global society, meaning that all of these paradigms are interconnected and not separate. Perhaps the use of dotted lines could better convey this.
Logical Congruence	- Unclear worldview that undermines this model. - The model reflects characteristics of the transcultural domain of healthcare knowledge. - For the most part, the model demonstrates logical congruency between its concepts, however the pictorial diagram of the model does not clearly depict the ***environment*** metaparadigm; it does not provide direction for the healthcare provider to aid in decision-making that is culturally sensitive in the practice setting; the zigzag line near the bottom of the model is not reflective of a nonlinear concept of cultural consciousness and the dark centre in the

	middle is ambiguous and not clearly discussed (dark circle represents unknown phenomenon – what are these unknown phenomenon? How are they managed, overcome, dealt with?).
Generation of Theory	- The author identifies this as a model/framework, however there is scholarly controversy as to whether this model should be classified as a conceptual model, a grand theory (or a middle range theory).
Legitimacy of the Nursing Model	- Some minor flaws have been identified in the model and the pictorial representation of the model. - Education and special skill training may be necessary for healthcare providers to be familiar with the phenomenon of transculturalism in healthcare and thus, the applicability and utility of this model in practice. - The author stats that this model has been used to guide clinical practice, education, administration, and research in USA, Canada, Central America and Europe.
Contribution to Nursing Knowledge and the Discipline of Nursing	- Same as previously noted in Table A2.

Table A4

Campinha-Bacote's Process of Cultural Competence in the Delivery of Healthcare Services (Campinha-Bacote, 2002)

Explication of Origins	- The philosophical underpinnings of the model are not discussed, but underlying assumptions of the model are described. - There is acknowledgement of the scholars who influenced the thinking for this model (Leininger and Pedersen). - Philosophical claims are partly described by the author's personal experiences that contributed in the development of this model.
Comprehensiveness of Content	- The definitions of the metaparadigm concepts of nursing (*human beings*, *environment* and *health*) are not discussed. The emphasis of the description in the theoretical paper is on the healthcare provider. - The relational propositions do not completely link the four metaparadigm concepts as these metaparadigm concepts lack definitions within the model. The author's focus is on assessing the concept of cultural competence

	of the healthcare provider (self-assessment of the healthcare provider to deliver culturally competent care). - The pneumonic ASKED (awareness, skill, knowledge, encounters, desire) provides self-assessment questions for the healthcare provider to assess his/her level of cultural competence in delivering care. The *Inventory for Assessing the Process of Cultural Competence Among Healthcare Professionals* has been developed as a self-assessment tool for the healthcare provider, however, no directions are provided on developing a course of action to aid in decision making after the tool is completed.
Logical Congruence	- Lack of clarity provided to determine the worldview that undermines this model. - The model reflects characteristics of the transcultural domain of healthcare. - Since the model lacks underlying definitions of key concepts of the metaparadigm, such as <u>*health*</u>, <u>*environment*</u> and <u>*human beings*</u>, it is difficult to say that the model is logically congruent. Health and the environment highly influence the nature of healthcare delivery and the perception of well-being and illness (for the client) and the management of diseases/chronic illness. This limitation signified a major gap in the model.
Generation of Theory	- The theoretical paper of this model does not identify the development of any theories.
Legitimacy of the Nursing Model	- The model is a useful guide for a healthcare provider to conduct a self-assessment to assess his/her level of cultural competence in providing care to a diverse population. The emphasis of this model is on the healthcare provider, not the client. - As mentioned previously, the lack of mention of the metaparadigm concept of <u>*health*</u> and the <u>*environment*</u> present major gaps in this model. Since the focus of this model is on the healthcare provider and not the client, it makes it difficult to determine its credibility in using the model for client assessment. Also to note, the author has refined her model and updated it in the year 2010, as mentioned on her website. However, the theoretical paper/publication remains unavailable. This makes it difficult to judge the legitimacy of the model.
Contribution to Nursing Knowledge and the Discipline of Nursing	- Same as previously noted in Table A2.

Table A5

Giger & Davidhizar's Transcultural Assessment Model (Giger & Davidhizar, 2002, 2008)

Explication of Origins	- The philosophical assumptions are not clearly described per se, but the assumptions/definitions of what culture entails, are described. - The scholars who influenced the thinking of the model author are acknowledged and their bibliographical citations are provided. These authors are Leininger; Spector; Orque, Bloch & Monrroy; Hall.
Comprehensiveness of Content	- The model provides descriptions of the metaparadigm concepts of ***nursing*** (as described by the definition of transcultural nursing), ***human beings*** [(defined by the concept of *Culturally Unique Individuals* "... a product of past experiences, cultural beliefs and cultural norms" (Giger & Davidhizar, 2002, p.187)], ***environment*** (defined by the concept of *Environmental Control* which includes cultural health practices of the individual values and their definition of health and illness), and ***health*** ["based on culturally specific illness and wellness behaviours – an individual's cultural beliefs, values, and attitudes all contribute to the overarching meaning of health for each individual" (Giger & Davidhizar, 2002, p.187)]. The author does not specify human beings as either being individuals, families, communities). - The concepts of the model link well to the four metaparadigm concepts. - This model provides the healthcare provider (particularly nurses), with a set of questions for each of the model concepts (*Culturally Unique Individuals, Communication, Space, Social Organization, Time, Environmental Control and Biological Variations*). Each of these concepts is subdivided into relevant assessment questions that can be asked to the client to gain a holistic understanding of the individual's culture and health status/views. This overall assessment is identified as "*Nursing Assessment*" which specifies this model for the nursing profession. - The sole focus of this model is to gather assessment data, so the healthcare provider is not given a prescribed/guided element in the framework that enables the execution of a course of action or how decision making can take place from the assessment data that is collected.
Logical Congruence	- Unsure of the worldview that undermines this model (interpretivist?) - The model reflects characteristics of the Transcultural domain of (nursing) knowledge and the assessment guide provided within the model appears very conducive to nursing - Overall, the model is logically congruent, as the underlying assumptions of the authors demonstrate congruency

	with the actual Transcultural Assessment Model. The model provides a guide to gather assessment data, but severely lacks in the "What next" as no direction is given to the healthcare provider of what to do with the collected assessment data. - The pictorial representation of the model has a focus on the *Culturally Unique Individual*, which forms a central link to all the other concepts in the model. However pictorially, the model is represented in a very linear fashion which denotes a "start" and "end" point in the model. The model would be more "fluid" if it was represented as a process, with no definitive start or end point. This linear representation of the model is not congruent with the authors' definition of "culturally competent care: a dynamic, fluid, continuous process whereby an individual, system, or health care agency finds meaningful and useful care delivery strategies based on knowledge of the cultural heritage, beliefs, attitudes and behaviours of those to whom they render care" (Giger & Davidhizar, 2002, p. 187).
Generation of Theory	- The theoretical papers of this model do not identify the development of any theories.
Legitimacy of the Nursing Model	- The evaluation of this model demonstrates that it is a fair assessment tool to gather data from the client for his/her cultural practices, values, beliefs and cultural norms. The model does omit certain important data collecting domains that might be important for the healthcare provider to know such as the client's education level. Also, the authors list "church" as a subcategory under their concept of *Social Orientation*. That term ought to be changed to something more generic such as "faith" to make it applicable to a diverse population. Also, under the concept of *Time*, a proposed statement to gather data from the client is listed as "Sleeps at least 8 hours at night" (Giger & Davidhizar, 2008, p. 10). Again, this statement is very limiting because it is not open-ended to include those clients who may be employed in shift work and may not be able to sleep at night, but rather in the day. One of the definite limitations in this assessment guide is that some of the questions are close-ended and lack open-endedness that is necessary to enable the client to speak openly with the healthcare provider. - Unfortunately, the model does lack the next step as to what the decision making process should entail after the assessment data has been collected from the client. - Healthcare providers who wish to apply this model in their practice may require education in the area of transcultural healthcare/nursing to understand the underlying concepts that govern this area of healthcare/nursing.
Contribution to Nursing Knowledge and the Discipline of Nursing	- Same as previously noted in Table A2.

Table A6

Spector's Health Traditions Model (Spector, 2002, 2009)

Explication of Origins	- The author lists her assumptions that form the basis of the model – "The assumption is that there is a relationship in people between strong identities – either with one's heritage or the level at which one is acculturated into the dominant culture – and its health beliefs and practices" (Spector, 2002, p. 198). - The author mentions "basic nursing, community/public health nursing theory, sociology, and political awareness related to the plethora of ethnocultural and social issues that are integrated in this text" (Spector, 2002, p. 198) as the resources upon which this model is based, however, no specific authors who influenced the development of this model are acknowledged.
Comprehensiveness of Content	- The model provides definitions for the metaparadigm concept of ***human being*** in its definition for *Patient*; ***environment*** in its definition of *Environment* (this definition is quite vague and requires further explanation from the author to enhance clarity); and a definition of ***health*** in its definition of *Health*. The model does not provide a definition for the metaparadigm concept of ***nursing***. - The concepts of this model link to the metaparadigm concepts of ***nursing*** in this model, however the actual definition for the metaparadigm concept of nursing is not discussed. - This model is depicted in two figures/tables in the author's text, which seem quite similar in nature (Spector, 2009). The author does not provide a comparison or description of these two figures, so it presents a lack of clarity on the part of the reader to interpret these figures. The figures consist of a table of nine parts divided into *Maintain Health*, *Protect Health* and *Restore Health* along the vertical axis and *Physical*, *Mental* and *Spiritual* along the horizontal axis. It is hard to interpret the differences between the two figures as they present quite similar information. It can be assumed that the contents of the nine parts in the figure/table warrant assessment topics for the healthcare provider to consider when gathering cultural assessment data related to the client's health, values, beliefs. - This model does not provide any next steps as to what to do next with the gathered assessment information that is collected from the client. There is no concept in the model that highlights an execution of a course of action. - The model solely focuses on traditions of the client, as the name of the model suggests, and thus, it eliminates crucial aspects of the environment of the client, such as education status, work life, financial status and accessibility to (health) resources which can reveal important information about the client to be taken into consideration when developing a culturally-tailored plan of care.

Logical Congruence	- Lack of clarity to determine the worldview that undermines this model. - The model reflects characteristics of the transcultural domain of (nursing) knowledge, however the author has not discussed the metaparadigm of nursing in the model. - There is congruency between the author's stated assumptions, definitions and the elements of the conceptual model itself. However, as stated previously, the model lacks some important environmental considerations that should be added to the healthcare provider's assessment in addition to the aspects of the client's health traditions, as this information is necessary to aid in decision making and implementation of a plan of care. In this sense, the model is not very holistic in nature.
Generation of Theory	- The theoretical papers of this model do not identify any theories.
Legitimacy of the Nursing Model	- This nursing model is a fair guide for nursing activities because it does not provide a holistic view in terms of examining a client's culture in the context of the client's health and environment. Health traditions are an important part of the holistic nature of human beings. Clients also live their routine lives which revolve around their employment and financial situations, which can depict their ways of living and being in the world, in addition to social and kinship supports, religious beliefs, cultural norms and traditions amongst many other factors. The fact that the author has decided to focus solely on health traditions, limits how effectively this model can be implemented in practice. - Healthcare providers who wish to apply this model in their practice settings may require education in the area of transcultural healthcare/nursing to understand the underlying concepts.
Contribution to Nursing Knowledge and the Discipline of Nursing	- Same as previously noted in Table A2.

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Appendix B

Final Search Strategy by Different Search Engines

Table B1

Medline search strategy (n = 368) identified by search terms for the population and intervention

Search Number	Search Term
1	Patient Education as Topic/
2	self care/
3	self-management.tw.
4	self-efficacy/
5	motivational interviewing.tw.
6	health coaching.tw.
7	solution focused therapy.tw.
8	support.ti.
9	social support/
10	*health education/
11	*Education/
12	((self or home) adj3 (monitoring or testing)).tw.
13	*patient participation/
14	Blood Glucose Self-Monitoring/
15	(smbg or dsme).tw.
16	empowerment.tw.
17	Health Educators/
18	family involvement.ti.
19	family involvement.tw.
20	or/1-19
21	*Blood Glucose Self-Monitoring/
22	(smbg or dsme).tw. or ((diabetes or diabetic) and education).ti.
23	21 or 22
24	(pediatric* or paediatric* or child* or adolescent?).jn.
25	(pediatric* or paediatric* or child* or adolescent? or youth? or teenager? or teen?).ti.
26	(gestation* or pregnan*).ti.
27	exp Asian Continental Ancestry Group/
28	exp India/ or india*.mp.
29	indian*.mp.
30	exp Bangladesh/ or exp india/ or exp Nepal/ or exp Pakistan/ or

	exp sri lanka/
31	pakistan*.mp.
32	pakistani*.mp.
33	bangladesh*.mp.
34	bengali*.mp.
35	nepal*.mp.
36	(Srilanka* or Sri Lanka*).mp.
37	asian canad*.mp.
38	south asian*.mp.
39	indo Canadian*.mp.
40	indo asian*.mp.
41	or/27-40
42	exp diabetes mellitus, type 2/
43	(type 2 diabetes or adult onset diabetes).ti.
44	(type 2 diabetes or adult onset diabetes).ab. /freq=3
45	diabetes mellitus/ not diabetes mellitus, type 1/
46	or/42-45
47	20 and 46
48	23 or 47
49	41 and 48
50	limit 49 to english language
51	limit 50 to (comment or editorial or letter or news or newspaper article)
52	50 not 51
53	24 or 25 or 26
54	52 not 53

Table B2

EMBASE search strategy (n = 975) identified by search terms for the population and intervention

Search Number	Search Term
1	patient education/
2	exp self care/
3	self-management.tw.
4	self-efficacy.mp.
5	motivational interviewing.tw.
6	health coaching.tw.
7	solution focused therapy.tw.
8	support.ti.

9	social support/
10	health education/ or diabetes education/
11	education/ or adult education/
12	((self or home) adj3 (monitoring or testing)).tw.
13	patient participation/
14	blood glucose monitoring/
15	(smbg or dsme).tw.
16	empowerment.tw.
17	health educator/ or diabetes educator/
18	family involvement.ti.
19	family involvement.tw.
20	or/1-19
21	blood glucose monitoring/
22	(smbg or dsme).tw. or ((diabetes or diabetic) and education).ti.
23	21 or 22
24	(pediatric* or paediatric* or child* or adolescent?).jn.
25	(pediatric* or paediatric* or child* or adolescent? or youth? or teenager? or teen?).ti.
26	(gestation* or pregnan*).ti.
27	asian continental ancestry group/
28	India/
29	india*.mp.
30	Indian/
31	Bangladeshi/
32	Nepal/
33	Pakistan/
34	Sri Lanka/
35	pakistan*.mp.
36	pakistani*.mp.
37	pakistani/
38	bangladesh*.mp.
39	bengali*.mp.
40	“bengali (people)”/
41	nepal*.mp.
42	nepalese/
43	Srilanka*.mp.
44	Sri Lanka*.mp.
45	sri lankan/
46	asian canad*.mp.
47	south asian*.mp.
48	south asian/ or bangladeshi/ or indian/ or nepalese/ or pakistani/ or sri lankan/
49	indo canadian*.mp.
50	indo asian*.mp.

51	or/27-50
52	diabetes mellitus/
53	exp non insulin dependent diabetes mellitus/ or exp insulin dependent diabetes mellitus/
54	(type 2 diabetes or adult onset diabetes).ti.
55	(type 2 diabetes or adult onset diabetes).ab. /freq=3
56	diabetes mellitus/
57	diabetes mellitus, type 1.mp.
58	56 not 57
59	or/52-58
60	20 and 59
61	23 or 60
62	51 and 61
63	limit 62 to English language
64	limit 63 to (book or book series or editorial or letter or note)
65	63 not 64
66	24 or 25 or 26
67	65 not 66

Table B3

Cochrane CENTRAL search strategy (n = 57) identified by search terms for the population and intervention

Search Number	Search Term
1	MeSH descriptor: [Patient Education as Topic] this term only
2	MeSH descriptor: [Self Care] this term only
3	self-management (Word variations have been searched)
4	MeSH descriptor: [Self Efficacy] this term only
5	"motivational interviewing" (Word variations have been searched)
6	"health coaching" (Word variations have been searched)
7	"solution focused therapy" (Word variations have been searched)
8	support:ti (Word variations have been searched)
9	MeSH descriptor: [Health Education] this term only
10	MeSH descriptor: [Education] this term only
11	((self or home) near/3 (monitoring or testing)) (Word variations have been searched)
12	MeSH descriptor: [Patient Participation] this term only
13	MeSH descriptor: [Blood Glucose Self-Monitoring] this term

	only
14	(smbg or dsme) (Word variations have been searched)
15	empowerment (Word variations have been searched)
16	MeSH descriptor: [Health Educators] this term only
17	"family involvement":ti (Word variations have been searched)
18	{or #11-#17}
19	MeSH descriptor: [Blood Glucose Self-Monitoring] this term only
20	(smbg or dsme) or ((diabetes or diabetic) and education):ti (Word variations have been searched)
21	#19 or #20
22	(pediatric* or paediatric* or child* or adolescent?):ti,ab,kw (Word variations have been searched)
23	(pediatric* or paediatric* or child* or adolescent? or youth? or teenager? or teen?):ti (Word variations have been searched)
24	(gestation* or pregnan*):ti (Word variations have been searched)
25	MeSH descriptor: [Asian Continental Ancestry Group] 1 tree(s) exploded
26	MeSH descriptor: [India] 1 tree(s) exploded
27	india*:ti,ab,kw (Word variations have been searched)
28	indian*:ti,ab,kw (Word variations have been searched)
29	MeSH descriptor: [Bangladesh] 1 tree(s) exploded
30	MeSH descriptor: [Nepal] 1 tree(s) exploded
31	MeSH descriptor: [Pakistan] 1 tree(s) exploded
32	MeSH descriptor: [Sri Lanka] 2 tree(s) exploded
33	pakistan*:ti,ab, kw (Word variations have been searched)
34	pakistani*:ti,ab,kw (Word variations have been searched)
35	bangladesh*:ti,ab,kw (Word variations have been searched)
36	bengali*:ti,ab,kw (Word variations have been searched)
37	nepal*:ti,ab,kw (Word variations have been searched)
38	(Srilanka* or Sri Lanka*):ti,ab,kw (Word variations have been searched)
39	asian next canad*:ti,ab,kw (Word variations have been searched)
40	south next asian*:ti,ab,kw (Word variations have been searched)
41	indo next asian*:ti,ab,kw (Word variations have been searched)
42	{or #25-#41}
43	MeSH descriptor: [Diabetes Mellitus, Type 2] explode all tress
44	type 2 diabetes:ti or adult onset diabetes:ti (Word variations have been searched)
45	type 2 diabetes:ti,ab,kw or adult onset diabetes:ti,ab,kw (Word variations have been searched)

46	MeSH descriptor: [Diabetes Mellitus] this term only
47	MeSH descriptor: [Diabetes Mellitus, Type 1] this term only
48	#46 not #47
49	{or #43-#48}
50	#18 and #49
51	#21 or #50
52	#42 and #51
53	#22 or #23 or #24
54	#52 not #53

Table B4

CINAHL search strategy (n = 210) identified by search terms for the population and intervention

Search Number	Search Term
1	(MM "Patient Education") OR (MH "Diabetes Education")
2	(MM "Self Care") OR (MH "Blood Glucose Self-Monitoring")
3	TX self-management
4	(MH "Self-Efficacy")
5	TX motivational interviewing
6	TX health coaching
7	TX solution focused therapy
8	TI support
9	(MM "Health Education")
10	(MM "Education")
11	(MH "Adult Education")
12	TX ((self or home) N3 (monitoring or testing))
13	(MH "Consumer Participation")
14	(MH "Blood Glucose Self-Monitoring")
15	(MH "Blood Glucose Self-Monitoring)
16	"diabetes self management education"
17	S15 OR S16
18	TX empowerment
19	(MH "Health Educators") OR (MH "Diabetes Educators")
20	TI family involvement
21	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20
22	(MH "Blood Glucose Self-Monitoring")
23	TX self-monitoring of blood glucose OR TX diabetes self

	management education
24	(MH "Diabetes Mellitus, Type 2") OR (MH "Diabetic Patients")
25	S23 OR S24 AND education
26	S22 OR S25
27	JT pediatric* OR JT paediatric* OR JT child* OR JT adolescent
28	TI pediatric* OR TI paediatric* OR TI child* OR TI adolescent OR TI youth OR TI teenager OR TI teen
29	TI gestation* OR TI pregnan*
30	(MH "Bangladesh") OR (MH "Asia, Western") OR (MH "India") OR (MH "Nepal") OR (MH "Pakistan") OR (MH "Sri Lanka")
31	TX indian*
32	TX pakistani*
33	TX bangladesh*
34	TX bengali*
35	TX nepal*
36	TX Srilanka* OR TX Sri Lanka*
37	TX india*
38	TX pakistan*
39	TX asian canad*
40	TX south asian*
41	TX indo canadian*
42	TX indo asian*
43	S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42
44	(MH "Diabetes Mellitus, Type 2")
45	TI type 2 diabetes OR TI adult onset diabetes
46	AB type 2 diabetes OR AB adult onset diabetes
47	(MM "Diabetes Mellitus") OR (MH "Diabetes Mellitus, Type 2")
48	(MM "Diabetes Mellitus, Type 1")
49	S47 NOT S48
50	S44 OR S45 OR S46 OR S47 OR S48 OR S49
51	S21 AND S50
52	S26 OR S51
53	S43 AND S52
54	S53 – Limiters – English Language
55	S54 – Limiters – Publication Type: Abstract, Academic Journal, Algorithm, Biography, Care Plan, Case Study, CEU, Classification Term, Clinical Trial, Code of Ethics, Computer Program, Consumer/Patient Teaching Materials, Corrected Article, Critical Path, Diagnostic Images, Directories, Doctoral

	Dissertation, Equations & Formulas, Historical Material, Journal Article, Masters Thesis, Meta Analysis, Meta Synthesis, Nurse Practice Acts, Nursing Diagnoses, Nursing Interventions, Periodical Practice Acts, Practice Guidelines, Proceedings, Protocol, Questionnaire/Scale, Randomized Controlled Trial, Research, Research Instrument, Review, Standards, Statistics, Systematic Review, Tables/Charts, Teaching Materials, Tracings, Trade Publication
56	S27 OR S28 OR S29
57	S55 NOT S56

Appendix C

Title and Abstract Screening Form

Question	Response
1. Is the research study in the English language?	Yes – No – Unclear
2. Is the research study about type 2 diabetes?	Yes – No – Unclear
3. Is the population being studied classified as belonging to South Asian descent (South Asian countries to include: India, Pakistan, Sri Lanka, and/or Bangladesh)?	Yes – No – Unclear
4. Is this a randomized control trial/non-randomized study with a comparison group?	Yes – No – Unclear

Appendix D

Full Text Screening Form

Question	Response
1. Is the research study about type 2 diabetes?	Yes – No – Unclear
2. Is the population being studied classified as adults (18 years of age or older) belonging to South Asian descent (South Asian countries to include: India, Pakistan, Sri Lanka, and/or Bangladesh)?	Yes – No – Unclear
3. Does this research study involve participants who are residing in their native country (i.e., India, Pakistan, Sri Lanka and/or Bangladesh)? (*Please exclude if Yes)**	Yes – No – Unclear
4. Is this a randomized control trial/non-randomized study with a comparison group?	Yes – No – Unclear
5. Is the intervention about diabetes self-management education and/or support [(targeting knowledge and skills development, behavioural, or psychological interventions, i.e., counseling, behaviour change, self-management, or something that fits the description of education)	Yes – No – Unclear

	(*Please exclude if the intervention is training for a new insulin or drug – intervention must be focused on diabetes education and/or support)?**	
6.	**Does the intervention have at least one component that is delivered by a healthcare provider?** **(***Please exclude if No)**	Yes – No – Unclear
7.	**Does the outcome to be measured include A1C as a continuous outcome (i.e., mean, median or standard deviation)?**	Yes – No – Unclear

Appendix E

Data Extraction Form 1 – Study Characteristics

Study ID:

Citation:

Study Design:

Study Duration:

Study Setting:

Funding Source:

Participant Demographics

	Intervention Group	Control Group
Age of participants (mean, standard deviation, percentages)		
Sample size	Beginning of study: End of study:	Beginning of study: End of study:
Male to female split		
Length of diabetes duration		
Type of diabetes treatment (lifestyle, oral antihyperglycemic agents,		

insulin, or a combination)		
Specific cultural background		
Baseline A1C as mean (SD)		

Results

Estimation of treatment effect:

P-Values	
Mean (HbA1c as %) & Confidence Interval	
Standard Deviations	

Conclusion of Study Findings

Study Included:

Study Excluded:

Reason of exclusion if study is excluded:

Appendix F

Data Extraction Form 2 – Leininger's Sunrise Model

Study ID:

Citation:

Brief description of study intervention:

Cultural and Social Structure Dimensions

Technological Factors	
Religious & Philosophical Factors	
Kinship & Social Factors	
Cultural Values, Beliefs & Lifeways	
Political & Legal Factors	
Economic Factors	
Educational Factors	

Transcultural Care Decisions & Actions (Check mark all that apply):

Culture Care Preservation/Maintenance:

Culture Care Accommodation/Negotiation:

Culture Care Repatterning/Restructuring:

Appendix G

Risk of Bias Assessment Form

Study ID:

Citation:

Domain	**Description**	**Judgement of Review Author**
Sequence generation		
Allocation concealment		
Blinding of participants, personnel, and outcome assessors		
Incomplete outcome data		
Selective outcome reporting		
Other sources of bias (i.e., co-intervention, contamination, confounders)		