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The University of Southern Mississippi

EFFICACY OF BEHAVIORAL INTERVENTIONS IN AFRICAN AMERICANS WITH TYPE II DIABETES: A COMPARATIVE EFFECTIVENESS ANALYSIS

by

Tangela Nicole Hales

Abstract of a Dissertation Submitted to the Graduate School of The University of Southern Mississippi in Partial Fulfillment of the Requirements for the Degree of Doctor of Philosophy



ABSTRACT

EFFICACY OF BEHAVIORAL INTERVENTIONS IN AFRICAN AMERICANS WITH TYPE II DIABETES: A COMPARATIVE EFFECTIVENESS ANALYSIS by Tangela Nicole Hales

May 2015

Context: The efficiency and effectiveness of the healthcare system are prime foci for nursing research.

Objective: The purpose of this study was to review and critically appraise the current state of the evidence in the treatment of African American adults with type II diabetes. To address this objective, a systematic review was undertaken that investigated the comparative effectiveness of behavioral interventions in improving glycemic control.

Methods: Robust methodological approaches to comparative effectiveness research (CER) serve to improve the transparency, consistency, and scientific rigor of the research. The methods for this systematic review of literature followed those recommended in the Agency of Healthcare Research Quality's (AHRQ) Methods Guide for Effectiveness and Comparative Effectiveness Reviews (2014). Searches for the review were conducted in Medline, Cochrane Central Register of Controlled Trials, CINAHL, Psych Info, Google scholar, and clinicaltrials.org using a precise replicable strategy. All methods were determined a priori.



Results: Fourteen articles met the inclusion criteria for this analysis. Nine of the 14 articles reported positive changes in glycemic control between the intervention group and the control/usual care group. Articles were qualitatively synthesized and the methodological quality of each article was assessed. Characteristics of successful interventions involved the use of a nurse educator, the empowerment theory, and incentives to promote behavior change.

Conclusion: The findings of this review highlighted that the available evidence is of strong quality. The majority of the studies (64%) reported positive results, indicating that the clinical benefit of this treatment approach in achieving glycemic control is effective. Results from this study are qualitative and are intended to guide future research. Prospective research studies should explore the impact of behavioral interventions in African American adults with type II diabetes on different outcomes, such as self-efficacy, psychological well-being, mindfulness, and coping.



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A Dissertation Submitted to the Graduate School of The University of Southern Mississippi in Partial Fulfillment of the Requirements for the Degree of Doctor of Philosophy

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Dean of the Graduate School

May 2015



DEDICATION

This dissertation is dedicated to all of my family and friends. My deepest appreciation is expressed to them for their prayers, love, understanding, and inspiration. Without their blessings and encouragement, I would not have been able to finish this work.



ACKNOWLEDGMENTS

I would like to express my deepest gratitude to my Chair, Dr. Lachel Story for her mentorship, guidance, and support throughout out my doctoral training at The University of Southern Mississippi College of Nursing. Dr. Story has been instrumental in my growth and development as a student from the beginning of my nursing career journey until now. Special thanks go to my committee members: Dr. Janie Butts, Dr. Bonnie Harbough, Dr. Patsy Anderson, and Dr. Alyce Adams for their guidance and expertise throughout this journey.

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LIST OF ABBREVIATIONS



ACA Affordable Care Act

ACO Accountable Care Organization

ADA American Diabetes Association

AADE American Association of Diabetes Educators

AHEAD Action for Health in Diabetes

AHRQ Agency of Healthcare Research Quality

ANA American Nurses Association

ARRA American Recovery Reinvestment Act

BMI Body Mass Index

BP Blood Pressure

CER Comparative Effectiveness Research

CDC Centers for Disease Control

CDE Certified Diabetes Educator

CI Confidence Interval

CINAHL Cumulative Index to Nursing and Allied Health Literature

CHW Community Health Worker

CVD Cardiovascular Disease

DARE Diabetes Aerobic and Resistance Exercise Trial

DCCT Diabetes Complications Control Trial

DHHS Department of Health and Human Services

DPP Diabetes Prevention Program

Diabetes Support and Education

DSME Diabetes Self-Management Education



ED Emergency Department

ERIC Education Resource Information Center

FQHC Federally Qualified Health Center

HART-D Health Benefits of Aerobic and Resistance Training in Diabetes

HbA1c Hemoglobin A1c

IDEA Interactive Dialogue to Educate and Activate

IGT Impaired Glucose Tolerance

IOM Institute of Medicine

ILI Intensive Lifestyle Intervention

LDL Glycosated Low Density Lipoprotein

MEDLINE Medical Literature Analysis and Retrieval System Online

MI Motivational Interviewing

MNT Medical Nutrition Therapy

MSSP Medicare Shared Savings Program

PCMH Patient Centered Medical Home

PCORI Patient-Centered Outcomes Research Institute

PICOTS Population, Intervention, Comparator, Outcomes, Time, Setting

PUBMED Public MEDLINE

QOL Quality of Life

RCT Randomized Controlled Trial

SDM Shared Decision-Making

SR Systematic Review

UKPDS United Kingdom Prospective Diabetes Study





CHAPTER I

INTRODUCTION

Nurse leaders play an indispensable role in shaping the nursing profession to be more responsive to the demands of our constantly changing healthcare system. The 2011 Institute of Medicine (IOM) Report, *The Future of Nursing: Nursing Leading Change and Advancing Health*, recommended that nurses should be full partners with physicians and other healthcare professionals in redesigning health care in the United States (U.S). The IOM's call to nursing gives rise to leadership roles in the healthcare system that transcend beyond concomitant perceptions of the nursing profession. As the single largest unit of healthcare professionals in the nation, nurses are in a pivotal position to become key players in healthcare system transformation. The American Nurses Association (ANA) noted that nurses are fundamental to the critical shift needed in health service delivery with the goal of transforming the current "sick care" system into a true "healthcare" system (ANA, 2014).

The *Patient Protection and Affordable Care Act of 2010* (ACA) PL-111-48 heralds a plethora of opportunities for researchers, healthcare providers, and policymakers concerned with measures aimed at promoting quality health care and ameliorating rising healthcare costs. Whilst the U.S. healthcare system has made great strides in advancing health care, there is still a wide consensus that large gaps exist between quality healthcare and healthcare outcomes (IOM Committee on Quality of Health Care in America, 2001; Manchikanti, 2008; McClellan, 2011; Yong, Saunders, & Olsen, 2010). In other words, the outcomes do not match the investments. Lack of evidence regarding the scientific certainty of the effectiveness of medical treatments has



been identified as a significant source of ineptitude in America's healthcare system (Fineberg, 2012).

The ACA, to its credit, recognized this fatal flaw in the U.S. healthcare system and brought to the forefront a burgeoning research paradigm entitled comparative effectiveness research (CER). As an impetus to drive CER efforts, the *American Recovery and Reinvestment Act (ARRA) of 2009* (P.L. 111-5) allocated \$1.1 billion to national public service entities to promote the new research agenda. In the fresh wave of research enthusiasm, CER has received widespread attention as a potential approach to improving health outcomes, lowering healthcare costs, and progressing the relevance and quality of clinical and health services research (Tunis, Benner, & McClellan, 2010).

Nursing Science, Knowledge, and Research

In her seminal work, *The Fundamental Patterns of Knowing in Nursing*, author Barbara Carper (1978) suggested that there are ethical, personal, aesthetic, and empirical ways of knowing in nursing. The empirical nature of nursing is committed to rigorous scientific inquiry that provides the scientific basis for the practice of the profession. In alignment with my interest in CER as a nurse scientist, this study contributed to the epistemological infrastructure of nursing research on healthcare systems and outcomes.

The effectiveness and efficiency of the healthcare system are prime foci for nursing research. The CER framework is essential for the development of scientific evidence that can help patients, clinicians, and policymakers in making decisions that will advance health care (Hastings-Tolsma, Mathews, Nelson, & Schmiege, 2013). The rigorous scientific integration of research findings extrapolated from CER forms the groundwork to guide practice and policy decision-making. Therefore, the success of the



national investment in CER is contingent on using the power of science to reverse the trajectory of contemporary healthcare trends.

In particular, the context for this comparative effective analysis is the efficacy of behavioral interventions in African American adults with type II diabetes. The literature is replete with evidence that supports the use of behavioral interventions for improving glycemic control in individuals with diabetes. However, the translation of evidence-based behavioral interventions has proven to be challenging in the African American population.

Purpose of the Study

The purpose of this study was to review and critically appraise the current state of evidence in the treatment of African American adults with type II diabetes. To address this objective, a systematic review was undertaken that examined the comparative effectiveness of behavioral interventions in improving glycemic control.

Background of the Study

Diabetes affects approximately 29.1 million people or 9.3% of the U.S. population and is the seventh leading cause of mortality in the U.S. (Centers for Disease Control [CDC], 2014). In 2012, diabetes cost the U.S. \$245 billion (CDC, 2014). Of that, \$176 billion accounted for direct medical costs (e.g. medical care, drugs, insulin, and other supplies), and \$69 million was attributed to indirect costs (e.g. disability, work loss, premature death) (CDC, 2014).

Diabetes is the leading source of new cases of blindness, heart disease, stroke, kidney failure, and lower-limb amputations (CDC, 2011). Diabetes and its associated complications are significant sources of hospitalization and medical expenditures (CDC,



2011; Fraze, Jiang, & Burgess, 2011). In 2010, diabetes accounted for approximately 12.1 million emergency department (ED) visits for adults aged 18 years or older (515 per 10,000 U.S. population), or 9.4% of all ED visits (Washington, Andrews, & Mutter, 2013).

Despite tremendous efforts put forth in the prevention and treatment of diabetes, the prevalence rates are steadily increasing. An estimated 522 million people will be diagnosed globally by 2030 (Boyle et al., 2001). Given the significant impact of diabetes, healthcare systems are aggressively seeking more effective and efficient approaches for preventing and treating the disease.

Statement of the Problem

Whereas diabetes affects all races, a disparate share of the encumbrance falls on the African American population. In 2010, the prevalence of diabetes among African American adults was nearly twice as large as that for Caucasian adults (CDC, 2011). The CDC (2011) found that approximately 4.9 million, or 18.7%, of all African Americans aged 20 years or older have diabetes (CDC, 2011). In 2011, the age-adjusted incidence of diagnosed diabetes was 12.4 per 1,000 in blacks, 11.1 per 1,000 in Hispanics, and 7.0 per 1,000 in Caucasians (CDC, 2014). Figure 1 provides a detailed illustration of the age-adjusted incidence of diabetes by race/ethnicity.

African Americans are almost twice as likely to suffer from type II diabetes and to experience diabetes-related blindness and lower-limb amputations, and two to six times more susceptible to developing kidney disease compared to Caucasians (Brewer-Lowry, Arcury, Bell, & Quandt, 2010). African Americans are 2.2 times as likely as non-Hispanic Whites to die from diabetes (Department of Health and Human Services



[DHHS], 2013). To make matters worse, the rates of diabetes in African Americans have been projected to triple by the year 2050, while the rates in Caucasians have been estimated to only double (Boyle et al., 2001). The high prevalence of type II diabetes in the African American adult population coupled with reports of high rates of complications and mortality informed the aims of this study.

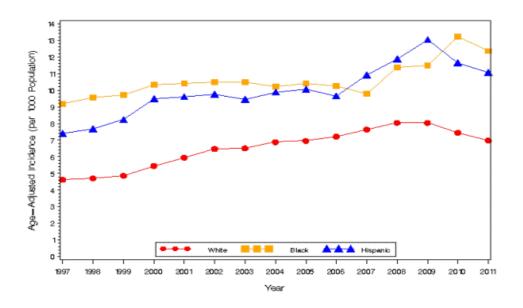


Figure 1. Age-adjusted incidence of diagnosed diabetes per 1,000 population aged 18–79 years, by race/ethnicity, United States, 1997–2011 (CDC, 2014).

Behavioral Interventions

Diabetes requires a lifelong commitment. Deciding on which intervention works best is difficult due to the complex nature of the individual and the complex nature of the chronic, progressive disease. Healthcare providers constantly grapple with how to best support, educate, and work with patients to improve glycemic control. Multiple medications, new technology, needles, dietary restrictions, increased physical activity, and numerous visits to healthcare providers are just a few of the challenges that individuals with diabetes have to face. Patients are encouraged to adopt and adhere to



several self-care or self-management behaviors in order to prevent complications of the disease.

Behavioral interventions are often referred to in the diabetes literature as self-management interventions. The terms are synonymous and are sometimes used interchangeably. For the purposes of this analysis, an operational definition of a *diabetes behavioral intervention* was developed. The definition focuses on *health interventions*, defined as any measure whose purpose is to improve health or alter the course of disease (Dorland, 2007) or an intervention designed to improve the health of a patient or change the conditions, which may have negative impact on the patient's well-being (Jonas, 2005).

The operational definition of a diabetes behavioral intervention is listed below and will be referred to as such throughout the remainder of this manuscript:

A coordinated, non-pharmacological, diabetes-specific, single or multicomponent patient-centered action/program with a duration ≥ 4 weeks that improves glycemic control.

Detailed below are attributes of diabetes behavioral interventions that make their use favorable in treating diabetes:

1. Behavioral interventions facilitate empowerment. Empowerment is an important concept in relation to life with chronic illness as it illuminates and capitalizes on the increased capacity to deal with health problems (Sigurdardottir & Jonsdottir, 2008).
Patient empowerment has been thought to improve patient decision-making. Several interventions based on the empowerment concept have been implemented in diabetes self-management with significant levels of success (Anderson et al., 2005; Anderson,



- Funnell, Fitzgerald, & Marrero, 2000; Hernandez-Tejada et al., 2012; Ho, Berggren, & Dahlborg-Lyckhage, 2010; Raffel, Goddu, & Peek, 2012).
- 2. Behavioral interventions are specific and measurable. The measurable nature of diabetes behavioral interventions both pre-intervention and post-intervention allows for easy data collection. This attribute allows for accurate assessment of the intervention's efficacy. The primary outcome of this study is glycemic control, which is measured by the hemoglobin A1c (HbA1c).
- 3. Behavioral interventions are collaborative between the healthcare provider and the patient. Both parties, the healthcare provider and patient, have to work together in order to achieve mutually exclusive goals.
- 4. Behavioral interventions are conducive to effective policy planning. Policymakers can make better decisions on appropriate strategies to prevent and treat diabetes with various levels of dissemination and implementation.

Comparative Effectiveness Research: A Burgeoning Research Paradigm

When defining what CER is, one must first decide on what is being "compared," how one defines "effectiveness," and area of "research" being investigated (Ratner, Eden, Wolman, Greenfield, & Sox, 2009). Several leading national healthcare organizations have developed definitions of CER to narrow the broad research concept. However, this analysis was based on the central tenets of the widely used IOM definition, "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care" (Ratner et al., 2009, p. 29).



The IOM was instrumental in the development and implementation of CER. The U.S. Congress asked the IOM to define CER and produce a list of top priorities for CER to address by soliciting stakeholder input (Ratner et al., 2009). The IOM responded and released the *Initial National Priorities for Comparative Effectiveness Research* (IOM Committee on Comparative Effectiveness Research Prioritization, 2009). The list of priorities emphasized diseases and conditions with the greatest effects on the healthcare system (Ratner et al., 2009). Diabetes and health disparities were among the top 100 CER priorities.

Patients and stakeholders play an instrumental role in promoting and enhancing CER efforts. Under the ACA, the Patient-Centered Outcomes Research Institute (PCORI) was established. PCORI's agenda is "to assist patients, clinicians, purchasers, and policymakers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed" (Selby, Beal, & Frank, 2012, p. 4). The efforts of CER and PCORI offer valuable and efficacious solutions for the public and provide answers to today's pressing healthcare issues.

Rationale for an Evidence Review

No evidence of any comparative effectiveness reviews focusing on efficacy of behavioral interventions in African Americans adults with type II diabetes was identified in the literature. However, previous comparative effectiveness reviews on topics relevant to this review have been identified that involved the use of behavioral and psychological

interventions. Table 1 provides a list of existing comparative effectiveness studies in the diabetes literature.

This comparative effectiveness study built upon existing scholarship by identifying and investigating factors contributing to the effectiveness of single and multicomponent diabetes behavioral interventions targeted at African Americans adults. A diverse evidence base exists supporting the effectiveness of diabetes behavioral interventions for African American adults with type II diabetes; however, which combination(s) of program components and delivery mechanisms are most effective for their success is unknown. Therefore, a comparative effectiveness review is warranted in this area of and will add to the body of knowledge of diabetes treatment and management.

Table 1

Previous Comparative Effectiveness Studies in Diabetes

Reference	Diabetes-Practice Context	Title of Study
Miller, Kristeller, Headings, Nagaraja, & Miser (2012)	Mindful eating	Comparative Effectiveness of a Mindful Eating Intervention to a Diabetes Self-Management Intervention among Adults with Type II Diabetes: A Pilot Study.
Naik, Teal, Rodriguez, & Haidet (2011)	Diabetes Education	Knowing the ABCs: A Comparative Effectiveness Study of Two Methods of Diabetes Education.

Table 1	(continued).
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Naik et al., (2011)	Goal Setting	Comparative Effectiveness of Goal Setting in Diabetes Mellitus Group Clinics.
Sperl-Hillen et al., (2011)	Patient Education Methods	Comparative Effectiveness of Patient Education Methods for Type II Diabetes.

The Key Questions

Researchers, healthcare professionals, policymakers, and other stakeholders are uniquely positioned to provide informed clinical and methodological expertise to guide the appropriate application of CER toward transforming the healthcare system. In alliance with the principles of PCORI, key questions (KQs) were developed with the input of stakeholders, which included diabetes health professionals, diabetes policy experts, public health representatives, community members, and representatives from professional societies focusing on diabetes.

Key Question #1: In African American adults with type II diabetes, what is the effectiveness of diabetes behavioral interventions as an adjuvant to usual care for outcomes related to glycemic control?

Key Question #2: In African American adults with type II diabetes, how does the efficacy of diabetes behavioral interventions vary depending on the *setting* for outcomes related to glycemic control?



Key Question #3: In African American adults with type II diabetes, how does the efficacy of diabetes behavioral interventions vary depending on the *mode of delivery* of behavioral interventions for outcomes related to glycemic control?

Key Question #4: In African American adults with type II diabetes, how does the efficacy of diabetes behavioral interventions vary depending on the *duration* for outcomes related to glycemic control?

Key Question #5: In African American adults with type II diabetes, how does the efficacy of diabetes behavioral interventions vary depending on the *theoretical* framework for outcomes related to glycemic control?

PICOTS Criteria

The Population, Intervention, Comparator, Outcomes, Timing, and Setting (PICOTS) framework was utilized to guide all stages of the analysis, including literature searching, study selection, and data abstraction. Table 2 provides a detailed illustration of the PICOTS.

Table 2

PICOTS

Domain	Description	
Population	 African Americans adults 	
	 Type II Diabetes 	
	Age ≥ 18 years	
	■ HbA1c ≥ 7	
Interventions	Diabetes behavioral intervention -A coordinated, non-	
	pharmacological, diabetes-specific, single or multi-component	
	patient-centered action/program aimed at improving glycemic	
	control. The diabetes intervention must focus on changing	
	behaviors and improving diabetes self-management.	
Comparators	Usual or standard care	
Outcomes	Glycemic control is the primary outcome and is measured by the	
	hemoglobin A1C (HbA1c).	



Table 2 (continued).

Domain	Description
Time	Duration ≥ 4 weeks.
Setting	All settings.

Analytical Framework

The analytical framework depicts the population of interest (African American adults with type II diabetes) and illustrates how diabetes behavioral interventions and intervention components are instrumental in improving glycemic control. The analytical framework is presented in Figure 2.

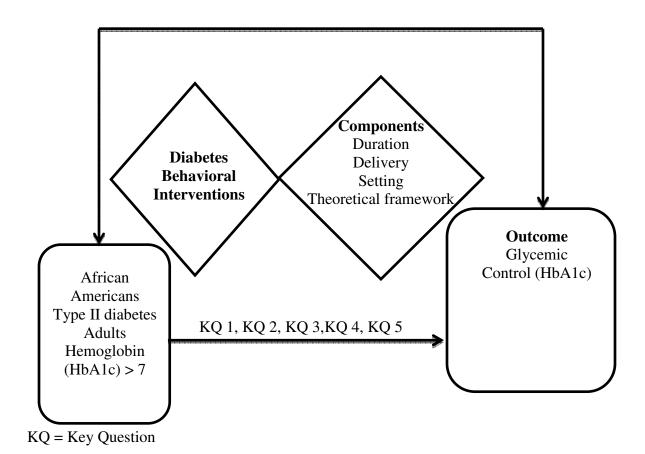


Figure 2. Analytical framework for diabetes behavioral interventions in African Americans with type II diabetes.

Theoretical Framework



Type II diabetes in African American adults is the result of a myriad of genetic, behavioral, social, economic, and environmental dynamics. The effective and sustainable use of diabetes behavioral interventions in achieving glycemic control in the African American population must consider these factors, which offers itself to a systems approach. Green (2006) stated that:

Public health asks of systems science, as it did of sociology over 40 years ago, that it help us unravel the complexity of causal forces in our varied populations, and the ecologically layered community and societal circumstances of public health practice. (p. 409)

We can infer from Green that if we are to transform the current state of the public healthcare system, we must glean a deeper understanding of the system as whole through systems thinking. One approach to understanding systems thinking is to compare it with the reductionist approach. Reductionist thinking has been extremely successful, specifically in constructing concepts, theories, and models. The basic perspective of the reductionist approach is a "top to bottom" approach; whereas, systems thinking values the interconnectedness of the parts of the system. There are important arguments to be made in systems thinking versus reductionism in healthcare systems research. Systems thinking considers not only the healthcare of the U.S., but also considers the connectedness the U.S. has with other nations because of globalization.

Author, Peter Senge (1990), of *The Fifth Discipline: The Art and Practice of the Learning Organization* described systems thinking as cornerstone of a learning organization. The learning organization is a concept that is becoming an increasingly widespread philosophy in modern healthcare systems and organizations. The foundation



for a learning organization in healthcare systems is the continuous knowledge development through the configuration of a closed feedback-learning loop. The learning loop represents a mechanism for the perpetual flow of information input and output that provides the foundation for improving healthcare systems outcomes. Collaboration among researchers, healthcare providers, policymakers, and other stakeholders is imperative to incite the learning loop mechanism to raise our healthcare system's level of performance.

A high-functioning system continually exchanges feedback among its various parts to ensure that they remain closely aligned and focused on achieving the goal of the system (Johnson & Ollivier, 2007). The IOM report, *Finding What Works in Health Care Standards for Systematic Reviews*, suggested that Americans should be served by a healthcare system that constantly delivers reliable performance and continuously improves systematically and seamlessly with each experience and transition (Morton, Levit, Berg, & Eden, 2011). The IOM's vision infers that applying the appropriate leadership, stakeholders, and incentives in the healthcare learning loop can promote the transformation into a continuously learning healthcare system.

In solving today's healthcare problems, a learning healthcare system must surface as a means of translating research and other evidence into practice and policy in a more meaningful and efficacious manner. A learning healthcare system fused with CER synergy and systems thinking will propel practice-based evidence to the point of care where its application will mean improved healthcare quality and patient outcomes in vulnerable populations. Figure 2 describes the feedback loop represented in a learning health care system. The figure explains the continuous flow of science, evidence and care



and how patients, clinicians, and communities are the key players in this flow of information.

Organization of the Report

Chapter I presented an introduction to CER and the significance of the diabetes health disparities among African Americans. The chapter also elaborated upon the significance of the study described in this manuscript, presented the key research questions, and provided an overview of the conceptual model. Chapter II presents a comprehensive literature review supporting and guiding the study. Chapter III discusses the methodology employed. Chapter IV then discusses the results of all analyses conducted. Lastly, Chapter V presents a set of recommendations for CER.

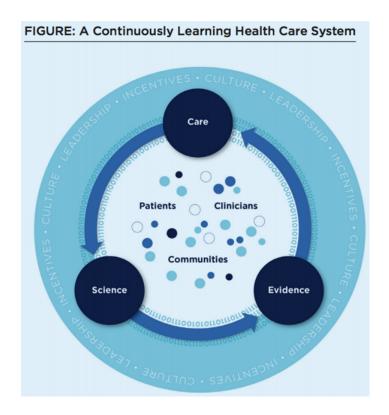


Figure 3. A continuously learning healthcare system (Smith, Halvorson, & Kaplan, 2012).



CHAPTER II

REVIEW OF LITERATURE

Introduction

Diverse areas of the literature that bear directly on the success of diabetes behavioral interventions, particularly on their effect to achieve glycemic control were reviewed in this chapter. Electronic searches were conducted from 1993 to 2014 using Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulative Index to Nursing and Allied Health Literature (CINAHL), EBSCO Host, Public MEDLINE (PubMed), Education Information Resource Center (ERIC), Psych Info, Cochrane Trials, and Google Scholar. Key words searched included: type II diabetes interventions, diabetes behavioral interventions, glycemic control, physical activity interventions, dietary interventions, diabetes self-management education (DSME), and diabetes outcomes.

Glycemic Control

The principal objective of treating patients with type II diabetes is to achieve glycemic control. Glycemic control is a significant predictor of the development of complications associated with diabetes (Albers et al., 2010; Al-Khawaldeh, Al-Hassan, & Froelicher, 2012; American Diabetes Association [ADA], 2010; ADA, 2013; Duong et al., 2011; Fradkin, Cowie, Hanlon, & Rodgers, 2013; Stolar, 2010) and is measured by the hemoglobin A1c (HbA1c). The HbA1c is considered the "gold standard" for the clinical diagnosis and management of diabetes (Bonora & Tuomilehto, 2011; Sacks, 2011; Selvin, Steffes, Gregg, Brancati, & Coresh, 2011; Weiler, Sutherland, Simonson, &



Glogowski, 2012). Lowering the HbA1c to 7% or below has been found to reduce the risk of developing microvascular and macrovascular complications (ADA, 2014).

Behavioral Interventions

Knowledge, proper nutrition, and adequate physical activity form the foundation of a healthy lifestyle. These interventions are especially important for individuals living with type II diabetes, as they are the most practical non-pharmacological means that will lead to an effective change in self-management behaviors. An effective patient-centered regimen that emphasizes adjusting self-care behaviors is necessary to avoid the devastating complications of the disease.

Landmark Trials

The Diabetes Control and Complications Trial and the United Kingdom Prospective
Diabetes Study

Several landmark randomized controlled trials (RCTs) were conducted during the 1990s that established the importance of tightly and consistently managing HbA1c levels among type I and type II diabetic patients (Diabetes Control and Complications Trial [DCCT], 1995; United Kingdom Prospective Diabetes Study [UKPDS], 1998). The DCCT and the UKPDS established that tight glycemic control could result in a low risk of developing serious complications in type I and type II diabetes (Turner et al., 1998; Turner, Cull, Frighi, Holman, & UKPDS Group, 1999).

The DCCT assessed the relationship between glycemic control and the development of microvascular complications in persons with type I diabetes (DCCT, 1995). The UKPDS evaluated the relationship between glycemic control and the development of macrovascular and microvascular complications in individuals with type



II diabetes (UKPDS, 1998). In the DCCT, the experimental group reached a mean HbA1c of 7.2%, whereas, compared with 9.1% in the control group (DCCT, 1995). The experimental group resulted in an approximate reduction of 60% in the risk of microvascular complications (DCCT, 1995). In addition, for every 10% reduction in HbA1c there was a 43% reduction in retinopathy progression (DCCT, 1995).

The UKPDS results indicated that each 1% reduction of HbA1c is associated with reductions in risk of 21% for any end related to diabetes, 21% for deaths related to diabetes, 14% for myocardial infarctions, and 37% for microvascular complications (Stratton et al., 2001; UKPDS, 1998). Both the intervention and control groups in the DCCT as well as the UKPDS achieved statistically significant differences in glycemic control. The DCCT and the UKPDS trials deepened the evidence base in diabetes research and guided many clinical and policy decisions.

Diabetes Prevention Program

Diabetes prevention is of equal import as in the treatment of the disease. The Diabetes Prevention Program (DPP) was another landmark study that was based on the empirical literature on nutrition, exercise, and behavioral weight control (DPP, 2002). The goal of the 27-center RCT was to determine whether lifestyle intervention or pharmacological therapy would prevent or delay the onset of diabetes in individuals with impaired glucose tolerance (IGT) that were at high risk for the disease (DPP, 1999). The intensive lifestyle interventions set goals to achieve and maintain a weight reduction of at least 7% of initial body weight through healthy eating and physical activity and to achieve and maintain a level of physical activity of at least 150 min/week through moderate-intensity activity (such as walking or bicycling) (DPP, 1999).



The DPP acknowledged the difficulty of achieving long-term changes in eating and exercise behaviors and in body weight by using interventions such as training in diet, exercise, and behavior modification skills (DPP, 1999). In addition, the DPP indicated that lifestyle intervention decreased the incidence of type II diabetes by 58% compared with 31% in the pharmacological group (DPP, 2002). Results of the DPP were intended to guide diabetes prevention programs, policymakers, and health care providers. The DPP did not identify glycemic control as an outcome. However, the DPP trial did strengthen the diabetes evidence base by supporting behavioral interventions as an effective treatment of diabetes. A significant recommendation of the DPP was that more RCTs be conducted to test both behavioral and pharmacological treatments (DPP, 1999).

Diabetes Self-Management Education

Diabetes Self-Management Education (DSME) is considered the cornerstone of diabetes care (Clark, 2008; Mulcahy et al., 2003). The overall objective of DSME is to promote positive self-behaviors and improve diabetes outcomes using practical behavioral interventions. By definition, DSME is a collaborative process through which people with diabetes gain the knowledge and skills needed to modify behavior and successfully self-mange the disease and its related conditions (Burke, Sherr, & Lipman, 2014; Duncan et al., 2011; Magee et al., 2011; A. L. Martin & Lipman, 2013; Martin, McWhorter, Shwide-Slavin, & Kushion, 2005; Sperl-Hillen et al., 2011). Acquiring diabetes knowledge through education plays an essential role in diabetes self-management, as improved knowledge will lead to an effective change in self-management behaviors (Booker, Morris, & Johnson, 2008). Several studies have found a



positive correlation between DSME and improved clinical outcomes (Brunisholz et al., 2014; Philis-Tsimikas et al., 2004; Thorpe et al., 2013).

Sperl-Hillen and associates (2011) conducted a study to assess the effectiveness of DSME methods in either a group or individual setting. In this study, 623 participants were randomized into DSME group education, DSME individual education, and usual care (Sperl-Hillen et al., 2011). A general linear mixed model methods study was used to assess patient-level changes between treatment groups in mean HbA1c levels from baseline to follow-up (Sperl-Hillen et al., 2011). The authors reported that the mean HbA1c concentration decreased in all groups but significantly more with individual (-0.51%) (p = .01) than group education (-0.27%) (p = .01) and usual care (-0.24%) (p = .01) (Sperl-Hillen et al., 2011). Results from this study proved that individual education for patients resulted in better glucose control than did group education. However, in a separate study, Rickheim, Weaver, Flader, and Kendal (2012) randomly assigned 170 subjects with type II diabetes into group and individual settings and found that when both groups were compared, the results were equally valid.

Attrition and retention rates in DSME programs are a challenge. Initially, subjects may agree to participate in DSME, but often fail to attend or complete the program.

Adams and colleagues (2013) conducted a study exploring factors influencing patient completion of DSME. The Interactive Dialogue to Educate and Activate (IDEA) study was a behavioral intervention to evaluate diabetes outcomes in patients randomized to group and individual DSME interventions (Adams et al., 2013). The study evaluated personal characteristics influencing attendance at individual and group DSME. The results concluded that illness, travel distance, depression, pain, and time constraints were



all factors that affected program participation (Adams et al., 2013). This study implied that future studies need to examine how attendance can be improved among groups differing in demographics, health status, and psychosocial functioning (Adams et al., 2013).

Physical Activity

The terms "physical activity," "exercise," and "being active" are often used interchangeably and are considered to be planned structured, repetitive, and performed with the objective of positively impacting physical fitness and/or health outcomes (American Association of Diabetes Educators [AADE], 2009; Kavookjian, Elswick, & Whetsel, 2007). Physical activity plays a vital role in diabetes management (ADA, 2011; Boulé, Haddad, Kenny, Wells, & Sigal, 2001; Colberg & Swain, 2000; Shultz, Sprague, Branen, & Lambeth, 2001; Sigal, Kenny, Wasserman, Castaneda-Sceppa, & White, 2006; Umpierre et al., 2011). Regular physical activity is necessary for overall fitness, weight management, and glycemic control (Lavie, Church, Milani, & Earnest, 2011; Warburton, Nicol, & Bredin, 2006). Because of this, adequate physical activity offers enormous benefits to patients with diabetes. The literature is abundant with studies demonstrating positive effects of physical activity on various outcomes in diabetes.

Several systematic reviews and meta-analyses (Boulé et al., 2001; Sigal et al., 2007; Snowling & Hopkins, 2006; Thomas, Elliott, & Naughton, 2006; Umpierre et al., 2011; Zanuso, Jimenez, Pugliese, Corigliano, & Baldacci, 2010) reported that increased physical activity and exercise produce a significant improvement in glucose control in people with type II diabetes. Exercise increases insulin sensitivity (Bradley, Jeon, Liu, & Maratos-Flier, 2008; Dube, Allison, Rousson, Goodpaster, & Amati, 2012; Mackenzie et



al., 2012). Current guidelines set by the ADA recommend that patients with type II diabetes should perform at least 150 minutes per week of moderate-intensity aerobic exercise and should perform resistance exercise 3 times per week (ADA, 2014).

Numerous studies using various research designs and populations reveal compelling evidence for the incremental benefits of combined aerobic and resistance training for individuals with diabetes (Church et al., 2010; Sigal et al., 2007; Snowling & Hopkins, 2006). The Diabetes Aerobic and Resistance Exercise trial (DARE) (clinicaltrials.gov 001958840) was a large RCT (n=251) designed to determine the effects of aerobic and resistance training versus a sedentary control group on glycemic control and other cardiovascular risk factors in adults with type II diabetes (Sigal et al., 2007).

DARE was a 26-week, single-center RCT with a parallel group design (Sigal et al., 2007). The participants of this study were randomly assigned in equal numbers to the aerobic training resistance training, combined exercise training, and control groups. The absolute change in the HbA1c value in the combined exercise training group compared with the control group was 0.51 percentage point (95% CI, 0.87 to 0.14) in the aerobic training group and 0.38 percentage point (95% CI, 0.72 to 0.22) in the resistance training group (Sigal et al., 2007). Combined exercise training resulted in an additional change in the HbA1c value of a 0.46 percentage point (95% CI, 0.83 to 0.09) compared with aerobic training alone, and a 0.59 percentage point (95% CI, 0.95 to 0.23) compared with resistance training alone respectively (Sigal et al., 2007).

Church and colleagues (2010) conducted the Health Benefits of Aerobic and Resistance Training (HART-D) study on people living with type II diabetes. HART-D was created to compare the effects of aerobic training, resistance training, and a



combination of the two on glycemic control in individuals with type II diabetes that lived sedentary lifestyles (Church et al., 2010). The HART-D exercise trial proved that while both exercise activities provided benefits, only the combination of the two was correlated with a reduction of HbA1c levels (Church et al., 2010). Compared with the control group, the absolute mean change in HbA1 in the combination training exercise group was significant (P = 0.03) (Church et al., 2010). The mean changes in HbA1c were not statistically significant in either the resistance training (P = 0.32) or aerobic training (P = 0.14) compared with the control group (Church et al., 2010).

The HART-D and the DARE studies showed that aerobic activity and resistance training significantly improves glycemic control in type II diabetes. Most importantly, the two studies found that improvements in glycemic control were maximized with combined aerobic activity and resistance training (Church et al., 2010; Sigal et al., 2007).

Dietary Interventions

Nutrition is a critical component of diabetes management (Baruah, Kalra, & Kalra, 2014; Rovner et al., 2012; Singh & Singh, 2012; Tanasescu, Cho, Manson, & Hu, 2004). A diet that promotes healthy food choices, weight management, and optimal glycemic control is recommended for people with diabetes (ADA, 2008). The goal of a healthy eating intervention is to assist and facilitate individual lifestyle and eating behavior changes that will lead to improved glycemic control, a reduced risk for complications, and overall improved health. A healthy diet can result in decreases in HbA1c, Low-Density Lipoprotein (LDL), blood pressure (BP), and weight (Centers for Disease Control and Prevention [CDC], 2011). Many people with diabetes may be able to

manage their condition without pharmacological intervention by making appropriate food selections, controlling weight, and achieving optimal blood glucose levels.

Nutrition therapy is recommended for all people with type I and type II diabetes as an active component of the overall treatment plan (Evert et al., 2013). Nutrition therapy goals should be developed collaboratively with the individual with diabetes and be based on an assessment of the individual's current eating patterns, preferences, and metabolic goals (Evert et al., 2013). Evert and colleagues (2013) suggested that effective nutrition therapy interventions be a component of a comprehensive group diabetes education program or an individualized session.

Medical Nutrition Therapy (MNT) is an effective behavioral intervention used for achieving glycemic control (American Diabetes Association, 2014; Evert et al., 2014; Gosmanov & Umpierrez, 2012; Pastors, Warshaw, Daly, Franz, & Kulkarni, 2002). In 1999, the Institute of Medicine (IOM) released a report noting that MNT improved clinical outcomes and decreased the cost to Medicare of managing diabetes (Pastors et al., 2002; Neumann et al., 2005). As a result, the IOM recommended that individualized MNT be a covered Medicare benefit as part of the multidisciplinary approach to diabetes care (Pastors et al., 2002). The added benefit of MNT is the reduction of daily fat (5-8%), saturated fat (2-4%), energy intake (232-710 kcal/day) as well as lower triglycerides (11-31%) LDL, cholesterol (7-22%), and total cholesterol (7-21%) (Evert et al., 2013a; 2014b).

Numerous studies implicated the importance and effectiveness of medical weight loss in diabetes management (Appel et al., 2011; Unick et al., 2011). The Look Action for Health in Diabetes (AHEAD) trial (2003) examined the effects of an intensive lifestyle



intervention (ILI) on weight loss, cardiovascular disease (CVD) risk, and program adherence. Participants in the Look AHEAD trial were randomly assigned to ILI or diabetes support and education (DSE). DSE participants received a less intense educational intervention, whereas ILI participants received an intensive behavioral treatment to increase physical activity and reduce caloric intake. At the end of the study (10 years), the mean weight loss from baseline was 6% in the intervention group and 3.5% in the control group (Unick et al., 2011).

Glycemic Control in African Americans

Type II diabetes poses a significant concern for all racial and ethnic groups. However, African Americans with type II diabetes show increased prevalence rates, higher risks of complications, and higher rates of mortality (Cowie et al., 1989; Harris, Klein, Cowie, Rowland, & Byrd-Holt, 1998; Lavery et al., 1996; Pugh, Stern, Haffner, Eifler, & Zapata, 1988). Poor glycemic control among African Americans has been a key contributor to diabetes disparities among this population. A large number of social determinants of health have been suggested that drive differences in glycemic control African American adults. According to the CDC, the social determinants of health are the circumstances in which people are born, grow up, live, work, and age as well as the systems put in place to deal with illness (2014).

Schneider, Zaslavsky, and Epstein (2002) reported that African Americans are less likely to have routine HbA1c screenings than their Caucasian counterparts. Johnson and Roter (2004) noted that the communication between African American patients and Caucasian physicians during medical visits was poor and contributed to adverse outcomes. Rhee and colleagues (2005) found that lack of access to health care affects



glycemic control among minorities. Bach, Pham, Schrag, Tate, and Hargraves (2004) suggested that reasons for racial differences in glycemic control might be related to the lower quality of care within clinics serving predominantly African American communities. Other studies have determined that African Americans are less likely to have prescription drug coverage, which limits their ability to afford medications once they have been diagnosed (Adams, Soumerai, & Ross-Degnan, 2001). More studies concluded that African Americans report lower rates of health insurance than Caucasians (Becker Gates, & Newsom, 2004; Proctor, 2006). Adams et al. (2008) noted that most African Americans wait too long before seeking medical treatment.

Discussion

The research findings suggest that African Americans with type II diabetes need accessible and practical strategies to improve disease management and reduce the negative impact of the disease. Innovations in research, practice, and policy such as CER are warranted in that more effective treatment options are needed to combat the disease. The current review discusses CER as a feasible option in effective treatment and management of type II diabetes in African Americans.

CHAPTER III

METHODS

The methods for this systematic review of literature followed those suggested in the Agency of Healthcare Research Quality's (AHRQ) *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* (2014). This chapter reflects key elements of the established protocol. All methods were determined a priori.

Search Strategy

Searches for the primary studies were conducted in the following databases:

Medical Literature Analysis and Retrieval System Online (MEDLINE), EBSCO Host, the

Cumulative Index to Nursing and Allied Health Literature (CINAHL), Psych Info, and

Google scholar. Clinical trial registries for grey literature of unpublished randomized

controlled trials (RCTs) were searched using ClinicalTrials.gov. The university research

librarian provided guidance with the search process. Multiple searches were conducted to

identify all relevant studies for the review. The following search terms were used:

African- Americans, type II diabetes, diabetes interventions, behavioral interventions,

diet, nutrition interventions, physical activity interventions, diabetes self-management

education (DSME) interventions, glycemic control, and diabetes outcomes. The reference

lists of all included articles and related systematic review articles were also reviewed.

Criteria for Inclusion/Exclusion of Studies in the Review

Inclusion criteria. The following criteria was set to determine study eligibility for the review:



- Studies between (1993-2014). The earliest publication date chosen for the studies was
 1993. This specific date was chosen due to the research findings from the Diabetes
 Prevention Programs (DPP) that began that year.
- Only African American adults aged 18 and over were eligible for this study. If at least
 of the sample were African Americans, the article was considered qualified.
- 3. Described an intervention aimed at changing behaviors. Interventions were considered behavioral interventions if they concentrated on changing one or more of the following self-care behaviors: self-efficacy, diet, improving knowledge of self-care, physical activity, or weight loss.
- 4. Studies that measured glycemic control as an outcome.

Exclusion criteria. Studies where the intervention was not clearly defined as a behavioral intervention were excluded (e.g. pharmacological). Other exclusion criteria include studies that focused on patients with type I diabetes. Table 3 provides a description of the inclusion/exclusion criteria.

Table 3

Inclusion/Exclusion Criteria

Inclusion Criteria

- English language literature
- Studies published between 1993-2014
- African American Adults \geq 18 years of age
- Type II diabetes
- Reporting outcomes of glycemic control measured by the hemoglobin A1C (HbA1c)



Exclusion Criteria

- Studies without a clearly defined behavioral intervention
- Type I Diabetes
- Studies with an HbA1c < 7

Ethical Considerations

All included studies received Institutional Review Board (IRB) approval. This review was exempt from a separate review. The data used was not generated directly by individual participants, nor were they drawn from the medical or health records of individuals. Only summaries from previous studies were used in this study.

Data Extraction and Data Management

The results of the searches were imported into the RefWorks reference database and transferred to DistillerSR, a web-based software package developed for systematic reviews and data management. The DistillerSR database was used to track the details of the article review process. During the search, titles were thoroughly screened using broad inclusion/exclusion criteria. The studies were classed as "YES" or "NO" or "UNSURE". The full text of studies classed as "YES" and "UNSURE" were retrieved for full review and assessed for eligibility using the inclusion/exclusion criteria as the standard.

Data from the included studies were exported into Microsoft Excel and are shown in Tables 4-7. Table 4 provides a general overview of specific characteristics of the study including the following: the number of participants, study design, setting, mode of delivery, duration, and theoretical framework. Table 5 provides a detailed description of



the intervention features. Table 6 describes the intervention, data collection points, and intervention follow-up information. Table 7 details specific information about the dependent variable of the study, such as the mean baseline HbA1c, the difference in HbA1c (intervention), the difference in HbA1c (control), and the statistical significance of the HbA1c changes of the study.

Data Synthesis and Analysis

The results of the included studies were qualitatively synthesized and presented in narrative form in the results section. The qualitative synthesis oriented the reader to the clinical and methodological landscape of the study, provided a detailed description of the intervention (pre-intervention and post-intervention), and integrated the general summary of the strength of the evidence based on the setting of the study, the intervention duration, method of delivery, and the theoretical framework of each included study.

Assessment of Methodological Risk-of-Bias of Individual Studies

Higgins and Green (2008) defined risk-of-bias as the risk of a systematic error or deviation from the truth in results or inferences from a study. The AHRQ's *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* (2014) suggested strategies to reduce the possibility of bias at every step. In order to improve the speed of adoption and diffusion of CER-recommended practices into health systems, continual and robust methodological tactics to control for internal validity and reduce the potential for bias are necessary.

The risk-of-bias for the included studies for this analysis was assessed using the Downs and Black Checklist for Measuring Quality (1998) (see Appendix C). This tool was selected because it is used to assess the methodological quality of randomized



controlled trials (RCTs) and non-RCTs. The checklist addresses the increasing demand for the use of evidence from systematic reviews and meta-analyses to support program and policy decisions in health decision-making (Downs & Black, 1998).

The checklist allows an overall score for study quality to be reported as well as scores for each of the subscales. The maximum score achievable for each of the subscales is 11 for reporting, 3 for external validity, 7 for internal validity, and 6 for internal validity totaling to maximum score of 27, with a higher score indicating a stronger study (Downs & Black, 1998). Experienced epidemiologists and statisticians conducted validity and reliability on the original version of the checklist as well as a revised version (Downs and Black, 1998). Further assessment of the revised checklist demonstrated that Quality Index had high internal consistency, suitable test-retest reliability (r = 0.88), inter-rater reliability (r = 0.75), and strong face and criterion validity (Downs and Black, 1998). Each article was assessed by utilization of this checklist and a corresponding score was independently applied. Table 8 details individual scores from the Downs and Black instrument. The quality index was rated as being strong, moderate, limited, or poor. Table 9 provides a categorization of the scores.

CHAPTER IV

RESULTS

Study Selection

Following a thorough evaluation, fourteen studies were selected based upon the preset eligibility criteria (Anderson et al., 2005; Anderson-Loftin et al., 2005; Bray, Thompson, Wynn, Cummings, & Whetstone, 2005; Carter, Nunlee-Bland, & Callender, 2011; Davis et al., 2010; Hawkins, 2010; Long, Jahnle, Richardson, Loewenstein, & Volpp, 2012; Mayer-Davis et al., 2004; Rimmer, Silverman, Braunschweig, Quinn, & Liu, 2002; Skelly, Carlson, Leeman, Soward, & Burns, 2009; Tang, Funnell, Brown, & Kurlander, 2010; Utz et al., 2008; Weinstock et al., 2011). The process used to screen the studies is shown in the flow diagram in Figure 4.

Qualitative Synthesis of Included Studies

Anderson et al. (2005). The focus of this study was to assess the effectiveness of a problem-based patient education program designed for urban African Americans (Anderson et al., 2005). The study used a randomized controlled trial (RCT) pretest/post-test design with repeated measures (Anderson et al., 2005). Participants were randomly assigned to either a 6-week intervention group or a 6-week control group.

Baseline data were collected from both groups at the beginning of enrollment. The baseline data served as the pre-test measure for the intervention group. In contrast, for the control group, the data collected at the end of the 6-week control period served as the pre-intervention data (Anderson et al., 2005). The intervention consisted of 6 weekly, 2-hour group visits. Upon completion of the intervention, participants were given a choice



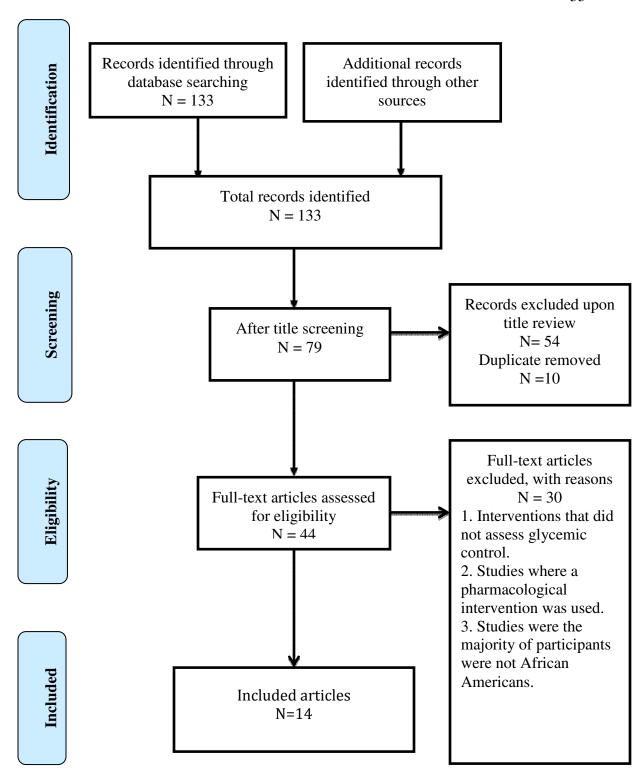


Figure 4. Flow diagram of study selection.

to select a monthly support group session or nurse-led phone call each month. Follow up data were collected following the intervention and control periods. Data was also obtained at 6 and 12-month intervals. Significant pre-intervention and post-intervention changes in HbA1c (P<. 001) in both groups were found (Anderson et al., 2005). As an incentive, participants were given a \$50 monetary reward for completion of the 6-month and 12-month assessments (Anderson et al., 2005). The theoretical framework used to guide the study was the empowerment theory.

Score on Downs and Black Checklist: 21

Anderson-Loftin et al. (2005). The primary focus of this investigation was to assess the effectiveness of a culturally competent, dietary self-management intervention in African Americans with type II diabetes that lived in a rural area (Anderson-Loftin et al., 2005). This was an experimental study whereby the participants were randomly assigned to the intervention group or usual care group. The intervention was comprised of 4 weekly classes in fat reduction dietary strategies, five monthly group discussions, and telephone follow-up calls each week. However, the control group was referred to a regular diabetes class. A nurse case manager who was a certified diabetes educator (CDE) conducted the sessions. The culturally competent approach reflected the ethnic beliefs, values, customs, food preferences, language, learning methods, and health care practices of southern African Americans (Anderson-Loftin, 2005). All participants, including those in the control group received a financial incentive of \$15 for their attendance. Data were collected at baseline and 6-months post-intervention. The following outcomes data were assessed: the HbA1c, lipids, BMI, and dietary behaviors. No significant differences between groups in HbA1c were reported. However, HbA1cs

were relatively low in the experimental group at baseline (7.5%, SD = 1.6) (Anderson-Loftin et al., 2005).

Score on Downs and Black Checklist: 22

Bray et al. (2005). Bray and colleagues (2005) sought to explore the efficacy of combining care management and interdisciplinary group visits for African American adult patients in rural primary areas. A convenience sample (n=160) of adult patients was recruited from two primary care fee-for-service practices in rural counties in North Carolina (Bray et al., 2005). In the intervention practice, an advanced practice nurse visited the practice weekly for 12 months and facilitated diabetes education, patient flow, and management. Patients participated in a four-session group visit education/support program led by a nurse, a physician, a pharmacist, and a nutritionist. The control patients received usual care. The median HbA1c was not significantly different at baseline in the intervention and control groups but was significantly different at the end of the 12-month follow-up period (P < .05) (Bray et al., 2005). In the intervention group, the median HbA1c at baseline was 8.2 +/- 2.6%, and median HbA1c at an average follow-up of 11.3 months was 7.1 + -2.3%, (P < .0001) (Bray et al., 2005). These findings suggested that a redesigned care management model that combines nurse-led case management with structured group education visits can be successfully incorporated into rural primary care practices and can significantly improve glycemic control (Bray et al., 2005).

Score on Downs and Black Checklist: 20

Carter et al. (2011). This study described the design and operation of an internet-based diabetes self-management intervention for urban African American adults (n=47) with type II diabetes (Carter et al., 2011). The study employed the use of a coordinated service delivery model that promoted continuous patient and provider communication.

Patient self-management education on diabetes and other health education topic were available online (Carter et al., 2011). The study aimed to determine if African Americans adults with type II diabetes who had access to an online diabetes self-management intervention would achieve better outcomes in terms of HbA1c, blood pressure, and body mass index (BMI) measures in comparison to African American adults with type II diabetes who were not granted such access (Carter et al., 2011). The participants were recruited from a primary care practice in Washington, DC. The participants of the study were received a randomized assignment to the treatment group (n=26) and the control (n=21) group by a random-numbers table (Carter et al., 2011). Each participant received a computer, a blood pressure cuff, a glucometer, and a wireless weight scale. The clinic's telehealth nurse trained members of the intervention group on how to operate the equipment. Members of the control group were denied access to the online information any type of contact with the telehealth nurse. All learning activities were designed to assist participants in developing better diabetes self-care behaviors. The results indicated a significant association (P<. 05) in the online intervention (Carter et al., 2011). The findings from this study promote telehealth interventions as an effective means to improve diabetes management in underserved populations. Limitations to the study were the relatively small sample size, accessibility, and the participant's health literacy level. Score on Downs and Black Checklist: 21

Davis et al. (2010). This study was a 1-year RCT that was designed to analyze Diabetes TeleCare, a remote comprehensive diabetes self-management education (DSME) intervention (Davis et al., 2010). The intervention was conducted by a dietician and a nurse/certified diabetes educator (CDE). Participants were recruited from three federally qualified health centers (FQHC) in rural South Carolina (Davis et al., 2010).

Only three sessions were conducted face to face; all other sessions were conducted via live interactive video conferencing by the self-management education staff. Make-up sessions were conducted via telephone. The Health Belief Model and the Transtheoretical Models were used to guide the study. Outcomes data were collected on all participants at 6 months (p = 0.05) and 12 months (p = 0.004) (Davis et al., 2010). Participants were given a gift card as an incentive to complete each session (Davis et al., 2010).

Score on Downs and Black Checklist: 23

Hawkins (2010). The objective of this study was to evaluate the impact of a videophone motivational interviewing (MI) diabetes self-management education (DSME) intervention to improve HbA1c levels in rural adults (Hawkins, 2010). Sixty-six participants (n=66) with HbA1c levels >7 were enrolled in a videophone intervention that lasted 6 months (Hawkins, 2010). The videophone interventions were completely opposite in both groups. The experimental group (n=34) received videophone MI DSME calls weekly, then every month. The control group (n=32) received videophone healthylifestyle education calls once a month (Hawkins, 2010). Whilst both groups experienced a decreased HbA1c, a statistically significant difference was noted in experimental group mean values (P=.015), but not in the control group (P=.086) (Hawkins, 2010). The theoretical framework that guided the study was MI based on the Transtheoretical Model of Behavioral Change and Social Cognitive Theory. The experimental group demonstrated statistically significant increases in diabetes knowledge (P = 0.023) and diabetes self-efficacy (P = .002) (Hawkins, 2010). Experimental group participants with high self-efficacy in contrast to low self-efficacy had a statistically significant decrease in HbA1c (P = .043) (Hawkins, 2010).

Score on Downs and Black Checklist: 22

Long et al. (2012). Long and associates (2012) conducted a 6-month RCT to determine whether peer mentors or financial incentives are superior to usual care in helping African American veterans with type II diabetes. Patients were randomly assigned to one of three groups (usual care, peer mentoring, or financial incentives). The sample size consisted of 118 participants: 39 were assigned to the control group, 39 to the peer-mentoring group, and 40 to the financial incentive group. Usual care patients were notified of their starting HbA1c level and recommended goals for HbA1c. Those participants in the peer-mentoring group were assigned a mentor who formerly had poor glycemic control but now had good control (HbA1c level $\leq 7.5\%$) (Long et al., 2012). The mentor was instructed to talk with the patient at least once per week. Peer mentors were matched by race, sex, and age. Patients in the financial incentive group could earn \$100 by decreasing their HbA1c level by 1% and \$200 by decreasing it by 2% or to an HbA1c level of 6.5% (Long et al., 2012).. Mentors and mentees talked the most in the first month (mean calls, 4; range, 0 to 30), but calls decreased to a mean of 2 calls (range, 0 to 10) by the sixth month. Levels of HbA1c decreased from 9.9% to 9.8% in the control group, from 9.8% to 8.7% in the peer mentor group, and from 9.5% to 9.1% in the financial incentive group (Long et al., 2012).. Mean change in HbA1c level from baseline to 6 months relative to control was -1.07% (95% CI, -1.84% to -0.31%) in the peer-mentoring group and -0.45% (CI, -1.23% to 0.32%) in the financial incentive group (Long et al., 2012). The study determined that financial incentives could enhance diabetes self-care and promote positive behaviors. Results indicated that peer mentorship significantly improved glycemic control.

Score on Downs and Black Checklist: 23



Mayer-Davis et al. (2004). This study was a 12-month RCT entitled POWER (Pounds off with Empowerment). The study was designed to examine the impact of a state-of-the-art lifestyle intervention for weight management and metabolic control of diabetes (Mayer-Davis et al., 2004). The participants of the study were given a study goal of achieving and maintaining a 10% weight loss over 12 months based on weight measured at randomization (Mayer-Davis et al., 2004). A nutritionist conducted the interventions. Participants were randomized into one of three interventions: intensivelifestyle intervention, reimbursable-lifestyle intervention, or usual care (Mayer-Davis et al., 2004). Findings from the study showed improvements in both weight and glycemic control. Of the 187 participants, only 152 stayed for 12-month follow-up measurements (Mayer-Davis et al., 2004). Modest weight loss occurred by 6 months among intensivelifestyle participants and greater than the weight loss among usual-care participants (2.6kg vs. 0.4 kg, P<0.1) (Mayer-Davis et al., 2004). At 12 months, a greater proportion of intensive-lifestyle participant had lost 2 kg or more than usual-care participants (49%) vs. 25%, P > .05) (Mayer-Davis et al., 2004). HbA1c was significantly decreased in all groups (P<. 05) but showed no difference between groups.

Score on Downs and Black Checklist: 20

Rimmer et al. (2002). The objective of this study was to determine if a group of predominately low-income, low-education, African American women with type II diabetes could achieve compliance and improved health outcomes with a carefully structured health promotion intervention (Rimmer et al., 2002). The 12-week feasibility study employed a quasi-experimental, single-group, pretest-posttest design (Rimmer et al., 2002). Participants attended a university-based, health promotion program in which they completed a 12-week intervention that addressed diet, nutrition, and health behavior.



Subjects were randomized to either an intervention (12 weekly group session, 1 individual session, and 6 biweekly group sessions) or usual care (1 class and 2 informational mailings) (Rimmer et al., 2002).. The intervention groups received an individualized weight-reduction plan. Classes of 8 to 10 participants per group met once a week for 12 weeks. Session consisted of 60 minutes of nutrition followed by 30 minutes of exercise in a physical therapy clinic (Rimmer et al., 2002). Each participant in the experimental group also had one individual diet counseling session. Classes were held in a medical clinic. Program participants were taught dietary changes and encouraged to exercise 20 to 30 minutes a day, 3 times a week (Rimmer et al., 2002). Behavior modification techniques were employed. Results for this study were not significant. No p value was reported.

Score on Downs and Black Checklist: 22

Skelly et al. (2009). This RCT evaluated the impact of a symptom-focused diabetes behavioral intervention that focused on skills training for diet and weight management (Skelly et al., 2009). The population sample for this study consisted of 180 rural African American women (n=180) (Skelly et al., 2009). The study was designed to allow the women the opportunity to tell about their lived experiences with diabetes. Active participants were randomly assigned to three groups: a symptom-focused intervention group, a telephone booster group, and an attentional control group. Overall, glycemic control was reduced in the entire sample by (0.57%) (Skelly et al., 2009). Seventeen women did not complete the study due to illness, death, and relocation. The conceptual model for this study was the Symptoms Management Model.

Score on Downs and Black Checklist: 19



Spencer et al. (2011). Spencer et al., (2011) sought to investigate the effectiveness of a culturally tailored, community health worker (CHW) intervention aimed at improving glycemic control. Glycemic control measured as the HbA1c was the primary outcome measure. Using an empowerment-based theoretical approach, CHWs provided participants with DSME, regular home visits, and accompanied them to a clinic visit during the 6-month intervention period (Spencer et al., 2011). Participants in the intervention group had a mean HbA1c value of 8.6% at baseline, which improved to a value of 7.8% at 6 months, for an adjusted change of –0.8 percentage points (P<. 01) (Spencer et al., 2011). No change in mean HbA1c among the control group (8.5%) was noted. Intervention participants also had significantly greater improvements in self-reported diabetes understanding compared with the control group. This study contributed to the growing evidence for the effectiveness of CHWs and their role in multidisciplinary teams engaged in culturally appropriate health care delivery (Spencer et al., 2011).

Tang et al. (2010). This study aimed to assess the effectiveness of a diabetes self-management support (DSMS) intervention compared to a control group without the intervention (Tang et al., 2010). The intervention lasted for 6 months. Participants in the control group received general weekly educational newsletters that contained information about diabetes (Tang et al., 2010). However, participants in the intervention group were allowed to attend weekly DSMS group sessions as many times as desired. The HbA1c was obtained at baseline, 6-month, and 12-month assessment intervals. The sessions placed high emphasis on learning from experiences, as well learning how to problem solve, cope with diabetes, and set attainable goals. Positive improvements in the HbA1c (p<0.001) were found (Tang et al., 2010). Findings indicated that an empowerment

driven, DSME intervention is hopeful for improving glycemic control in African Americans adults with type II diabetes.

Score on Downs and Black Checklist: 25

Utz et al. (2008). The purpose of this study was to assess the effectiveness of a culturally tailored diabetes intervention for rural African American adults (Utz et al., 2008). The Social Cognitive Theory guided the study. The participants were randomly assigned to either a group or individual DSME groups that were centered on goal-setting behaviors and problem-solving (Utz et al., 2008). The sessions were offered over a 10week timeframe and were held at a local community center. Outcomes of the study included the HbA1c, self-care actions, self-efficacy level, goal attainment, and satisfaction with the DSME program. Participants in both groups (group and individual) improved slightly over the 3-month period in self-care activities, HbA1c level, and goal attainment (Utz et al., 2008). Although differences were not statistically significant, trends indicate improved scores on dietary actions, foot care, goal attainment, and empowerment for those who participated in group DSME (Utz et al., 2008). The culturally tailored approach was a proven success. Improvements among those receiving individual DSME indicated that brief sessions using a culturally tailored approach could enhance self-care and improve glycemic control in African Americans (Utz et al., 2008). Score on Downs and Black Checklist: 22

Weinstock et al. (2011). The Informatics for Diabetes Educators and Telemedicine (IDEA-Tel) project randomized ethnically diverse underserved older adults with diabetes into a telemedicine intervention or usual care. This large randomized trial (n = 1,665) examined the effectiveness of telemedicine in diabetes management in ethnically diverse adults living in underserved areas (Weinstock et al., 2011). Participants

were Medicare beneficiaries with diabetes living in federally designated medically underserved areas. Assessments included the HbA1c as the primary outcome. Participants in the telemedicine intervention received a home telemedicine unit to videoconference with a diabetes educator every 4 to 6 weeks for self-management education. The diabetes educator also reviewed self-monitoring of home glucose recordings and blood pressure measurements. The results were significant (p< 0.01) (Weinstock et al., 2011). No precise p value was reported in the studies.

Score on Downs and Black Checklist: 14

Characteristics of Studies

This systematic review investigated and evaluated the efficacy of diabetes behavioral interventions in African American adults based on their significance of improving glycemic control. The 14 included studies were conducted from 2002 through 2012. All studies were performed in the U.S. Sample sizes ranged from 22 to 1,665, with a overall population of 3,255 investigated. Ten of the 14 studies were RCTs (Anderson et al., 2005; Bray et al., 2005; Carter et al., 2011; Davis et al., 2010; Hawkins, 2010; Long et al., 2012; Mayer-Davis et al., 2004; Skelly et al., 2009; Spencer et al., 2011; Weinstock et al., 2011). Three of the 14 were Quasi-Experimental (Anderson-Loftin et al., 2005; Rimmer et al., 2002; Utz et al., 2008), and 1 out of the 14 studies was a control-intervention time series (Tang et al., 2010).

Interventions that were culturally tailored were evidenced in this review (Anderson et al., 2005; Anderson-Loftin et al., 2005; Carter et al., 2011; Davis et al., 2010; Hawkins, 2010; Mayer-Davis et al., 2004; Skelly et al., 2009; Spencer et al., 2011;



Utz et al., 2008). Of the seven studies that pointed out cultural tailoring as an intervention characteristic, four showed positive improvements in glycemic control.

A notable aspect of the studies reviewed was the geographic location of the participants. Seven of the 14 studies focused on rural populations (Carter et al., 2011; Davis et al., 2010; Hawkins, 2010; Spencer et al., 2011; Tang et al., 2010; Utz et al., 2008; Weinstock et al., 2011). Three focused on urban/inner city populations (Anderson et al., 2005; Anderson-Loftin et al., 2005; Spencer et al., 2011). Seven studies used telemedicine as a form of outreach (Carter et al., 2011; Davis et al., 2010; Hawkins, 2010; Mayer-Davis et al., 2004; Utz et al., 2008; Weinstock et al., 2011). Five studies that focused on rural populations using telemedicine were found to be significant in the review (Carter et al., 2011; Davis et al., 2010; Tang et al., 2010; Utz et al., 2008; Weinstock et al., 2011).

Table 4

Characteristics of Studies

Author(s) of Study, Year	Study Design	Sample Size	Setting	Mode of Delivery	Duration	Theoretical Framework
Anderson et al., (2005)	RCT	239	Community	Nurse, CDE	6 weeks	Empowerment Theory
Anderson-Loftin et al., (2005)	Quasi- Experimental	97	Rural clinic	Nurse	5 months	Model of Nursing Case Management
Bray et al., (2005)	RCT	160	Clinic	Nurse	1 year	None reported
Carter et al., (2011)	RCT	74	Online	Nurse	9 months	Coordinated Service Delivery
Davis et al., (2010)	RCT	165	Community health center; telehealth	Nurse, CDE, Dietician	1 year	Health Beliefs Model; Transtheoretical Model of Change
Hawkins (2010)	RCT	77	Videophone	CDE, Dietician	6 months	Motivational Interviewing
Long et al., (2012)	RCT	118	Veterans Medical Center	Peer Mentors	6 months	None reported
Mayer-Davis et al., (2004)	RCT	187	Rural health care center	Dietician	1 year	Empowerment Theory
Rimmer et al., (2002)	Quasi- Experimental	30	Local hospital and clinic	CDE, Dietician	12 weeks	Health Promotion



Table 4 (continued).

Author(s) of Study, Year	Study Design	Sample Size	Setting	Mode of Delivery	Duration	Theoretical Framework
Skelly et al., (2009)	RCT	180	In home, telephone	Nurse	9 months	Symptom Management Model
Spencer et al., (2011)	RCT	164	Community health center	CHWs	6 month	Empowerment Theory
Tang et al., (2010)	Control- intervention time series	77	Mailing and in person		6 months	Empowerment Theory
Utz et al., (2008)	Quasi- Experimental	22	Community center	CDE	10 weeks	Social Cognitive Therapy
Weinstock et al., (2011)	RCT	1665	Telemedicine	CDE	5 years	No stated theory

CDE=Certified Diabetes Educator, CHW=Community Health Worker



Intervention Features

Author(s) of Study, Year	Cultural Tailoring	Urban Population	Rural Population	Individual Session	Group Session	Tele- medicine	Incentives
2 0002	- w vg	1 op unuson	1 openion		2032011		
Anderson et al., (2005)	✓	✓			√		✓
Anderson-Loftin et al., (2005)	✓	✓			✓		
Bray et al., (2005)					✓		
Carter et al., (2011)	✓		✓	✓		✓	
Davis et al., (2010)	✓		✓	✓	✓	✓	✓
Hawkins (2010)			✓	✓		✓	
Long et al., (2012)					✓	✓	✓
Mayer-Davis et al., (2004)	✓					✓	
Rimmer et al., (2002)					✓		
Skelly et al., (2009)	✓					✓	
Spencer et al., (2011)	✓	✓	✓	✓			
Tang et al., (2010)			✓	✓			
Utz et al., (2008)	✓		✓	✓	✓	✓	
Weinstock et al., (2011)			✓	✓		✓	

Table 6



Author(s) of Study,	Intervention	Data	Intervention
Year			Follow-Up
Anderson et al.,	The intervention was held for 6 weeks with weekly, 2-hour	At baseline; 6-	Monthly follow up
(2005)	group sessions held community-based locations. The weekly	weeks, 6 months, 1	with a phone call or
	group session was structured to reflect on self-management	year post	a support group
	experiences, emotions about having diabetes, how to engage	intervention	session.
	in problem solving, question and answer time, and		
	educational literature that was culturally tailored. The		
	sessions were led by a nurse and a dietician and were		
	centered on questions prompted by the patients.		
Anderson-Loftin et	A nurse case manager provided educational classes on	At baseline;	A home visit and
al., (2005)	dietary self-management interventions. Essential elements of	5- months	weekly phone calls.
	the class included educational classes about low-fat dietary	post- intervention	
	strategies. Peer professionals led group discussions and		
	follow-up care was provided by a nurse case manager was		
	used in this intervention.		
Bray et al., (2005)	The intervention consisted of group visits comprised of an	At baseline, 6	1 year
	education/support program led by a nurse, a physician, a	months	
	pharmacist, and a nutritionist over 4 sessions.		
Carter et al., (2011)	The intervention comprised of a patient-centered, diabetes	At baseline, 9	No follow-up
	telehealth self-management program. Participants were	months	reported.
	granted access to online diabetes educational tools. A		
	videoconference with the nurse was scheduled bi-weekly for		
	intervention contact and support. The nurse helped develop		
	patient -centered strategies to help the participants better		
	manage diabetes and improve glycemic control.		

Table 6 (continued).

Author(s) of Study,	Intervention Summary	Data	Intervention
Year			Follow-Up



Davis et al., (2010)	The intervention consisted of a comprehensive remote DSME intervention using videoconferencing, telephone, fax line, and telehealth-enabled cameras. Only three sessions were conducted face to face; all other sessions were facilitated via live video conferencing by the education staff.	At baseline; 6 months, 12 months	2 years
Hawkins (2010)	The telemedicine intervention was led by a nurse practitioner. The nurse made 15-minute weekly videophone calls for 3 months followed by 15-minute monthly calls for another 3 months. Patients selected topics of their choice. The discussions were centered on patient experiences, emotions, problem-solving techniques, and clinical questions. Participants provided consent for all videophone calls to be recorded.	At baseline; 6 months	No follow-up reported.
Long et al., (2012)	Participants in the peer-mentoring group were matched to a peer mentor within 1 to 3 weeks. The peer mentors were all African American patients whose glucose was not controlled. This attribute allowed the peers to be able to relate to the struggles of the participants. The peermentoring consisted of telephone calls in which the mentors used motivational interviewing techniques.	At baseline; 6 months	No follow-up reported.
Mayer-Davis et al., (2004)	Participants were randomized into an intensive intervention group, a reimbursable group or a usual care group. The program focused on weight loss. Information consisted of weight loss strategies and materials.	At baseline, 3 months, 6 months, 9 months	No follow-up reported.

Table 6 (continued).

Author(s) of Study,	Intervention Summary	Data	Intervention
Year			Follow-Up



Rimmer et al.,	The intervention in this study comprised of a structured	At baseline, 12-	No follow-up
(2002)	exercise plan, dietary education, and general diabetes	weeks	reported.
	education. All interactions were centered on promoting		
	better self-management skill for the participants. Support		
	groups were encouraged for the participants to aid in coping		
	with diabetes.		
Skelly et al., (2009)	The intervention was conducted in the participant's home	At baseline, 3	No follow-up
	over a series of four 1-hour visits twice a month. Four	months, 6 months,	reported.
	education modules that focused on signs and symptoms of	9 months	
	hyperglycemia, hypoglycemia, signs and symptoms of		
	neuropathy, and prevention of cardiovascular symptoms		
	guided the intervention.		
Spencer et al.,	The intervention used CHWs. CHWs provided DSME	At baseline; 6	No follow-up
(2011)	during regular home visits to participants and accompanied	months	reported.
	participants to a clinic visit during the 6-month intervention		
	period.		
Tang et al., (2010)	The intervention was held weekly and conducted by a CDE	At baseline, 6	2 years
	and a psychologist. The intervention focused on individual	months	
	patient experiences, emotions, problem-solving skills, and		
	goal-setting tactics aimed at controlling glycemic levels.		
Utz et al., (2008)	A culturally tailored intervention that focused on problem-	At baseline, 10	No follow-up
	setting strategies and goal setting in the community.	weeks	reported.

Table 6 (continued).

Author(s) of	Intervention Summary	Data	Intervention



Study,			Follow-Up
Year			
Weinstock et al.,	A videoconference was held every 4-6 weeks by the diabetes	At baseline, 6	Every year for 5
(2011)	educator to educate and encourage better self- management	months, 12 months	years.
	tactics to improve glycemic control.		

CDE=Certified diabetes educator, CHW=Community Health Worker, DSME=Diabetes self-management education

Hemoglobin A1c Outcomes

Table 7

Anderson et al., (2005)	8.6%	Reduced by 0.4%;	Reduced by 0.28%;	P < .001
		8.74% baseline; 8.34%	8.41% baseline; 8.13%	
		post-intervention	post-intervention	
Anderson-Loftin et al.,	7.9%	Reduced by 0.5%;	8.3% baseline; 8.0%	P =. 518; NS
(2005)		7.5% baseline; 7.0%	post-intervention	
		post-intervention		
Bray et al., (2005)	8.3%	Reduced by 1.1%	Increased by 0.3% in	P<. 05
			the control group	
Carter et al., (2011)	8.9%	Reduced by 2.18%	Reduced by 0.9%	P<. 05
		from baseline to post-		
		intervention.		

Table 7 (continued).

Author(s) of Study, Mean Baseline Mean Change in Mean Change in Statistic



Year	HbA1c% (Intervention and Control)	HbA1c% (Intervention)	HbA1c (Control)	Significance
Davis et al., (2010)	9.1%	Reduced by 1.2%: 9.4% baseline; 8.3% (6-month post-intervention); 8.2% (12-month post-intervention)	Reduced by 0.2%:	P=. 003
Hawkins (2010)	8.95%	Reduced by 1.7%	Reduced by 0.6%	P = .015
Long et al., (2012)	9.7%	Reduced 1.2% in the peer mentor group; reduced 0.4% in the financial incentive group	Reduced by 1%	Not significant
Mayer-Davis et al., (2004)	9.8%	Decreased 0.8% in the reimbursable group; Reduced 1.6% in the intensive care group.	Reduced by 1.1%	Not significant
Rimmer et al., (2002)	10.8%	10.8% baseline; 10.3% post-intervention	Not reported in the study.	Not significant
Skelly et al., (2009)	8.3%	8.3% baseline	8.44% baseline	Not significant
Spencer et al., (2011)	8.6%	8.6% baseline, 7.8%6 months post-intervention	8.5% baseline, 8.5% post-intervention	P < 0.01

Table 7 (continued).



Author(s) of Study, Year	Mean Baseline HbA1c%	Mean Change in HbA1c% (Intervention)	Mean Change in HbA1c (Control)	Statistical Significance
Tang et al., (2010)	8.0%	Reduced 0.68%	Improved 0.32%	P = .008
Utz et al., (2008)	8.1%	Reduced 0.32%	Reduced 0.45%	P < 0.01
Weinstock et al., (2011)	7.6%	Reduced 0.71%	Reduced 0.36%	P < 0.01



Effectiveness

Key Question #1: In African American adults with type II diabetes, what is the effectiveness of diabetes behavioral interventions as an adjuvant to usual care for outcomes related to glycemic control?

Nine out of the 14 articles, (Anderson et al., 2005; Bray et al., 2005; Carter et al., 2011; Davis et al., 2010; Hawkins, 2010; Spencer et al., 2011; Tang et al., 2010; Utz et al., 2008; Weinstock et al., 2011) reported positive changes in glycemic control between the intervention group and the control group. Of the 14 included articles, five articles did not reveal a significant change in glycemic control (Anderson-Loftin et al., 2005; Long et al., 2012; Mayer-Davis et al., 2004; Rimmer et al., 2002; Skelly et al., 2009). Moreover, this evidence is sufficient enough to conclude that diabetes behavioral interventions are effective.

Recommendations

Future studies are warranted to determine the best approach to designing behavioral interventions to African Americans. Eight studies (Anderson et al., 2005; Anderson-Loftin et al., 2005; Carter et al., 2011; Davis et al., 2010; Mayer-Davis et al., 2004; Skelly et al., 2009; Spencer et al., 2011; and Utz et al., 2008) described using a culturally tailored approach. Future studies should provide clear, precise information about the intervention and what measures are required to ensure that it is culturally tailored. Given that optimal glycemic control in the African- American population must consider culture as a factor, culturally tailored approaches are advantageous and will bring added value to future treatment plans.

Key Question #2: In African American adults with type II diabetes, how does the efficacy of diabetes behavioral interventions vary depending on the *setting* for outcomes related to glycemic control?

Evidence of the effectiveness of behavioral interventions was reviewed in various settings: community centers (Anderson et al., 2005; Davis et al., 2010; Spencer et al., 2011; Utz et al., 2008), clinics (Anderson-Loftin et al., 2005; Bray et al., 2005; Long et al., 2012; Mayer-Davis et al., 2004; Rimmer et al., 2002), and in-home (Carter et al., 2011; Hawkins, 2010; Skelly et al., 2009; Tang et al., 2010). All interventions held in the community setting reported significant improvements in HbA1c.

Recommendations

Based on the significant outcomes, sufficient evidence of the effectiveness of the community setting was identified to recommend that diabetes programs be accessible in the community setting. Community-based interventions offer the added benefit of shared cultural beliefs and traditions. Future studies that evaluate the effectiveness of behavioral interventions in various settings such as the workplace and school settings.

Key Question #3: In African American adults with type II diabetes, how does the efficacy of diabetes behavioral interventions vary depending on the *mode of delivery* of behavioral interventions for outcomes related to glycemic control?

Optimal management of diabetes involves patients engaging with the collective and coordinated efforts of several healthcare professions. The identified studies used a range of educators that influenced the effectiveness of the behavioral interventions on improving glycemic control. Of these, six used a certified diabetes educator (CDE), (Anderson et al., 2005; Mayer-Davis et al., 2004; Spencer et al., 2011; Tang et al., 2010),



six used a nurse (Anderson et al., 2005; Anderson-Loftin et al., 2005; Bray et al., 2005; Carter et al., 2011; Davis et al., 2010; Skelly et al., 2009), four used a dietician, (Davis et al., 2010; Hawkins, 2010; Mayer-Davis et al., 2004; Rimmer et al., 2002) one used CHWs (Spencer et al., 2011), and one used peer mentors (Long et al., 2012). CDEs appeared to be the most effective as they were used in five of the nine statistically significant studies

Recommendations

These findings indicate that more health professional become certified in diabetes education. Nurses, physicians, dieticians are qualified to attempt for certification.

Key Question #4: In African American adults with type II diabetes, how does the efficacy of diabetes behavioral interventions vary depending on the *duration* for outcomes related to glycemic control?

Intervention duration of the included studies varied widely—6 weeks (Anderson et al., 2005), 10 weeks (Utz et al., 2008), 12 weeks (Rimmer et al., 2002), 5 months (Anderson-Loftin et al., 2005), 6 months (Hawkins, 2010; Long et al., 2012; Spencer et al., 2011; Tang et al., 2010), 9 months (Carter et al., 2011), 12 months (Bray et al., 2005; Davis et al., 2010; Mayer-Davis et al., 2004), and 5 years (Weinstock et al., 2011). The 6-week study reported significant improvements in HbA1c, as well as the 5-year study. The number of participants who did not complete the programs throughout the duration of the intervention was included in some of the studies. High attrition rates present a challenge to the effectiveness of the interventions.

Recommendations

High attrition rates in behavioral intervention programs indicate that retention needs to become a prime focus in program policy, planning, and evaluation to improve program effectiveness. These studies suggest that behavioral programs that are practical, convenient, and accessible will increase retention.

Key Question #5: In African American adults with type II diabetes, how does the efficacy of diabetes behavioral interventions vary depending on the *theoretical* framework for outcomes related to glycemic control?

The 14 studies identified used a wide range of theories and behavior change strategies that influenced the effectiveness of the interventions. Four studies used an empowerment theoretical framework (Anderson et al., 2005; Mayer-Davis et al., 2004; Spencer et al., 2011; Tang et al, 2010); one used the Model of Nursing Case Management (Anderson-Loftin et al., 2005); one used a coordinate service delivery model (Carter et al., 2011); one used motivational interviewing (Hawkins, 2010); one used the Health Belief Model and the Transtheoretical Model of Change (Davis et al., 2010); one used the Health Promotion Model (Rimmer et al., 2002); one used the Symptom Management Model (Skelly et al., 2009); and one used the Social Cognitive Therapy (Utz et al., 2008). Two of the studies did not state the theoretical framework (Long et al., 2012; Weinstock et al., 2011). Three studies used financial incentives (Anderson et al., 2005; Davis et al., 2010; and Long et al., 2012) as a "perceived benefit" which reflects one of the central theoretical propositions of the Health Belief Model (Hochbaum, Rosenstock, & Kegels, 1952).



Recommendations

Changing behaviors in the healthcare system will require strategies that will encourage patients to want to change. In theory, most people change when something is given to them or something is taken away from them. For today's healthcare issues, future studies are recommended that use the Health Belief Model. The Health Belief Model seeks to explain and predict human health behaviors based on four constructs: perceived susceptibility, perceived severity, perceived benefits, and perceived barriers. These concepts were proposed to account for people's readiness to change.

Methodological Assessment

All studies were analyzed using the Downs and Black checklist, which is structured to assess both RCTs and non-RCTs. The tool was easy to use and provided an overall score for study quality and a numeric score out of a possible 27 points. Overall, the results of the critical appraisal of the evidence were (median score, 21 of 27), indicating that the overall quality of the included studies was strong. Table 8 provides an assessment of the methodological quality of included articles using the Downs and Black assessment tool. Table 9 entails a categorization of total scores obtained by the Downs and Black Checklist.

Conclusion

This analysis identified and analyzed the effectiveness of diabetes behavioral interventions specifically targeted to African Americans observing that most of them can significantly improve glycemic control. However, the long-term effects on patient-centered and clinically important outcomes, as well as cost effectiveness, remain unknown. Innovative strategies to improve glycemic control such as the ones described in



this review have the potential to profoundly impact the morbidity and mortality rates associated with type II diabetes in African Americans.



Table 8

Methodological Assessment Chart

Author, Year														Q	uesti	ions												Sum
1 cai	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	
Anderson et al., (2005)	1	1	0	1	1	1	1	0	0	1	1	1	1	1	0	0	1	1	1	1	1	0	1	1	1	1	1	21
Anderson- Loftin et al., (2005)	1	1	1	1	1	1	1	0	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1		0	0	22
Bray et al., (2005)	1	1	0	0	1	1	0	0	1	0	1	1	1	0	0	0	1	1	1	1	1	1	1	1	1	1	1	20
Carter et al., (2011)	1	1	1	0	1	1	1	0	1	0	1	1	1	1	0	0	1	1	1	1	1	1	1	1	0	1	1	21
Davis et al., (2010)	1	1	0	1	1	1	0	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	0	1	1	1	23
Hawkins (2010)	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	0	1	1	1	1	0	0	1	1	1	1	1	22
Long et al., (2012)	1	1	0	1	1	1	1	0	1	1	1	1	1	1	0	1	1	1	1	0	1	1	1	1	1	1	1	23
Mayer- Davis et al., (2004)	1	1	1	1	1	1	0	0	0	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	0	0	1	20

Table 8 (continued).



														()uest	ions												
Author, Year																												
Rimmer et al., (2002)	1	1	1	1	0	0	0	1		1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	22
Skelly et al., (2009)	1	1	1	0	1	1	1	1	1	0	0	1	1	1	0	1	1	1	1	1	0	1	1	0	1	0	0	19
Spencer et al., (2011)	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	26
Tang et al., (2010)	1	1	1	1	1	1	1	1	0	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	25
Utz et al., (2008)	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	24
Weinstock et al., (2011)	1	0	0	0	1	1	0	1	0	0	1	0	0	0	1	1	1	1	1	0	0	0	1	0	1	1	1	14

Table 9

Categorization of Scores

Quality Index	Percentage	Methodological Quality Score
Strong	≥75%	≥21
Moderate	50-74%	14-20

Table 9 (continued).



Quality Index	Percentage	Methodological Quality Score
Limited	25-49%	7-13
Poor	<25	<7



CHAPTER V

DISCUSSION

Summary of the Evidence

The present review identified studies that evaluated the effectiveness of behavioral interventions aimed at African American adults with type II diabetes based on the impact of glycemic control. The results of this review indicate that the available evidence is of strong quality. Most of the studies (64%) reported statistically significant outcomes, implying that the clinical benefit of this treatment approach in achieving glycemic control is effective.

Methodological Issues

Future studies on the effectiveness of behavioral interventions should address a number of methodological issues. Most importantly, strong assessments of the risk-of-bias and the methodological quality of the studies should be performed using different assessment tools. In addition, more randomized controlled trials (RCTs) using a common data elements (e.g., hemoglobin A1c) should be used to provide conclusive evidence about the efficacy and causal inference of the intervention. Unarguably, other designs are valuable in assessing effectiveness; however, strict adherence to controlling for potential confounders and other trends can produce higher quality findings. Moreover, offering detailed information describing population demographics, patient recruitment strategies, inclusion/exclusion criteria, and interventions can improve intervention replication and study appraisal. If this information is incomplete, it is difficult to conclude what components of the interventions may lead to improved outcomes, and most important,

how to apply the results. Furthermore, instruments with sound reliability and validity should be used and appropriate statistical analyses should be provided.

Limitations

This study had several limitations that need to be mentioned. First, the review was restricted to studies that assessed the hemoglobin A1c (HbA1c) as the primary outcome of interest. The restriction to the HbA1c limited the number of other interventions and outcomes that may have been examined; therefore, other interventions may exists that are effective with African American adults with type II diabetes that did not include HbA1c as a dependent variable. Another limitation may have been publication bias. Albeit, publication bias is a potential threat in all areas of research since most studies with significant results have a high likelihood of becoming published; however, other interventions may exists that are effective with African American adults with type II diabetes that are unpublished.

Notably, several variations were examined across studies in terms of settings, design, sample sizes, theoretical frameworks, interventions, intervention duration, data collection, follow-up timing, and statistical methods. These variants made it challenging to make precise cross-matches and cross-comparisons. The heterogeneity of the studies prohibited the performance of a meta-analysis. Therefore, the findings from this study are qualitative and are intended to guide future research in diabetes. Forthcoming research should seek to analyze the effectiveness of diabetes behavioral interventions on diverse outcomes, such as self-efficacy, psychological well-being, mindfulness, and coping skills. Additionally, whether these interventions would be equally effective in other groups other than African American adults with type II diabetes is unclear.



Implications

The findings of this comparative effectiveness analysis suggest several implications for research, practice, and policy.

Research

Requiring comparative effectiveness research (CER) as a method of research in health disparities such as diabetes can ensure that the most effective and efficacious interventions are used with a specific population. Diabetes affects millions of people worldwide. Evidence to treatments about what works best and for whom should be readily available. However, evidence is scant in terms of the comparative effectiveness of different treatment options available in diabetes. Due to the lack of efficient data to support wise clinical and health policy decision-making, more CER studies are immediately needed to produce dependable information that can create rapid change.

Nurses are in a pivotal position to assume leadership role in CER research. CER will enhance the ability for of nurses to shape health policy and further guide nursing practice. In nursing research, seeking research opportunities with existing data sets can identify more efficacious solutions to problems in the healthcare system.

In addition, stakeholders should be engaged at every phase of CER research.

Stakeholders have a stake in the outcomes associated with CER studies. Patients,
healthcare providers, policymakers, and other relevant stakeholders should be involved in
every aspect of CER synthesis and translation.

Practice

Individuals with diabetes should receive specialized medical care from a multidisclipinary team approach that may include nurses, physicians, nurse practitioners,



physician assistants, dietitians, and pharmacists with expertise in diabetes (ADA, 2008). The treatment plan framed as a collaborative approach between the patient and family, the nurse, the physician, and other members of the healthcare team will produce optimal outcomes (ADA, 2008). A variety of strategies and techniques that provide practical education and development self-management skills in the various aspects of diabetes management can be utilized. Treatment plan implementation requires individualized goals and objectives and involve a patient-centric approach. Establishing and recognizing diabetes self-management education (DSME) and ongoing diabetes support as an integral component of care in primary practice is important to include in the management plan (ADA, 2014).

Policy

Innovations in healthcare delivery that encourage the adoption and translation of CER in new models of care can produce sustainable, positive diabetes outcome. New models of care being implemented in primary care include Patient Centered Medical Homes (PCMH), Shared Medical Appointments (SMA), Shared Decision-Making (SDM) and Accountable Care Organizations (ACO). These models are fertile ground for CER. From the vantage point of these new care models, CER is beneficial to achieving the twofold goal of attaining quality health care and lowering healthcare costs. Building on CER, the new models can ensure and incentivize behavior change. The new care models can facilitate CER translation and align resources to meet the clinical care needs of different populations. Priorities of future research include evaluating the effectiveness of the new care models and CER.



Conclusion

Optimal glycemic control is contingent upon multiple factors that go beyond changing the behavior of the individual. Systems-level approaches provide the opportunity to recognize and understand the interactions between the social determinants of health and healthcare systems factors that impact morbidity and mortality rates of African Americans with type II diabetes. The adoption of a systems approach facilitates the development of an in-depth understanding of the complex dynamics that influence optimal diabetes management and glycemic control in the U.S. healthcare system. By improving diabetes management and glycemic control, I mean increasing the visibility and accessibility of various options that CER offers to effectively and efficiently manage the disease.

APPENDIX A

DOWNS AND BLACK CHECKLIST

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Appendix

Checklist for measuring study quality

Reporting

1. Is the hypothesis/aim/objective of the study clearly described?

yes	1
no	0

 Are the main outcomes to be measured clearly described in the Introduction or Methods section?

If the main outcomes are first mentioned in the Results section, the question should be answered no.

yes	1
no	0

3. Are the characteristics of the patients included in the study clearly described?

In cohort studies and trials, inclusion

In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.

yes	1
no	0

4. Are the interventions of interest clearly described?

Treatments and placebo (where relevant) that are to be compared should be clearly described.

yes	1
no	0

5. Are the distributions of principal confounders in each group of subjects to be compared clearly described?

A list of principal confounders is provided.

yes	2
partially	1
no	0

6. Are the main findings of the study clearly described?

Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).

yes	1
no	0

7. Does the study provide estimates of the random variability in the data for the main outcomes? In non normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

yes	1
no	0

8. Have all important adverse events that may be a consequence of the intervention been reported? This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

yes	1
no	0

9. Have the characteristics of patients lost to follow-up been described?

This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.

yes	1
no	0

10. Have actual probability values been reported(e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?

yes	1
no	0

External validity

All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited?

The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant

population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

12. Were those subjects who were prepared to participate representative of the entire population from which they were recruited?

The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

yes	1
no	0
unable to determine	0

13. Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive? For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

yes	1
no	0
unable to determine	0

Internal validity - bias

14. Was an attempt made to blind study subjects to the intervention they have received? For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

yes	1
no	0
unable to determine	0

15. Was an attempt made to blind those measuring the main outcomes of the intervention?

yes	1
no	0
unable to determine	0

16. If any of the results of the study were based on "data dredging", was this made clear? Any analyses that had not been planned at the outset of the study should be clearly

the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.

yes	1
no	0
unable to determine	0

17. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?

Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

yes	1
no	0
unable to determine	0

18. Were the statistical tests used to assess the main outcomes appropriate?

The statistical techniques used must be appropriate to the data. For example non-parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

yes	1
no	0
unable to determine	0

19. Was compliance with the intervention/s reliable?

Where there was non compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.

yes	1
no	0
unable to dete	ermine 0

20. Were the main outcome measures used accurate (valid and reliable)?

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For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.

yes	1
no	0
unable to determine	0

Internal validity - confounding (selection bias)

21. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population? For example, patients for all comparison groups should be selected from the same

For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.

yes	1
no	0
unable to determine	0

22. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time? For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

23. Were study subjects randomised to intervention groups?

Studies which state that subjects wereran-

Studies which state that subjects wererandomised should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no because it is predictable.

yes	1
no	0
unable to determine	0

24. Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable? All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.

yes	1
no	0
unable to determine	0

25. Was there adequate adjustment for confounding in the analyses from which the main findines were drawn?

This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In nonrandomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

yes	1
no	0
unable to determine	0

26. Were losses of patients to follow-up taken into

account?

If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.

yes	1
no	0
unable to determine	0

Power

27. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?

Sample sizes have been calculated to detect a difference of x% and y%.

	Size of smallest intervention group	
Α	<n,< td=""><td>0</td></n,<>	0
В	\mathbf{n}_1 – \mathbf{n}_2	1
С	n ₃ -n ₄	2
D	n ₅ -n ₆	3
E	n ₇ -n ₈	4
F	n ₈ +	5

APPENDIX B

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