MEDICAL NUTRITION THERAPY IN A CHRONIC CARE MODEL FOR THE
TREATMENT OF DIABETES—A BASELINE STUDY AS PRECURSOR TO A
PILOT STUDY COLLABORATIVE

A Thesis
Presented to
The Graduate Faculty of The University of Akron

In Partial Fulfillment
of the Requirements for the Degree
Master of Science

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May, 2007
MEDICAL NUTRITION THERAPY IN A CHRONIC CARE MODEL FOR THE TREATMENT OF DIABETES—A BASELINE STUDY AS PRECURSOR TO A PILOT STUDY COLLABORATIVE

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ACKNOWLEDGEMENTS

With great appreciation, I acknowledge those whose assistance played a vital role in the completion of this study. I would like to extend my sincere gratitude to thesis committee members, Mrs. Cinda Chima, Dr. Richard Steiner, and Mrs. Evelyn Taylor of The University of Akron, for contributing their expertise and time in order to guide this project. In particular, I thank Dr. Deborah Marino, thesis advisor, for her endless guidance, support, encouragement, and generous efforts.

I also thank all of those affiliated with the Summa Health System, Kent State University, and University of Akron Chronic Care Model pilot study. I thank the project developers whose planning allowed me this opportunity to contribute. I also thank those personnel who administered the research surveys and assisted with data-gathering which allowed me to relatively seamlessly conduct this study.
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CHAPTER I

INTRODUCTION

Background and Objectives

Diabetes mellitus continues to increase in prevalence despite conventional healthcare interventions. Diabetes exacerbates risks for debility, morbidity, and mortality, and it increases healthcare costs (1, 2, 3). Gaps exist within current healthcare modalities in chronic care—where chronic ailments are treated with acute care strategies and care diverges from standards of practice (2, 4, 5, 6, 7). New strategies like the Wagner Chronic Care model present new hope for those living with chronic disease. The new chronic care models (CCMs) promote self-management and the interdisciplinary team approach among other elements (8, 9). As Medical Nutrition Therapy (MNT) is a key in the prevention and treatment of diabetes, it should be a vital component within the CCM for diabetes (3, 10, 11, 12, 13). Effective MNT within the CCM will prepare patients for nutrition self-management by providing knowledge and resources related to diet and nutrition and by enhancing patients’ perceived self-efficacy, support, and confidence.

A collaborative among the Summa Health System, The University of Akron, and Kent State University will incorporate MNT into a CCM as part of a multidisciplinary pilot study utilizing a patient population from the Family Medicine
Center (FMC) at Akron City Hospital. As a precursor to the larger pilot study, the current study evaluated baseline data on the patient population from FMC. Demographics were gathered, knowledge and activation were measured, and these were related to blood glucose control via glycosylated hemoglobin measurements. The glycosylated hemoglobin test, also known as glycated hemoglobin, HgbA1C, and A1C, reflects blood glucose control over approximately 2 to 3 months. This tool allows patients and caregivers to track the effectiveness of interventions and to make guided adjustments as necessary. Through self-management, the trained patient can glean progress and evaluate his diabetes self-care performance as a whole—including the appropriateness of his nutrition regimen and his adherence to it.

Limited studies are found in the literature relating knowledge and activation to behavior change. Furthermore, few studies incorporate and/or thoroughly describe Medical Nutrition Therapy within the new Chronic Care Model. As a result, this current study provided an additional opportunity to correlate these variables and to provide baseline data in support of a CCM, and the following hypotheses were tested.

**Hypotheses**

Three hypotheses were tested in attempt to correlate knowledge, activation and glycosylated hemoglobin levels.

Hypothesis 1: Higher nutrition scores, as measured by the MNT knowledge test, will correlate with lowered blood glucose as measured by glycosylated hemoglobin (A1C) levels.
Hypothesis 2: Higher patient activation scores, as measured by the PAM (Patient Activation Measure) tool, will correlate with lowered blood glucose levels as measured by A1C.

Hypothesis 3: Higher patient knowledge scores will correlate with higher patient activation scores.

Definitions of Terms

Self-management: An approach to health management where the goal is to empower activated, knowledgeable patients who possess the resources and support necessary to manage their own health. Patients set goals and actively participate in management and treatment decisions (2, 4, 5, 14).

Chronic Care Model (CCM): A newer healthcare model comprised of several components that collectively aim to provide patient-focused care—providing patients with the knowledge, tools, and resources required to manage their own disease (6).

Medical Nutrition Therapy (MNT): Any and all diagnostic, therapeutic, or counseling services provided by a registered dietitian for management or treatment of any disease, condition, disorder, or illness (15).

Blood glucose: The main simple sugar found in the blood, and it is used in the body for energy (16).

Glycosylated hemoglobin (glycated hemoglobin, HgbA1C, A1C): A test that approximates average blood glucose level over the past 2 to 3 months. Hemoglobin is the part of a red blood cell that carries oxygen to the cells, and it joins with glucose in the bloodstream. Also called hemoglobin A1C or
glycosylated hemoglobin, the test shows the amount of glucose that binds to the red blood cell which is proportional to the amount of glucose in the blood. This test is currently not used for diagnosing diabetes but is helpful with tracking diabetes management. Usually a level of 8% or higher suggests suboptimal control where action is required (16, 17, 18).

**Insulin**: A hormone that helps the body use glucose for energy. The beta cells of the pancreas make insulin. When the body cannot make enough insulin, it is taken by injection (16, 17).

**Hyperglycemia**: Excessive levels of glucose in the blood. Fasting hyperglycemia is a blood glucose measurement above a desirable level after a person has fasted for at least 8 hours. Postprandial hyperglycemia is blood glucose above a desirable level 1 to 2 hours after a person has eaten. Normal levels for fasting and 2-hour postprandial is considered <100 mg/dl and <140 mg/dl, respectively (16, 17).

**Hypoglycemia**: A condition that occurs when one's blood glucose is lower than normal, usually less than 70 mg/dL. Signs include hunger, nervousness, shakiness, perspiration, dizziness or light-headedness, sleepiness, and confusion. If left untreated, hypoglycemia may lead to unconsciousness. Hypoglycemia is treated by consuming a carbohydrate-rich food such as a glucose tablet or juice. It may also be treated with an injection of glucagon if the person is unconscious or unable to swallow (16).

**Diabetic Ketoacidosis (DKA)**: An emergency condition in which extremely high blood glucose levels, along with a severe lack of insulin, result in the breakdown
of body fat for energy and an accumulation of ketones in the blood and urine. Signs of DKA include nausea, vomiting, stomach pain, fruity breath odor, and rapid breathing. If untreated, DKA can lead to coma and death (16, 18).

**Patient Activation Measure (PAM):** A validated, reliable instrument for assessing individuals’ levels of readiness for change (19).

**Type 1 diabetes (formerly juvenile-onset diabetes, insulin dependent diabetes):** A condition characterized by high blood glucose levels caused by a lack of insulin. It occurs with cellular-mediated autoimmune destruction of the Beta-cells of the pancreas with a variable rate of destruction. In the later stages, DKA can present due to little or no insulin secretion. Causes are linked to genetics and environmental factors but are poorly defined at this time.

Type 1 diabetes develops most often in young people but can appear in adults. Diagnostic criteria include classic symptoms of polyuria, polydypsia, and unexplained weight loss; or a blood glucose level after fasting for 8 to 12 hours of ≥126mg/dl; or two-hour post load glucose ≥200mg/dl during an Oral Glucose Tolerance Test (OGTT). In the OGTT, a person's blood glucose level is measured after a fast and two hours after drinking a glucose-rich beverage; however, it is not recommended for routine clinical use. In the absence of unequivocal hyperglycemia, the criteria should be confirmed by repeat testing on a different day (15, 17, 18).

**Type 2 diabetes (formerly adult-onset diabetes, non-insulin dependent diabetes):** A condition characterized by high blood glucose levels caused by either a lack of insulin or the body's inability to use insulin efficiently due to insulin resistance and
relative insulin deficiency. Unlike type 1 diabetes, beta-cell destruction does not occur. Insulin resistance is usually associated with obesity or android body fat distribution, and insulin secretion is defective. Hyperglycemia usually develops gradually and ketoacidosis seldom occurs independent of a coexisting stress or illness. Environmental factors and strong genetic predisposition are associated with its etiology. This most common form of diabetes develops most often in middle-aged and older adults, but prevalence is growing among young people. See also “Type 1 diabetes” for diagnostic criteria (15, 17, 18).

**Medicare Modernization Act:** Law enacted for Centers for Medicare and Medicaid Services (CMS) which includes MNT coverage in the treatment of diabetes (20).

**Assumptions**

Several assumptions were made which impact the validity of the study. It was assumed that patients answered all surveys and questionnaires truthfully and that personnel conducting the interviews and surveys did so consistently among all participants after proper training. The researcher assumed the knowledge assessment tool was a valid, credible instrument (21). Although this tool has not undergone validation, it was the best tool available for this study at the time. It was also assumed that data was transcribed correctly, reviewed in a timely manner, and A1C measurements were accurate.

**Limitations**

Limitations were also considered. For example, due to subject unavailability, the sample size was smaller than desired. Because patients agreed to participate in the study, subjects were self-selected; therefore, the
sample may not have been representative of all diabetic patients within the FMC. Many factors were out of the present researcher’s control because many aspects to this study had been prearranged by virtue of the larger study. The researcher did not possess freedom to adapt protocols to meet needs of the current study. For example, body mass index (BMI) relates body weight to height and is associated with nutrition risk. Higher BMI is associated with exacerbation of diabetes and comorbidities and would have been valuable to include in the current study (22, 23). Unfortunately, because heights were not obtained, BMI could not be calculated. Finally, as discussed above, the knowledge tool was not yet validated.

Significance

Limited studies are available that relate knowledge and activation to behavior change. Furthermore, few studies incorporate Medical Nutrition Therapy within the new Chronic Care Model and/or thoroughly describe nutrition interventions. This current study provided an opportunity to correlate these aspects. As a result, this study will help lay the foundation for future-related studies—including the larger pilot study—perhaps by further developing the MNT piece of the Chronic Care Model. Hence, by laying the groundwork for the larger pilot study, the current study can assist in the process of developing diabetes treatment modalities that improve outcomes for those who live with diabetes—in ways current approaches have fallen short.
CHAPTER II

REVIEW OF LITERATURE

Background

Despite prior preventive and treatment interventions, diabetes mellitus continues to increase in prevalence and adversely impact lives through debilitating complications and increased morbidity and mortality (1, 2, 3). As of 2005, 20.8 million Americans (7.0%) were diagnosed with diabetes, and 90% to 95% of these cases were classified with type 2 diabetes (16, 24). The rise in diabetes also contributes to increases in hospitalization and healthcare costs—direct and indirect costs exceeded 132 billion dollars in the United States in 2002 for type 2 diabetes alone (1, 16). The direct medical costs associated with diabetes are substantial (1). While deaths due to diabetes are likely underreported, in 2000, it ranked as the sixth leading cause of death in the United States as listed on death certificates (16).

The complications of diabetes are numerous and can be life threatening. Acute conditions include hyperglycemia, hypoglycemia, and ketoacidosis. The well-established, long-term complications of uncontrolled blood sugars include: cardiovascular disease, eye and nerve damage, and kidney disease.
Impaired tissue perfusion combined with nerve damage often leads to severe, non-healing wounds of the extremities with potential for loss of limb (16).

Research has established that improved blood sugar control improves outcomes in those with diabetes, and with each percentage decrease in glycosylated hemoglobin values, significant reductions in complications occur (9). Furthermore, the acute and chronic complications of diabetes can be substantially lessened or even avoided with intensive management thereby enhancing quality of life and longevity (9, 11, 22, 25). Regardless, it has been found that most persons with diabetes do not maintain acceptable glycemic levels (26, 27).

Many factors contribute to inadequate glycemic control. The current healthcare system and chronic diabetes disease treatment strategies may be misdirected. Current treatment approaches utilize modalities appropriate for acute illness rather than chronic illness as they are reactive rather than proactive (4). Health care neglects to adequately arm patients with sufficient self-management skills, and it lacks effective employment of a clinical division of labor. Ancillary healthcare services are underutilized where they otherwise would more effectively contribute to positive patient outcomes (4, 6).

Furthermore, a gap exists between best practice guidelines for the treatment of diabetes and actual delivery of services (2, 5, 6, 7). Patients may receive care inconsistent with established standards. The suboptimal delivery of health care, patients unprepared to manage their conditions, and a continued rise in obesity prevalence—coupled with an aging population demographic, physical...
inactivity, and increased medical care costs each threaten to further exacerbate the rise in diabetes. New strategies offer hope for curtailing these trends.

The New Chronic Care Model

Advocates for improved chronic-illness care seek to realign organizational priorities, redesign healthcare systems, and train providers and patients to be partners in a collaborative care process (2). New models for treating chronic disease such as diabetes mellitus have been described. These models ultimately aim to provide patient-focused care—providing patients with the knowledge, tools, and resources required to manage their own disease (6).

The Wagner Chronic Care Model (CCM) proposes an interdisciplinary healthcare team approach that incorporates six components: community linkages, organization of the healthcare delivery system, self management support, delivery system design, decision support, and clinical information systems (8, 9). This approach recognizes the need for community support in the form of policies, service and resource development; high quality health care with incentives; education provision, emotional support, and strategies to promote patient self-management; healthcare team division of labor with planned management; routine monitoring and follow-up; evidence-based care aided by standards and guidelines; and effective clinical information services for data management (6, 8). The ultimate vision of the Wagner Chronic Care Model has been described to be “. . . an informed, activated patient interacting with a prepared, proactive practice team, resulting in high-quality, satisfying encounters and improved outcomes” (6). Applied to diabetes mellitus, the CCM may provide
the springboard to block today’s adverse trends in this endemic disease. A key strategy arms patients with necessary self-management skills.

The Empowerment Movement

Over the past decade, patient self-management has become a focus in the prevention and treatment of diabetes. Improved outcomes have been realized (14, 27). The strategy empowers activated, knowledgeable patients and provides the resources and support necessary to manage their own health. Diverging from the conventional approach, patients actively set goals and make management and treatment decisions regarding their self-care. Without trained, prepared, proactive practice teams and a supportive healthcare system, however, the concept remains just a concept (2, 4, 6, 14). Patients and healthcare professionals must redefine their roles and collaborate—reintegrate the clinical expertise of healthcare professionals with the concerns, priorities, and resources of the patient, and the healthcare system must support this reintegration (28).

The new paradigm shift faces challenges. There is difficulty in applying new techniques and approaches; in gaining acceptance among healthcare providers and the healthcare system; and in accomplishing a shift that could take generations to evolve. Furthermore, clinicians perceive the transition as time consuming when healthcare demands more with less time (28). Rotor et. al. suggest that the patient empowerment movement “fosters the competence and confidence necessary for personal transformation” (14). Self-management has also been incorporated into Medical Nutrition Therapy (29, 30, 31, 32).
MNT in Diabetes Treatment and Prevention

Any new approach to chronic-illness care as aforementioned must incorporate the known, effective components of disease prevention and treatment. One such critical piece in the case of diabetes management is Medical Nutrition Therapy (MNT). MNT has been defined as “. . . any and all diagnostic, therapeutic, or counseling services provided by a dietitian for management or treatment of any disease, condition, disorder, or illness” including the assessment of nutritional status and treatment—diet modification and counseling, and specialized nutrition therapies (15, 33).

It has been clearly established that diet plays an important role in the prevention and management of diabetes, and it is key to improving outcomes (13, 34, 35). In the case of type 1 diabetes, the Diabetes Control and Complications Trial (DCCT) showed that tight blood glucose control via intensive therapy reduced eye, nerve, and kidney damage by as much as 76% (11). A 2003 follow-up study showed that tight blood glucose control also lowered the risk of atherosclerosis. Furthermore, the EDIC (Epidemiology of Diabetes Interventions and Complications) follow-up study found that intensive therapy over 6.5 years reduced cardiovascular disease (CVD) by 42% while reducing occurrence of heart attack, stroke, and death by 57% (34, 36). Dietitians within the DCCT demonstrated improved glycemia among their patients when implementing several different MNT approaches with varied degrees of complexity (13). Throughout the many DCCT studies, it became apparent that
diet therapy played an increasingly central role in achieving glycemic control among insulin dependent diabetic patients (22).

In 2002, the Diabetes Prevention Program demonstrated that lifestyle changes (diet and exercise) delivered to high risk patients by registered dietitians reduced the incidence of type 2 diabetes more effectively than did medication (3). Beneficial outcomes (improved control of hyperglycemia, hyperlipidemia, and hypertension) are often associated with RD-provided MNT. Physical activity alone, however, appears to be insufficient (30). Research shows that MNT is most effective in managing diabetes upon onset, but it is also vital throughout disease progression (37).

In the Finnish Diabetes Prevention Study (n=522), the intensive lifestyle intervention group (individualized diet counseling, exercise training sessions at high frequency during the first year followed by a maintenance period) realized long-term (three years) beneficial changes in diet, physical activity, clinical and biochemical parameters. The study demonstrated a reduced risk of diabetes onset versus the control group (general dietary and exercise advice with annual physician exam) (12). The Finnish Study not only reinforced the importance of MNT but also the necessity of ongoing reinforcement and follow up.

Congress recognizes MNT’s effectiveness in fighting chronic disease and in reducing healthcare costs. In 1997, Congress launched a study which demonstrated evidence that MNT can improve outcomes in diabetes and cost effectiveness (13). In December 2000, Congress passed the Medicare Part B MNT provision which approved MNT reimbursement in the treatment of diabetes
as provided by a registered dietitian or licensed nutrition professional (15). MNT will also be required aspects of various Medicare expansion programs under the Medicare Modernization Act including the new Voluntary Chronic Care Improvement Programs (15).

Evidence demonstrates that is MNT is effective, and dietitians are best suited to provide it (13). Dietitians are extensively trained in MNT, and practice is guided by a national affiliate featuring a code of ethics and standards of practice and performance, professional networks, and resources. Outcomes studies have demonstrated that MNT for diabetes provided by a registered dietitian results in decreases in A1C levels and improvements in dyslipidemia. As previously discussed, these are associated with improved patient outcomes as well as lower healthcare costs. Outcomes research continues to further support the efficacy of MNT when provided by a registered dietitian (3, 31, 33, 38). Numerous references discuss dietitian-guided MNT’s critical role in the prevention and management of diabetes, and these are cited (3, 11, 13, 30).

Latest MNT Protocols for Diabetes

Over the years, the approach to MNT in diabetes care has changed in order to better facilitate behavior modification and improved patient outcomes. Strategy has veered from educating patients on a rigid diet prescription to encouraging lifestyle changes to help patients more successfully achieve their goals. These strategies include setting realistic, flexible goals based on patients’ individual abilities and willingness (30). The American Dietetic Association released its updated MNT protocol for type 2 diabetes in 2001 (29, 39). This
protocol outlines nutrition assessment, intervention, training, and follow-up plans along with timelines, guidelines, and goals. Similarly, an American Diabetes Association position paper on the standards of medical care in diabetes was published in 2007 and describes MNT as an integral component (11).

Barriers to MNT

Medical Nutrition Therapy has become an important piece in the prevention and treatment of diabetes. It is not without barriers, however. Patients who can benefit from MNT must be identified and referred by physicians. The literature describes the disparity between best practice guidelines for diabetes care and actual practice which clearly impacts MNT (2, 4, 5, 6). Often the diagnosis is not made promptly, nor is it clearly communicated to the patient. As a result, the patient may underestimate the seriousness of his condition and fail to promptly seek help and initiate change (40). Furthermore, missed physician follow-up appointments cause lost opportunities for further nutrition referrals and interventions (40). Other obstacles in providing MNT have been reported by registered dietitians including difficulty in obtaining recent laboratory values, lack of time, and inability to reach patients for follow-up appointments (38).

According to one study, 427 eligible, primary care physicians completed surveys pertaining to nutrition counseling. Of these, 62% of the physicians reported that they refer patients with type 2 diabetes to a nutrition counselor while 38% reported providing the instruction themselves. Perceived barriers to MNT included inadequate insurance reimbursement, patient disinterest, non-adherence to nutrition prescriptions, and lack of family support. Access to
professionals and programs were not perceived as significant problems among the participants although this may vary with locality (41). If physicians provide nutrition information, medical school curricula and continuing education programs must be enhanced. Lastly, physicians must also be encouraged to refer their patients to registered (or licensed) dietitians and not simply to “nutrition counselors” (41).

Patient-based barriers also exist. Low income, time constraints, competing demands, and knowledge deficits are associated with inhibited patient access to and/or successful outcomes with MNT (42). Access to affordable, nutritious food sources in the community must be improved (42). Advocates also suggest that accessible sites should be more frequently utilized for nutrition education (42).

MNT within the CCM

Medical Nutrition Therapy is a component in the prevention and treatment of diabetes. As a result, it is a vital entity within the CCM for diabetes. Effective MNT as part of the CCM will arm patients with tools for nutrition self-management—knowledge and resources related to diet and nutrition, perceived self-efficacy, support, and confidence—when all imparted in effective, educational venues.

As proposed by developers of the Chronic Care Model, the team approach and patient self-management are cornerstones to the treatment of chronic disease. While the RD would serve as the primary nutrition therapy provider, all team members should have a basic, working knowledge of the individualized MNT treatment guidelines and strategies. Furthermore, the educational
component of MNT must go beyond providing an individualized diet prescription based on evidence-based nutrition standards and guidelines. Each patient must be given all necessary tools that support behavior change along with adequate reinforcement and coaching over time. Although important, information and knowledge are insufficient.

The Role of Knowledge

Knowledge is an integral part of diabetes care. In the Fremantle Diabetes Study (n=1264), it was found that formal diet education programs, visits to dietitians and instruction on self-monitoring blood glucose are associated with improved nutrition knowledge in patients with type 2 diabetes. Only one third of the participants reported having visited dietitians, however. Those with longer duration of diabetes were more likely to have seen a dietitian implying that dietitians may not be seen early enough in the progression of the disease (43).

Although nutrition knowledge is necessary, it alone does not lead to positive outcomes in diabetes (44, 46). Knowledge studies have shown no association with glycosylated hemoglobin levels indicating that knowledge alone fails to address individuals’ attitudes and behaviors which foster change (43). Studies, however, may not have adequately accounted for motivation’s importance to knowledge and behavior change. It is possible that highly motivated patients tend to have higher levels of knowledge. Many factors add to the complexity of implementing diet and exercise changes and self-management as a whole.
The Roles of Confidence and Support

It has also been suggested that patients who understand the seriousness of their conditions and perceive self-efficacy will be more successful in self management. Peer and familial support also contribute (4, 30). A positive correlation between levels of confidence and later adherence has been described along with a negative correlation of depression and psychosocial distress with self-management and metabolic control (30, 46). In a 2003 study of women with type 2 diabetes (n=53), support and confidence were the best predictors of metabolic control, psychological adjustment (diabetes-related distress), and dietary self-management (46). The patient must also be motivated.

The Role of Motivation

Implementing changes in diet and physical activity is challenging and is unlikely to occur while a patient is unmotivated. How do healthcare providers assess patients’ readiness to change and use this in practice? Historically, the lack of a clear, appropriate definition of “motivation” confounds the ability to measure it. Limited tools are available. With the purpose to better utilize motivation in healthcare, the literature defines those who are “activated” as those who:

. . . believe patients have important roles to play in self-managing care, collaborating with providers, and maintaining their health. They know how to manage their condition and maintain functioning and prevent health declines; and they have the skills and behavioral repertoire to manage their condition, collaborate with the health providers, maintain their health functioning, and access appropriate and high-quality care (19).
Hibbard defined four stages of activation including believing the patient’s role is important, possessing confidence and knowledge, taking action, and maintaining the behavior change under stress (19). It has been shown that those patients who are clearly activated tend toward improved disease outcomes (19). The Patient Activation Measure (PAM) has been developed, tested, and validated. It promises to be a reliable, valuable instrument for assessing individuals’ levels of activation which dietitians can apply to MNT (19).

The Dietitian as a Member of the CCM Team

Medical Nutrition Therapy is an established component in the treatment of diabetes. In the changing face of chronic disease treatment, MNT must take its place among the disciplines of the CCM team. Within this context, the dietitian must effectively employ self-management techniques and utilize evidence-based information, strategies, tools, resources, and time. Medical Nutrition Therapy ought to assess a patient’s baseline knowledge and state of activation toward behavior change while applying interpersonal skills to build rapport and trust, and serve as a consistent source of support with routine follow up. The RD must arm the patient with excellent self-management skills—honing problem solving and goal setting skills and instilling self-confidence. The dietitian must also work effectively with all members of the CCM interdisciplinary team. An Ohio-based pilot study seeks to include MNT within a proposed CCM for diabetic patients and features a dietitian as an interdisciplinary team member.
Pilot Background—The Chronic Care Collaborative

In a chronic care collaborative among the Summa Health System (SHS), The University of Akron, and Kent State University, MNT protocols and group visits for diabetic patients will be included in a primary care residency in an effort to apply the CCM. Subjects will be randomly assigned to an augmented usual care group (diabetes-related care provided solely by their primary care providers) or assigned to individualized MNT and CCM group visits. Data will be gathered at baseline and at six months post intervention (45).

Current Proposed Study Purpose and Rationale

In the current study, baseline data on the patient population of the Summa Health System (SHS), The University of Akron, and Kent State collaborative effort were gathered and examined. Results will lay the foundation for the larger-scope, collaborative pilot which will investigate and implement diabetes-appropriate MNT in a chronic care model. The current study demographically characterized the patient sample based on several factors. It also studied baseline relationships between blood glucose control and patient knowledge and between blood glucose control and patient motivation prior to MNT intervention. The results will assist the pilot researchers with conducting MNT and group visit trials for diabetic patients. The pilot will attempt to effectively incorporate MNT into an interdisciplinary chronic care model for diabetes and consider the cost-effectiveness of individualized MNT and CCM group visits (45).
CHAPTER III

METHODOLOGY

Study Design

As previously described, the current study evaluated baseline data on a patient population from the Family Medicine Center (FMC) at Akron City Hospital. Subjects consisted of active, English-speaking male and female diabetic patients. They were to be at least eighteen years of age with A1C levels of at least 8%. Subjects presenting with renal disease, pregnancy, chemotherapy, radiation, axis II psychiatric disorder, and other communication problems were excluded.

In this convenience sample, subjects who met study criteria were recruited via letter. During follow-up phone calls, patients were invited to a free FMC visit to complete the informed consent process and to collect baseline data. Patients were offered ten dollars for participating in baseline activities. To characterize the population, baseline data included age, gender, smoking status, body weight, foot checks, and co-morbidities. Glycosylated hemoglobin, microalbumin checks and urinary albumin levels were also measured.

Other measured variables included knowledge and activation. Basic, baseline diabetes knowledge was measured using the MNT knowledge test (Appendix A). This test was developed by one of the pilot study researchers and
was adapted from the Michigan Diabetes Brief Diabetes Knowledge Test. A higher the score would imply greater knowledge (21, 47).

Patient activation was measured using the PAM measuring tool as previously described (Appendix B). To measure activation, the validated PAM test scores allowed for a maximum of 52 points (Appendix B). Thirteen statements were listed similar to statements that people sometimes make regarding their health. The tool offered response options: disagree strongly, disagree, agree, agree strongly, and N/A. The tool was scored by calculating a raw score by adding up all responses via the point system as indicated in Appendix B.

The raw score must be converted to the PAM score. A table delineates this conversion and is available in Appendix B. Interpretation guidelines explain that approximately one third of respondents tend to have scores between zero and 56; one third has scores between 56.5 and 66.6, and one third has scores of 67 or higher. The higher score reflects a person with higher activation.

As described, to characterize this pre-intervention stage, baseline data was gathered and analyzed and the results evaluated. Again, the subset was a convenience sample comprised of those who voluntarily agreed to participate and complete the knowledge and activation tools, as well as provide demographic information, at the point of baseline data collection. Because the subset was small, this presented difficulty in obtaining statistically significant results.
The project was approved by the Institutional Review Board for the Protection of Human Subjects at The University of Akron, Kent State University, and Summa Health System. Participant confidentiality was maintained as Summa personnel utilized password protected work stations for files and limited data access to study personnel. All pilot study staff had taken approved courses concerning the protection of human research subjects. Patients signed informed consent documents, and they were identified via a coded number system. Therefore, they were unidentifiable by name (Appendices C, D). Only non-identifiable data files were transferred to The University of Akron to protect confidentiality. Patients were advised that their participation was voluntary and their willingness or unwillingness to participate would not impact future medical care.

Research Hypotheses

Three baseline research hypotheses were tested in attempt to assess knowledge, activation, and glycosylated hemoglobin levels for associations. Hypothesis 1: Higher nutrition scores as measured by the MNT knowledge test will correlate with lowered blood glucose as measured by glycosylated hemoglobin (A1C) levels.

Hypothesis 2: Higher patient activation scores as measured by PAM will correlate with lowered blood glucose levels as measured by A1C.

Hypothesis 3: Higher patient knowledge scores will correlate with higher patient activation scores.
Data Collection, Analysis, and Interpretation

Summa personnel administered the instruments and collected baseline data from patient interviews and medical records. The researcher obtained the data from the Summa and university personnel in Excel database form. The data was entered into JMP statistical software for statistical analysis. Demographics were gathered for two groups—all participants (n=135) and the subgroup (n=18). Appropriate descriptive and inferential statistics were generated. Multivariate correlations and pair-wise correlations among A1C, the DM knowledge test scores, and PAM scores were applied in order to statistically test the hypotheses.
CHAPTER IV

RESULTS

One purpose of this study was to demographically characterize the patients that will be participating in the larger pilot study at baseline—prior to MNT (medical nutrition therapy) interventions. The participants represented diabetic patients from a Summa Health System primary care practice who would presumably reflect typical diabetic patients. Furthermore, this study intended to consider relationships between baseline diabetes knowledge and glycosylated hemoglobin (A1C) levels, patient activation and A1C levels, and patient knowledge of diabetes and activation. To look at these relationships, a smaller subset of this group had also completed baseline Diabetes Knowledge and PAM (Patient Activation Measure) tests which were evaluated in the current study to test the hypotheses.

Demographics

Subjects consisted of a patient population from the Family Medicine Center (FMC) at Akron City Hospital. Subjects were active, English-speaking male and female diabetic patients. They were at least eighteen years of age with glycosylated hemoglobin levels of at least 8%. Subjects presenting with renal
disease, pregnancy, chemotherapy, radiation, axis II psychiatric disorder, and with other communication problems were excluded.

Of the participants (n=135), 87 were female (64.4%) and 48 were male (35.6%). The patients ranged from 18 to 93 years of age, and the mean age was 56 years. Most subjects were non-smokers (73%). Body weights ranged from 117 pounds to 389 pounds with a mean of 212 pounds. Forty-five percent practiced routine foot checks, 29% presented with HTN (hypertension) where 13% presented with CAD (coronary artery disease), 7% with CHF (congestive heart failure), 9% with retinopathy, 18% with nephropathy, and 36% reported depression. About half of the subjects presented with hyperlipidemia.

Hemoglobin A1C levels ranged from 5.5 to 16.1% with an average of 8.3%.

Blood lipid levels and urinary albumin were measured and recorded. (Tables 1, 2).

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>25th Quartile</th>
<th>Median</th>
<th>75th Quartile</th>
<th>Max</th>
<th>Min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>135</td>
<td>56.0</td>
<td>16.0</td>
<td>45.0</td>
<td>56.0</td>
<td>69.0</td>
<td>93.0</td>
<td>18.0</td>
</tr>
<tr>
<td>Weight (lbs.)</td>
<td>133</td>
<td>212.0</td>
<td>52.0</td>
<td>175.0</td>
<td>208.0</td>
<td>238.0</td>
<td>389.0</td>
<td>117.0</td>
</tr>
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<td>Weight (Kg)</td>
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<td>95.5</td>
<td>25.0</td>
<td>80.0</td>
<td>93.4</td>
<td>107.9</td>
<td>176.8</td>
<td>30.4</td>
</tr>
<tr>
<td>Glycosylated Hemoglobin, A1C (%)</td>
<td>130</td>
<td>8.4</td>
<td>1.6</td>
<td>7.3</td>
<td>8.0</td>
<td>9.0</td>
<td>16.1</td>
<td>5.5</td>
</tr>
<tr>
<td>Total Cholesterol, TC (mg/dL)</td>
<td>127</td>
<td>180.3</td>
<td>43.4</td>
<td>152.0</td>
<td>177.0</td>
<td>202.0</td>
<td>318.0</td>
<td>80.0</td>
</tr>
<tr>
<td>Low Density Lipoproteins, LDL (mg/dL)</td>
<td>118</td>
<td>99.3</td>
<td>35.7</td>
<td>75.0</td>
<td>94.0</td>
<td>121.3</td>
<td>220.0</td>
<td>30.0</td>
</tr>
<tr>
<td>High Density Lipoproteins, HDL (mg/dL)</td>
<td>126</td>
<td>44.8</td>
<td>12.0</td>
<td>36.8</td>
<td>44.0</td>
<td>50.7</td>
<td>106.8</td>
<td>26.0</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)</td>
<td>126</td>
<td>195.2</td>
<td>170.9</td>
<td>108.8</td>
<td>156.0</td>
<td>214.8</td>
<td>1161.0</td>
<td>31.0</td>
</tr>
<tr>
<td>Urinary Albumin (mg/dL)</td>
<td>101</td>
<td>49.3</td>
<td>84.5</td>
<td>7.4</td>
<td>15.9</td>
<td>46.9</td>
<td>454.0</td>
<td>2.0</td>
</tr>
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</table>
Table 2: Group Health Indicators (n=135)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Percent Yes</th>
<th>Percent No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoker</td>
<td>24.4</td>
<td>72.6</td>
<td>3.0</td>
</tr>
<tr>
<td>Foot Check</td>
<td>45.2</td>
<td>54.8</td>
<td>-</td>
</tr>
<tr>
<td>Hypertension, HTN</td>
<td>28.9</td>
<td>70.4</td>
<td>0.7</td>
</tr>
<tr>
<td>Coronary Artery Disease, CAD</td>
<td>13.3</td>
<td>85.9</td>
<td>0.7</td>
</tr>
<tr>
<td>Congestive Heart Failure, CHF</td>
<td>7.4</td>
<td>91.1</td>
<td>1.5</td>
</tr>
<tr>
<td>Depression</td>
<td>36.3</td>
<td>62.9</td>
<td>0.7</td>
</tr>
<tr>
<td>Hyperlipidemia, HLP</td>
<td>50.4</td>
<td>48.1</td>
<td>1.5</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>17.8</td>
<td>80.7</td>
<td>1.5</td>
</tr>
<tr>
<td>Retinopathy</td>
<td>8.9</td>
<td>90.4</td>
<td>-</td>
</tr>
<tr>
<td>Microalbumin Check</td>
<td>49.6</td>
<td>50.4</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Of the subset (n=18), 10 were female (56%) and 8 were male (44%). The patients ranged from 23 to 82 years of age, and the mean age was 57 years.

Most subjects were non-smokers. Body weight ranged from 141 pounds to 354 pounds with a mean of 212 pounds. Sixty-seven percent practiced routine foot checks, 56% presented with HTN where 6% presented with CAD, none with CHF, 6% with retinopathy, 11% with nephropathy, and 33% reported depression. Over half of the subjects presented with hyperlipidemia. Hemoglobin A1C levels ranged from 6.3% to 16.1% with an average of 8.03%. Blood lipid levels and urinary albumin were measured and recorded (Tables 3, 4).
Table 3: Subset Baseline Data

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>25th Quartile</th>
<th>Median</th>
<th>75th Quartile</th>
<th>Max</th>
<th>Min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>18.0</td>
<td>57.2</td>
<td>16.3</td>
<td>52.3</td>
<td>58.0</td>
<td>70.0</td>
<td>82.0</td>
<td>23.0</td>
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<tr>
<td>Weight (lbs.)</td>
<td>18.0</td>
<td>211.6</td>
<td>55.7</td>
<td>169.0</td>
<td>204.5</td>
<td>251.5</td>
<td>354.0</td>
<td>141.0</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>18.0</td>
<td>96.1</td>
<td>25.4</td>
<td>76.8</td>
<td>93.1</td>
<td>114.5</td>
<td>160.9</td>
<td>64.1</td>
</tr>
<tr>
<td>Glycosylated Hemoglobin, A1C (%)</td>
<td>17.0</td>
<td>8.1</td>
<td>2.3</td>
<td>6.7</td>
<td>7.1</td>
<td>8.5</td>
<td>16.1</td>
<td>6.3</td>
</tr>
<tr>
<td>Total Cholesterol, TC (mg/dL)</td>
<td>17.0</td>
<td>181.9</td>
<td>46.7</td>
<td>142.5</td>
<td>182.0</td>
<td>197.5</td>
<td>318.0</td>
<td>118.0</td>
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<tr>
<td>Low Density Lipoproteins, LDL (mg/dL)</td>
<td>15.0</td>
<td>92.9</td>
<td>27.5</td>
<td>73.0</td>
<td>85.0</td>
<td>109.0</td>
<td>163.0</td>
<td>60.0</td>
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<tr>
<td>High Density Lipoproteins, HDL (mg/dL)</td>
<td>15.0</td>
<td>46.2</td>
<td>18.3</td>
<td>35.9</td>
<td>41.7</td>
<td>50.4</td>
<td>106.8</td>
<td>27.0</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)</td>
<td>16.0</td>
<td>212.4</td>
<td>158.5</td>
<td>84.5</td>
<td>151.0</td>
<td>323.0</td>
<td>589.0</td>
<td>42.0</td>
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<tr>
<td>Urinary Albumin (mg/dL)</td>
<td>15.0</td>
<td>46.5</td>
<td>75.7</td>
<td>3.8</td>
<td>11.8</td>
<td>36.0</td>
<td>233.0</td>
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Table 4: Subset Health Indicators (n=18)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Percent Yes</th>
<th>Percent No</th>
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</thead>
<tbody>
<tr>
<td>Smoker</td>
<td>22.2</td>
<td>77.8</td>
</tr>
<tr>
<td>Foot Check</td>
<td>66.7</td>
<td>33.3</td>
</tr>
<tr>
<td>Hypertension, HTN</td>
<td>55.6</td>
<td>44.4</td>
</tr>
<tr>
<td>Coronary Artery Disease, CAD</td>
<td>5.6</td>
<td>94.4</td>
</tr>
<tr>
<td>Congestive Heart Failure, CHF</td>
<td>0.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Depression</td>
<td>33.3</td>
<td>66.7</td>
</tr>
<tr>
<td>Hyperlipidemia, HLP</td>
<td>55.6</td>
<td>44.4</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>11.1</td>
<td>88.9</td>
</tr>
<tr>
<td>Retinopathy</td>
<td>5.6</td>
<td>94.4</td>
</tr>
<tr>
<td>Microalbumin Check</td>
<td>72.2</td>
<td>27.8</td>
</tr>
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</table>
Knowledge Tests

The subset’s 18 knowledge test scores were evaluated (Appendix A). The knowledge test had been adapted from the validated Michigan Diabetes Research and Training Center Diabetes Knowledge Test where a higher test score correlates with greater diabetes knowledge (47, 48). Out of 10 multiple choice questions within the adapted diabetes knowledge test, scores ranged from 2 to 9 with an average score of 5.7 correct. A higher score presumably correlated with higher knowledge, and a lower score with lower knowledge, although this adapted tool had not yet been validated.

Activation Measure

As previously discussed, a patient is activated when he believes his role in disease self-management is important, and he knows how to manage his disease to maintain his health and to access high-quality care. The Patient Activation Measure (PAM) has been developed to assess patients’ activation (19). To interpret the final PAM score, approximately one third of respondents tend to have scores between zero and 56; one third between 56.5 and 66.6, and one third have scores of 67 or higher (Appendix B). The higher score reflects a person with higher activation. In this study, the average PAM score was 39.3 with a range of 31 to 49 indicating that this group of 18 subjects scored within the lowest third in activation (Appendix B).

Table 5: Subset Knowledge and Activation Scores (n=18)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>25th Quartile</th>
<th>Median</th>
<th>75th Quartile</th>
<th>Max</th>
<th>Min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge Test Score</td>
<td>5.7</td>
<td>2.4</td>
<td>3.8</td>
<td>6.0</td>
<td>8.0</td>
<td>9.0</td>
<td>2.0</td>
</tr>
<tr>
<td>PAM Score</td>
<td>39.3</td>
<td>4.6</td>
<td>36.0</td>
<td>38.5</td>
<td>42.3</td>
<td>49.0</td>
<td>31.0</td>
</tr>
</tbody>
</table>
Hypotheses Testing

Three hypotheses were tested. Hypothesis 1 stated that higher nutrition scores, as measured by the MNT knowledge test, would correlate with lowered blood glucose as measured by glycosylated hemoglobin (A1C) levels. Similarly, hypothesis 2 stated that higher patient activation scores, as measured by the PAM tool, would correlate with lowered blood glucose levels as measured by A1C. Finally, hypothesis 3 would directly correlate higher patient knowledge scores with higher patient activation scores.

Multivariate and pair-wise correlation tests of the data found no significant relationships between knowledge and A1C (p=0.68) or between activation and A1C (p=0.16). Similarly, no significant relationship was found between knowledge and activation (p=0.87).

<table>
<thead>
<tr>
<th>Variable</th>
<th>A1C</th>
<th>Number Correct</th>
<th>PAM Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1C</td>
<td>1.0000</td>
<td>0.1087</td>
<td>0.3591</td>
</tr>
<tr>
<td>Number Correct</td>
<td>0.1087</td>
<td>1.0000</td>
<td>-0.0249</td>
</tr>
<tr>
<td>PAM Total</td>
<td>0.3591</td>
<td>-0.0249</td>
<td>1.0000</td>
</tr>
</tbody>
</table>

Table 7: Pair-wise Correlations

<table>
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<th>Variable</th>
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<th>Count</th>
<th>Significance Probability</th>
</tr>
</thead>
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<tr>
<td>Number Correct</td>
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</tr>
<tr>
<td>PAM Total</td>
<td>A1C</td>
<td>0.3591</td>
<td>17</td>
<td>0.1569</td>
</tr>
<tr>
<td>PAM Total</td>
<td>Number Correct</td>
<td>-0.0415</td>
<td>18</td>
<td>0.8702</td>
</tr>
</tbody>
</table>
CHAPTER V

DISCUSSION

In part, the current study served to characterize a diabetic population that will be studied in a larger pilot study where participants will undergo diabetes treatment within a Chronic Care Model (CCM). Medical Nutrition Therapy will be incorporated into the pilot study’s CCM. Furthermore, baseline diabetes knowledge and activation of a sample subset prior to pilot study interventions were also characterized in this current study. Although hypothesis testing resulted in statistical insignificance, much can be learned from this study.

Demographics—Age

In the current study, the subjects’ ages in both groups were similar on average—mean age 56 year (all participants), and 57 years (subset). Individuals under the age of 18 had been excluded. According to the National Diabetes Fact Sheet, 10% of patients in the United States with diabetes fell within the 40-59 year old age group in 2005, and most Americans diagnosed with diabetes (20%) were 60 years and older (24). According to the Center for Disease Control and Prevention’s (CDC) Diabetes Surveillance System, in 2004, diabetes prevalence data among people in the United States was 1% for those under the age of 45, fewer than 10% were aged 45-64 years, seventeen percent were aged 65-74
years, and greater than 18% of Americans were over 75 years of age (49). Of the nation’s diabetic population, according to the 1989 National Health Interview Survey (NHIS), 3.7% were 18-29 years of age, 6.7% were 30-39 years of age, 11.6% were 40-49% years of age, 20.2% were 50-59 years of age, 29.5% were 60-69 years of age, 22% were 70-79 years of age, and 6.5% were age 80 years and over (50).

Compared to 1989 age distributions of the nation’s diabetic population, the current participants were similar on average to 20% of the diabetic population as they were aged 50 to 59 years of age on average. Approximately 58% of nation’s diabetic patients would have been considered older than the current participants when comparing to 1989 data (50). According to the CDC, however, diabetes prevalence has increased with increased age, and in every age group, the prevalence of diabetes has increased up to twelve times since 1980 (49). More recent NHIS data might show that today more diabetic adults fall within the greater age brackets than do the 1989 data. It is possible that the majority of diabetic Americans are older than the participants of this study on average.

Demographics—Gender

On average, the study group and subset were composed of more women than men. Within the large group, 64% were women and 36% were men. Of the subset, 56% were female and 44% were male. The 1989 National Health Interview Survey found 58% of the nation’s type 2 diabetic patients were male while 42% were female (50). The CDC characterized the 2004 national diabetes gender differential as approximately 55% male and 45% female (49). In 1980,
more women than men had developed diabetes. While prevalence has increased for both genders, the rate significantly increased faster for men than for women between 1999 and 2004 (49). As later discussed, this trend is likely related to the increased prevalence in obesity and android-type obesity, in particular, of which men may be more predisposed (49, 51, 52, 53).

The current study diverged from national statistics as more diabetic subjects were female rather than male in both groups. Perhaps the community with access to the Summa Health System Family Medical Center was more concentrated with women than in the national community. It is possible that women may be more inclined to seek medical attention for their ailments than men, although this has not been documented. Otherwise, possibly women may have been more apt to volunteer and take part in this study than were men either because they were more motivated to try a new treatment approach or were more eager to assist with research.

Demographics—Weight

Increased body weight and obesity are risks for diabetes and related outcomes, and obesity is the second leading cause of preventable death in the United States (50). Many factors impact obesity—social, cultural, genetic, physiologic, metabolic, behavioral, and psychological components (51). The CDC reported that in 2004, of all diabetic Americans, over 80% were overweight or obese while over 50% were obese (49). Obesity prevalence studies showed that prevalence of overweight is higher for men (67 percent) than women (62 percent), but the prevalence of obesity and severe obesity is higher
for women (34 and 6.3 percent, respectively) than men (27.7 and 3.1 percent, respectively). Regardless of gender, however, overweight and obesity prevalence have both significantly increased over the last decade (49, 51).

Obesity and increased Body Mass Index (BMI) are risk factors for diabetes (22, 50). The BMI is a tool used to characterize weight status. BMI relates weight and height to weight status, and it associates relative health risk factors to it. A high BMI (greater than 25) is associated with overweight while a BMI over 30 indicates obesity. Both correlate with increased health risk, but the BMI should be used cautiously. BMI does not apply to all individuals as it does not account for body composition changes in special populations (for example athletes, pregnant women, or those with fluid overload, etc.) (51).

It has been documented that increased BMI and obesity lead to higher risk for developing diabetes and exacerbations of associated comorbidities (22, 23). Not only does the degree of obesity play a role, but the type of obesity—android or central tendency obesity—is known to particularly worsen insulin resistance in the metabolic syndrome. This syndrome is a condition of central obesity, dyslipidemia, hypertension, and abnormal glycemia tied together by exacerbated insulin resistance (54). Although controversial, studies suggest that android obesity may furthermore promote diabetes and worsen its outcomes more so than overall obesity, and both should be considered (52, 55, 56, 57, 58, 59). Because more men than women may be more predisposed to central distribution of adipose likely due to hormonal differences, it follows that national statistics demonstrate higher rates of diabetes among men than women, even though
more women are obese (52, 60). Body weight management plays a very important role in the prevention and treatment of diabetes.

The initial intention of the current study was to gather weight and height indices in order to calculate body mass indices to correlate Type 2 Diabetes and exacerbations of outcomes (61). Patient heights were unavailable; however, and BMIs could not be calculated. Regardless, the group’s and subset’s average body weights were 212.4 lbs. and 211.6 lbs., respectively.

Although little can be gleaned from weight alone, given the average height of the typical American male (69 inches), the predicted BMI based on the participants’ average weights was 31 which suggested a high prevalence of obesity among study participants (62). Because the height for the average American woman is 64 inches, the predicted BMI was 36, suggesting stage 2 obesity (62). Nevertheless, according to the National Health and Nutrition Examination Survey 1999-2000 (NHANES), the average adult American male and female BMIs are 26.6 and 26.5, respectively. This result suggested that the participants of the current study may have had higher BMI’s and been more overweight and/or obese than the average American which would have been expected due to the nature of type 2 diabetes with regard to weight status (49, 51, 62). BMI estimations suggest that the participants of this study would benefit from weight management emphasis as part of the pilot study intervention. Weight loss has been shown to promote diabetes prevention and improve outcomes particularly among type 2 diabetic patients (22, 23, 63).
Demographics—Comorbidities

Those with diabetes are at increased risk of developing heart disease, stroke, and hypertension (HTN) versus those without diabetes. Furthermore, uncontrolled diabetes promotes risk for morbidity and mortality (16, 46). One source reports about 73% of diabetic Americans have high blood pressure or are medically treated to manage it (24). The CDC reports that of Americans with diabetes in 2003, 52% were hypertensive and 51% presented with hyperlipidemia (HLP). In 2003, 22% of the diabetic patients reported coronary artery disease (CAD) and 9% reported stroke.

Congestive heart failure (CHF) is also a diabetes-related comorbidity. The CDC estimated CHF prevalence among diabetic patients by considering those admitted for hospitalization with CHF as the primary diagnosis. This estimate of CHF prevalence among diabetic patients as based on primary diagnoses upon hospitalizations was 18.5 per thousand diabetic population (or 1.85%) in 2003 (49). Because patients were also likely hospitalized with congestive heart failure even though it was not their primary diagnosis, these patients would not have been counted; therefore, the national estimate of diabetic patients with CHF is likely underreported due to the nature of the measurement approach.

In the study group, 29% presented with HTN, 13% with CAD, 7% with CHF, and 50% reported HLP. Of those among the subset, 56% reported HTN, 6% CAD, none reported CHF, and 56% reported HLP. The results suggest that the study participants had lower incidence in the diabetes-related comorbidities in
each condition except for CHF. The subgroup, however, had higher incidence of HTN and HPL than the nation but lower occurrences of CAD and CHF.

Retinopathy and nephropathy are also comorbid conditions of diabetes. Diabetes is the leading cause of blindness in those aged 20-74, and in 2002, forty-four percent of new kidney disease was diabetes related as diabetes is the leading cause of kidney failure (24). The CDC found that 22% of adults with diabetes reported visual impairment in 2003, while in 2002, 231 per 100,000 diabetic population presented with nephropathy. In the current study, the participants presented with retinopathy and nephropathy occurrences of 9% and 18%, respectively, while the subgroup presented with 6% and 11%, respectively. Overall, the participants of the study fared better with eye health than the nation’s diabetic patients, but the participants appeared to fare worse regarding kidney health.

About 60% to 70% of those with diabetes have nerve damage. Nerve damage can lead to peripheral impaired sensation, slowed gastric digestion, carpal tunnel syndrome, and amputations. Forty percent of people with diabetes have impaired feet sensation; therefore, routine foot checks are important to preventing further damage (24).

The CDC reported that in 2004 about 64% of Americans with diabetes performed routine foot exams and had annual foot exams (49). Within the study group, only 45% practiced routine foot checks, while 67% did among the subset. Although prevalence of diabetes-related neuropathy was not measured in this study, the results suggest that the subset may have been more knowledgeable
and/or more motivated regarding their diabetes than the overall group and the average American diabetic patient. As evidenced by a lower participation in foot checks compared to the subgroup and the nation, the overall group would benefit from pilot study intervention to include emphasis on self-foot checks. Implementation of the chronic care model ought to improve diabetes control and reduce risk of the associated diabetic comorbidities and improve overall health.

Demographics—Depression

A 2001 meta-analysis studied the prevalence of depression among people with diabetes. Results showed that the presence of diabetes doubles the odds of comorbid depression. The prevalence of comorbid depression was significantly higher among diabetic women (28%) than among diabetic men (18%). Rates of depression were higher in uncontrolled studies (30%) than in controlled studies (21%), and higher in clinical samples (32%) than in community (20%) samples. Depression was also more likely among those with diabetes when assessed by self-report questionnaires (31%) than when assessed by standardized diagnostic interviews (11%) (64). Studies suggest a negative association between depression and metabolic control (30, 46).

Among the participants of the current study, 36% reported depression while the subset reported 33% occurrence. Both groups compared similarly to the higher end of prevalence reported from the 2001 meta-analysis. Those among the subgroup may have had a slightly less depression prevalence than the entire group which would support an assumption that depressed persons may be at lower states of activation and may be less inclined to participate.
Activation is key to diabetes self-management. As depression could adversely impact activation, the Chronic Care Model should include appropriate interventions to assist those with depression in order to optimize diabetes-related outcomes. Because depression has been negatively associated with blood sugar control, and because about one third of the participants were affected, an intervention to address depression would be a valuable component in the ongoing study (30, 46).

Demographics—Smoking

Among the entire group and the subset, 24.4% and 22.2%, respectively, were smokers. According to a study done in 1990, 26% of diabetic patients were smokers (p<0.01) (65). Furthermore, according to the CDC, approximately 24% of diabetic Americans in 2004 were smokers, and smoking prevalence among diabetic patients had been relatively stable since 1994 (49). Comparatively, it appeared that smoking prevalence within the study groups was consistent with national statistics. It appears that diabetes and smoking are associated.

Several studies have addressed the interactions between diabetes and smoking. Studies suggest that smoking is associated with the development of diabetes; it worsens insulin insensitivity; it might interfere with timing and optimization of insulin therapy; and it likely exacerbates the already devastating complications of diabetes (66). Smoking prevalence might be slightly lower among the subset participants because these subjects might have had higher activation and/or greater knowledge than the overall group as evidenced by the subjects’ agreement to participate promptly. If smoking is addressed during the
pilot study intervention, patients may not only have improved diabetes-related outcomes, but they would also benefit from improved overall health.

Glycosylated Hemoglobin (A1C)

The A1C test has been the most widely accepted measure for associating blood sugar control with outcomes (67). It has been well established that tighter blood sugar control effects improved outcomes in the diabetes disease process (34). Because this test has been deemed the "gold standard" measure of diabetes control, it provides important feedback to healthcare professionals and patients so it plays a key role in disease management. Studies suggest that patients' understanding of this test and its implications for long-term health risk is essential (67). The CDC reports that in 2004, 69% of diabetic Americans had two or more A1C tests in the previous year (49). Testing frequency was not measured in the current study, however. Teaching patients about the significance of A1C via the future pilot interventions could increase patients' knowledge, appreciation, and tendency for routine blood sugar monitoring to help tighten blood glucose control which would improve outcomes.

The study group’s A1C levels averaged 8.35% while the subset averaged 8.05%. Exclusion criteria included patients with A1C less than 8% (the level usually considered substandard blood sugar control); however, several patients did not meet this criterion but were still included. The marker was central to this study as two hypotheses applied A1C as the dependent variable as a function of knowledge and activation, respectively. Studies suggest that interventions within a CCM framework is successful in lowering glycosylated hemoglobin levels which
is associated with improved outcomes (22, 68, 69, 70, 71). The participants within the Summa pilot study will likely realize similar results.

Knowledge

Hypothesis 1 suggested that higher nutrition scores, as measured by the MNT knowledge test, would correlate with lower blood glucose as measured by glycosylated hemoglobin levels. Only the subset completed the knowledge test (n=18), and mean knowledge scores were low (5.7 out of 10 possible). Multivariate and pair-wise correlation tests of the data found no apparent correlation (p=0.67).

Although nutrition knowledge is necessary in diabetes management, it is insufficient to improve outcomes. For example, it has been shown that those with increased diabetes knowledge may not always present with improved outcomes (43, 44, 46). However, in one study, respondents who knew their A1C values reported better diabetes care understanding and assessment of their glycemic control than those who did not. In another study, knowledge of one’s A1C level alone, however, was insufficient to instill confidence and motivation necessary to improve patients’ diabetes self-management (72).

Studies suggest that a significant percentage of diabetic patients have low knowledge of A1C measurements although few studies have examined diabetic patients’ knowledge and understanding of A1C testing. Some studies have shown that rapid availability of A1C values resulted in more frequent intensification of therapy which resulted in an A1C decrease. Furthermore, providing graphic A1C results to patients can lead to improved understanding
and to improved glycemia (67). Because information alone is insufficient, clinicians must incorporate other behavioral strategies to motivate and help patients effectively manage their diabetes (72). Because studies suggest that education about the significance and importance of the A1C marker could help with blood sugar control, it is recommended that A1C education be incorporated into the CCM pilot study.

Activation

The current study also measured activation’s impact on A1C. As previously discussed, a patient is activated when he believes in his role in disease self-management is important, and he knows how to manage his disease to maintain his health and access high-quality care. The Patient Activation Measure (PAM) has been developed to assess patients’ activation (19). Hypothesis 2 stated that higher patient activation scores, as measured by the PAM tool, would correlate with lower blood glucose levels as measured by A1C. Previous studies have shown that while patient knowledge alone is insufficient, activation is key in attaining improved outcomes (19). However, in this study, no significant correlation was noted between activation and A1C levels, perhaps due to a small sample size.

Finally, Hypothesis 3 stated that higher patient knowledge scores would correlate with higher patient activation scores. Studies are limited that correlate knowledge with motivation; however, evidence suggests that knowledge alone is insufficient to increase confidence and motivation which are necessary for diabetes self-management (72, 73). The expectation is that the Summa CCM
will provide necessary interventions that will not only improve patient knowledge of diabetes but will also inspire patient motivation to result in data that will support the hypotheses. Multivariate and pair-wise correlation tests of the current baseline data, however, found no significant association between patient knowledge and activation.

Likely due to study limitations and the small number of participants, the results of this study did not support the stated hypotheses. As the pilot study progresses, knowledge and activation scores will be collected on the entire sample (n=135) as opposed to simply the subset of this study (n=18). Consequently, the hypotheses will likely be supported. Regardless, research suggests that activation, or similar concepts, is key in diabetes prevention and management. CCM studies show improvements in “activation” concepts and associated improvements in health outcomes when the CCM is applied (68, 70). Patients within the Summa CCM will likely realize similar results.

Limitations

A critical limitation stemmed from the sample size (n=18). Furthermore, the sample was convenience-based; therefore, the sample may not be representative of typical diabetic patients. Many factors were out of the present researcher’s control because certain aspects of this study had been prearranged by virtue of the larger ongoing study. Consequently, the researcher was without freedom to adapt protocols to meet needs of the current study. Finally, as discussed above, the knowledge tool that was used had not been validated.
Furthermore, difficulties in obtaining the correct data were encountered. Patient heights were unavailable for the calculation of BMI, for example. Having actual BMIs would have provided another variable by which to characterize the subjects, particularly those with Type 2 Diabetes, instead of using a gross BMI estimate for the group.

Also, patients were included in the study whose glycosylated hemoglobin levels suggested good blood sugar control. However, those with poorer control may have been more representative of the Summa diabetic population. If patients with good blood sugar control participate in the CCM pilot, perhaps the results may not accurately reflect the true potential impact on improving outcomes as would more typical diabetic patients who have poorer control.

Summary Discussion of Findings and CCM Implications

In summary, the participants of this study were characterized and compared to national averages. In terms of average age, the participants compared to about 20% of Americans with diabetes falling within the 50 to 59 year age group; therefore, they were younger than the majority of Americans with diabetes as compared to 1989 data (50). Because the CDC has stated that the prevalence of diabetes has been increasing particularly among older Americans, it is possible that the current study participants are considerably younger than most diabetic patients when compared to more current data (49). While more men than women in the nation are diabetic, more women than men participated in this study.

Regarding weight status, although BMI’s were grossly estimated, the participants were likely more overweight than the average American, consistent
with what would be expected among people with Type 2 diabetes in particular. It follows that the pilot study CCM ought to include a weight management component among its interventions in order to realize decreases in A1C levels and to optimize patient outcomes. Recent studies of the CCM continue to show that the CCM is feasible and does improve outcomes (68, 69, 71).

In terms of comorbidities, it appears that the participants had lower incidences of CAD, HTN, HLP but a higher incidence of CHF as compared to national CDC data (49). The subgroup had a higher incidence of HTN and HPL than the nation but lower incidence of CAD and CHF. Overall, the participants experienced fewer retinal complications but possibly fared worse regarding kidney health as compared to the nation’s diabetic patients. A significant percentage of the participants reported depression as compared to national statistics. It is recommended that the ongoing study include a component related to addressing depression as studies have shown a negative correlation between depression and blood sugar control, and poor blood sugar control is correlated with adverse outcomes (30, 46).

It follows that the Summa CCM pilot promises to improve the outcomes associated with diabetic comorbidities because the CCM appears to improve A1C levels (68, 69, 71). Current studies show that CCM interventions have resulted in improved knowledge, motivation, behaviors and blood sugar control (68, 69, 71). Hence, current studies continue to support that the CCM has beneficial effects on the diabetes-related comorbidities and clinical outcomes (68, 69, 71).
As were comorbidity data, foot checks, smoking, and A1C results are also summarized. The participants were less likely to participate in routine foot checks than the nation’s diabetics, but slightly more patients within the subset practiced foot checks than the national average. Alternatively, it appeared that smoking prevalence among the diabetic participants was consistent with national statistics. In terms of A1C, the participants and subset results averaged 8.35% and 8.05%, respectively. Initially, patients with an A1C less than 8% were to be excluded; however, some patients with lower A1Cs were included which likely skewed the data. Surveying patients about their tendencies to have A1Cs measured routinely was not included in this study. This data, however, would have been helpful to compare with national trends.

Recent CCM studies showed improved routine foot check practices and A1C levels after interventions (68, 69, 71). In keeping with prior research, current participants will also likely demonstrate improved foot check behaviors and A1C levels after pilot study interventions. Perhaps they will also show improved habits regarding smoking particularly if participants are taught about the adverse effects of smoking on diabetes.

The hypotheses were tested among a small subset of participants where n=18. In terms of knowledge and activation, the subset had low scores at baseline. None of the three hypotheses were supported perhaps due to the small sample size. Regardless, current research suggests that the influence of the CCM increases knowledge and motivation (68, 69, 71). It is likely that knowledge and PAM scores will significantly increase after the Chronic Care
Model interventions while A1C will decrease. Furthermore, the sample size will be larger and the hypotheses will likely be supported.

Chronic Care Model Pilot and Future Research

Given an adequate sample size, one would hypothesize that implementation of the Chronic Care Model on a sample of diabetic patients would result in improved knowledge, activation, blood sugar control, and overall outcomes. It would be advantageous if the Summa collaborative group could follow its subjects over time in order to assess long-term diabetes outcomes and to compare progress to baseline. It is anticipated that the Summa project will add valuable, evidence-based data in support of the CCM to the collection of current, available research on this topic.

Particularly over the long term, routine follow-up is cornerstone to the Chronic Care Model. The group of subjects would likely realize improved long-term blood sugar control and a decrease in incidence of retinopathy, nephropathy, neuropathy, cardiovascular conditions and amputation among other long-term complications of diabetes. The end result would be improved morbidity and mortality which is the basis for adapting the current health care modality for the treatment of chronic disease.

The Ohio-based pilot is particularly valuable as it incorporates the important element, Medical Nutrition Therapy via a registered dietitian, where few CCM pilots have been documented to include this piece. Of those that have, it appears that often a dietitian does not provide the actual MNT or the dietitian may not play a central role even though the literature suggests that MNT is a
necessary piece and a registered dietitian is the preferred provider of this service (13, 68, 71). Where MNT has been included, it seems that detailed discussions of the MNT piece are not readily available. The Summa project, however, will be among the first to publish a fully developed description and assessment of MNT within the CCM. This current study sets the stage for Summa researchers to provide this much needed topic to the collection of available literature.

Conclusion

As evidenced by the endemic, worsening trends in diabetes, the need for change in the chronic disease healthcare approach is emergent. The Chronic Care Model provides hope for an improved course in the future of diabetes, and Medical Nutrition Therapy must take its place within this new framework. By applying the baseline data herewith, the Summa Health System, The University of Akron, and Kent State University CCM collaborative can not only serve to improve the health of its pilot study participants and provide additional evidence-based support for the CCM, but it can also help to position the dietetics profession as a key player within the Chronic Care Model framework.
REFERENCES


21. The Medical Nutrition Therapy (MNT) Knowledge Test prepared by Cinda Chima, The University of Akron, Appendix A.


29. The American Dietetic Association. Medical Nutrition Therapy Evidence Based Guides for Practice. Nutrition Practice Guidelines for Type 1 and Type 2 Diabetes Mellitus.


58. Hadaegh F; Zabetian A; Harati H, Azizi, F. Waist/height ratio as a better predictor of type 2 diabetes compared to body mass index in Tehranian adult men–a 3.6-year prospective study. Experimental and Clinical Endocrinology & Diabetes.2006; 114:310-5.


APPENDIX A
THE MNT KNOWLEDGE TEST

Diabetes Meal Planning

Multiple Choice
Identify the letter of the choice that best completes the statement or answers the question.

____ 1. (MDC) Which should NOT be used to treat low blood sugar?
   a. 3 hard candies
   b. 1/2 cup orange juice
   c. 1 cup diet soda
   d. 1 cup skim milk

____ 2. If you drink 100% fruit juice, what might happen to your blood sugar?
   a. lowers it
   b. raises it
   c. has no effect
   d. depends on what kind

____ 3. Corn belongs in what diabetes meal planning food group?
   a. free foods
   b. vegetables
   c. carbohydrates and starches
   d. fats

____ 4. Which is the most important change for someone with diabetes to make in their meal plan?
   a. eat more high-iron foods
   b. eat regular meals
   c. avoid sugar and sugar-containing foods
   d. eat a snack at bedtime

____ 5. In the meal plan for diabetes, cake should be
   a. substituted for fat exchanges
   b. substituted for fruit and/or starch exchanges
   c. always avoided
   d. sugar-free

____ 6. The diabetes diet is
   a. the way most people eat
   b. a healthy diet for most people
   c. too high in carbohydrate for most people
   d. too high in protein for most people
7. (MDC) Which of the following is highest in carbohydrate?
   a. Baked chicken
   b. Swiss cheese
   c. Baked potato
   d. Peanut butter

8. (MDC) Which of the following is a “free food”?
   a. any unsweetened food
   b. Any dietetic food
   c. Any food that says “sugar free” on the label
   d. Any food that has less than 20 calories per serving

9. (MDC) Which of the following is highest in fat?
   a. Low fat milk
   b. Orange juice
   c. Corn
   d. Honey

10. (MDC) If you are sick with the flu, which of the following changes should you make?
   a. Take less insulin
   b. Drink less liquids
   c. Eat more proteins
   d. Test for glucose and ketones more often

Diabetes Meal Planning Answer Section

MULTIPLE CHOICE

1. ANS: C
2. ANS: B
3. ANS: C
4. ANS: B
5. ANS: B
6. ANS: B
7. ANS: C
8. ANS: D
9. ANS: A
10. ANS: D

REF: From Michigan Diabetes Research and Training Center Diabetes Knowledge Test
APPENDIX B
PATIENT ACTIVATION MEASURE (PAM)

Patient Activation Measure

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think the doctor wants you to say.

If the statement does not apply to you, circle N/A.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>When all is said and done, I am the person who is responsible for managing my health condition</td>
<td>Disagree</td>
<td>Strongly Disagree</td>
<td>Agree</td>
<td>Strongly Agree</td>
<td>N/A</td>
</tr>
<tr>
<td>Taking an active role in my own health care is the most important factor in determining my health and ability to function</td>
<td>Disagree</td>
<td>Strongly Disagree</td>
<td>Agree</td>
<td>Strongly Agree</td>
<td>N/A</td>
</tr>
<tr>
<td>I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition</td>
<td>Disagree</td>
<td>Strongly Disagree</td>
<td>Agree</td>
<td>Strongly Agree</td>
<td>N/A</td>
</tr>
<tr>
<td>I know what each of my prescribed medications does</td>
<td>Disagree</td>
<td>Strongly Disagree</td>
<td>Agree</td>
<td>Strongly Agree</td>
<td>N/A</td>
</tr>
<tr>
<td>I am confident that I can tell when I need to go get medical care and when I can handle a health problem myself</td>
<td>Disagree</td>
<td>Strongly Disagree</td>
<td>Agree</td>
<td>Strongly Agree</td>
<td>N/A</td>
</tr>
<tr>
<td>I am confident I can tell a doctor concerns I have even when he or she does not ask</td>
<td>Disagree</td>
<td>Strongly Disagree</td>
<td>Agree</td>
<td>Strongly Agree</td>
<td>N/A</td>
</tr>
<tr>
<td>I am confident that I can follow through on medical treatments I need to do at home</td>
<td>Disagree</td>
<td>Strongly Disagree</td>
<td>Agree</td>
<td>Strongly Agree</td>
<td>N/A</td>
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<tr>
<td>I understand the nature and causes of my health condition(s)</td>
<td>Disagree</td>
<td>Strongly Disagree</td>
<td>Agree</td>
<td>Strongly Agree</td>
<td>N/A</td>
</tr>
<tr>
<td>I know the different medical treatment options available for my health condition</td>
<td>Disagree</td>
<td>Strongly Disagree</td>
<td>Agree</td>
<td>Strongly Agree</td>
<td>N/A</td>
</tr>
<tr>
<td>I have been able to maintain the lifestyle changes for my health condition that I have made</td>
<td>Disagree Strongly</td>
<td>Disagree</td>
<td>Agree</td>
<td>Agree Strongly</td>
<td>N/A</td>
</tr>
<tr>
<td>I know how to prevent further problems with my health condition</td>
<td>Disagree Strongly</td>
<td>Disagree</td>
<td>Agree</td>
<td>Agree Strongly</td>
<td>N/A</td>
</tr>
<tr>
<td>I am confident I can figure out solutions when new situations or problems arise with my health condition</td>
<td>Disagree Strongly</td>
<td>Disagree</td>
<td>Agree</td>
<td>Agree Strongly</td>
<td>N/A</td>
</tr>
<tr>
<td>I am confident that I can maintain lifestyle changes, like diet and exercise, even during times of stress.</td>
<td>Disagree Strongly</td>
<td>Disagree</td>
<td>Agree</td>
<td>Agree Strongly</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Score Table for the Patient Activation Measure**

Instructions: To calculate a raw score, add up all of the responses to the 13 questions. For each “Disagree Strongly” give the person a 1, for each “Disagree” give the person a 2, for each “Agree” give the person a 3, for each “Agree Strongly” give the person a 4.

If there are skipped items, divide by the number of items completed and multiply by 13 to get the raw score.

To convert the raw score into the measure of activation, use the table below. Simply find the raw score in the column on the left, then read across to find the person’s activation level. Roughly one third of respondents have scores between 0 and 56, one third have scores from 56.5 to 66.6, and one third have scores of 67 or higher.

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<table>
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### APPENDIX C

**INSTITUTIONAL REVIEW BOARD APPROVAL DOCUMENTATION**

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**HUMAN RESEARCH REVIEW APPLICATION**
**SUMMA HEALTH SYSTEM HOSPITALS**
**Form FO 301-A**

<table>
<thead>
<tr>
<th>Nancy Burzynski, EdD</th>
<th>330-672-2064</th>
<th>KSU/Dietetic Internship Program</th>
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<tbody>
<tr>
<td>Principal Investigator and Degree:</td>
<td>Phone #</td>
<td>Department/Division</td>
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<tr>
<td>Maggie Reifenbach</td>
<td>FMC</td>
<td>5-4049</td>
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<tr>
<td>IRB Contact:</td>
<td>Phone &amp; Room #</td>
<td>Fax #</td>
</tr>
<tr>
<td>Everett Logue, PhD</td>
<td>Co-investigator</td>
<td>Family Medicine</td>
</tr>
<tr>
<td>William Smucker, MD</td>
<td>Co-investigator</td>
<td>Family Medicine</td>
</tr>
<tr>
<td>E Taylor, MS, RD &amp; C China, MS, RD</td>
<td>Co-investigators</td>
<td>Department/Division</td>
</tr>
<tr>
<td>Personnel</td>
<td>Research Role</td>
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**Title**
KSU/Ohio Board of Regents & Summa FMRC

**Agency/Sponsor:**

<table>
<thead>
<tr>
<th>I. TYPE OF SUBMISSION</th>
<th>FACILITIES (Where research performed)</th>
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<td>[ ] New Submission: Full Board Review</td>
<td>SUMMA</td>
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**II. FUNDING**

- [ ] Federal Funding
- [ ] NIH
- [ ] NCI
- [ ] Other (explain)

**Ohio Board of Regents via KSU; FMRC**

**Departmental**

- Summa Health System Hospitals Foundation
- Other Foundation (explain)

- Other Funding (explain)

**III. WILL THE STUDY POPULATION INCLUDE ANY OF THE FOLLOWING?** You must check if your study might include any of the following vulnerable populations. Check all that apply.

- [x] Fetuses
- Human in vitro fertilization
- Institutionalized (mentally ill)
- Comatose Patients
- Terminally Ill Patients
- Minorities
- Children under 18 years of age
- Other likely vulnerable participants (Explain below)

- Men
- Women
- Prisoners
- Cognitively Impaired Persons
- Elderly/Aged Persons >65 years old
- Students
- Employees of the PI or Institution
- Normal Healthy Volunteers
- Pregnant Women
### IV. SPECIAL CONCERN RESEARCH AREAS: (Check all that apply)

| ☐ Drugs (attach appropriate Drug Information Sheet) | ☐ AIDS/HIV Related Research |
| ☐ Investigational New Drug (IND) | ☐ Alcohol & Drug Abuse Research |
| ☐ Marketed Drug | ☐ Human Genetic Research |
| ☐ Oncology Group/NCI Protocol | ☐ Radioactive Materials & X-Rays |
| ☐ Medical Devices | ☐ Transplants |
| | ☐ Vaccine Trials |

### V. WILL THE STUDY BE INTERDEPARTMENTAL?

1. Are patients, facilities, or resources from other departments within Summa Health System Hospitals being utilized for this specific research project outside of regular patient care?

☐ NO ☐ YES

If yes, please specify which departments will be used by checking ALL that apply.

- ☐ Biohazard/Radiation Safety Committee(s)
- ☐ Internal Medicine Clinic
- ☐ The Diabetes Care Center
- ☐ Medical Records
- ☐ Center for the Treatment and Study of Traumatic Stress
- ☐ Nursing Floor Specify:
- ☐ Clinical Laboratory
- ☐ Pharmacy
- ☐ DOVE Program
- ☐ Psychiatry
- ☐ Emergency Medicine
- ☐ Radiology
- ☐ Family Medicine Center
- ☐ Other Specify:
- ☐ Ignatia Hall
- ☐ Technology Committee
- ☐ Surgery

**NOTE:** Has these departments agreed to participate with the study? ☐ No ☐ Yes

Please see the signatory page (last page) of this application. You must obtain the signature of the Administrative Director of EACH department or area where Summa Health System resources are to be used, including your own. This is required before the application can be submitted to Research Administration. (If this is not done, the application will be returned to the investigator.)

### VI. EDUCATIONAL REQUIREMENT

1. Do you have a certificate of human subject protection education on file with the Office of Research and Research Administration?

☐ NO ☐ YES (No for Burzynski, Taylor, Chima) (on file for Logue & Smucker)

If no, attach a completion certificate to this form. ☐ Attached

### VII. CONFLICT OF INTEREST

1. Do you or any member of your family or other study personnel have any financial interest or relationship with a sponsor or agency that would appear to be a conflict of interest with your participation in this study? A conflict of interest is defined as any significant financial interest in the sponsoring company defined as $50,000 in the form of equity interest in a publicly held company or significant payments of any sort that have a cumulative monetary value of $25,000.

☐ NO ☐ YES

If yes, attach a letter regarding the Conflict of Interest Disclosure. ☐ Attached

### VIII. REMUNERATION

1. Will participants receive remuneration?

☐ NO ☐ YES ☐ for participation ☐ for expenses

2. Total Amount $250

Payment Schedule: $10 at baseline $15 at six months

### IX. ADVERTISEMENT
Will you advertise for participants? ☐ NO ☒ YES If Yes, attach a copy of the material to be used. 
Check appropriate box: ☒ Flyer ☒ Letter ☐ TV ☐ Radio ☐ Internet ☒ Other ☐ Other 
☐ Referral letter (If it will be directly read by the subjects)

X. HUMAN SUBJECTS

Respond to the six (6) items below under the heading of HUMAN SUBJECTS by referencing the protocol. Please indicate the specific page number(s) used to answer the question. Use same format (1. A, B, C, etc) as outlined below.

1. SUBJECT POPULATION INFORMATION

A. - Age range, include minimum and maximum.
   - Characteristics of the subject population, including health status. (Inclusion/Exclusion)

   All active English-speaking adult patients (>=18 years) with a diagnosis of diabetes in the Family Practice Center at Akron City Hospital with a history of inadequate blood glucose control (A1C > 8%) will be considered for inclusion in the study. Exclusions will include: Axis II psychiatric disorder, pregnancy, chemotherapy/radiation.

   The Family Medicine Center (FMC) of Akron at Summa Health System provides services to approximately 4,000 adult patients each year and receives approximately 15,000 patient contacts each year. The FPC serves a mixed population of middle class and economically disadvantaged patients. Eleven board-certified family physicians and 33 medical residents staff this urban center. As of 5/9/2005, 182 patients in the FMC appear to meet the study criteria. Records to determine possible eligibility were reviewed by FMRC staff.

   The study sample will be drawn from those who agree to participate. Once patients have provided informed consent, they will be randomized to an intervention or control group (n=20 in each group).
   - Rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, human in-vitro fertilization, prisoners, or other institutionalized individuals, or others who are likely to be vulnerable.
     Not Applicable
   
   B. Gender and Minority Inclusion/Exclusion

     None
     - Gender composition
       Approximately 60% female
     - Racial/ethnic composition
       Approximately 40% African-American
     - Identify the criteria for inclusion/exclusion - If gender and/or minorities are not included in the study, provide a clear rationale for their exclusion.
     Not Applicable

     - If women or women of childbearing potential are excluded, provide a clear rationale for their exclusion.
     Not Applicable

   C. Detailed description of the proposed involvement of human subjects. Include all procedures and identify those that are experimental.

   Patients will be randomized to different counseling strategies. See attached proposal

2. SOURCES OF RESEARCH MATERIAL
A. Identify sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data.

Patient interviews, medical records, measurements

B. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Existing charts and research related interviews and measurements

3. IDENTIFICATION OF SUBJECTS, RECRUITMENT OF SUBJECTS, AND INFORMED CONSENT PROCESS

A. Describe plans for identifying potential subjects and recruitment of subjects (advertisements, referrals, etc.). If identification of potential subjects includes the review of medical records, discuss who will access these records.

A recruitment letter on Summa letterhead and a consent form will be mailed to all Family Medicine Center patients who meet study criteria. The letter will invite patients to participate in a pilot diabetes intervention project. Similar information will also be posted in the Family Medicine Center or handed to patients appearing for diabetes planned visits. Either during face to face encounters or during recruitment telephone calls from research staff, patients will be asked to come to a free FMC visit to complete the informed consent process and to provide baseline data. The study sample will be drawn from those who agree to participate.

B. Consent process

- Who will obtain consent?

Research staff

- Who will give consent? (patient, patient representative, or both)

☐ Waiver ☑ Consent Form

4. RISK / BENEFIT ASSESSMENT

A. Assess risks (physical, psychological, social, legal, or other) versus potential benefits.

Minimal. No known risks. See proposal

B. Describe provisions for monitoring the data to insure the safety of subjects.

Not Applicable

C. Will a database be created for this study? ☐ No ☑ Yes

5. MINIMIZING RISKS

A. Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality and privacy (e.g. substituting codes for identifiers, limiting access to identifying data, launching research staff about the importance of confidentiality, storing records in locked cabinets, restricting access and protecting against unauthorized access to medical and/or research records, etc.), and assess their likely effectiveness.

Adult FMC patients with diabetes are involved in this pilot randomized trial. Informed consent will be obtained by a procedure approved the MRC at Summa and the IRBs at Kent State University and the University of Akron. The interventions involve alternative counseling or patient support strategies. Standard care provided by FMC physicians will not be altered. The study interventions supplement this standard care.

Risks to patients from participation should be no more than minimal. The MedGem device uses disposable mouth pieces to minimize cross-contamination. Patients will be advised that participation is voluntary and that their decision to participate or not will not affect future medical care. Patients will be paid $10 for completing the baseline assessment and $15 for completing the six month assessment.
Data will be maintained in a confidential manner by using password protected work stations or files and limiting data access to study personnel only. Only de-identified data files will be transferred to Kent State or the University of Akron. Password protected files with identifiers will be maintained at Summa. All study staff have taken approved courses concerning the protection of human research subjects.

B. Discuss provisions for insuring necessary medical or professional intervention in the advent of adverse effects to the subjects.

Not Applicable

XI. INFORMED CONSENT FORMS

Attach the original informed consent(s) to be used in this study. Informed Consent(s) must follow accepted format; include ALL required elements, which can be obtained from ORRA, in lay language.

XII. PROTOCOL

Attach a complete research plan: (a) specific aims; (b) background and significance; (c) preliminary studies; (d) research design (including data analysis/statistics and a plan for data safety and monitoring); (e) plan for protection of privacy of medical and research records; (f) references; and (g) Investigator's Brochure (if applicable).

I understand that approval of this research involving human subjects is contingent upon my agreement:
1. To report to the Institutional Review Board for Human Research (IRB) any adverse effect of research related injuries, which might occur in relation to the human experimentation. I have read and will comply with IRB Reporting Requirements for Adverse Events.
2. To submit in writing for prior IRB approval any alterations to the plan of human research.
3. To submit timely continuing review reports of this research as requested by the IRB.
4. To maintain copies of all pertinent information related to the research activities in this project including copies of informed consent agreements obtained from participants.
5. To notify the IRB immediately upon termination of this project and/or the departure of the principal investigator from this institution and the project.
6. Data and other research products produced under this research will be maintained in a central location and will be kept in a manner that will allow other qualified scientists to verify the accuracy and integrity of reported results of the research.
7. Individuals supported in whole or in part by this research and who are in a training status will be given explicit training in the responsible conduct of research.
8. Any individual who has a substantive scientific role in the proposed research has been provided a copy of the application and has had an opportunity to comment on it.
9. Criteria for authorship of publications resulting from the proposed research have been discussed and agreed to by all investigators and contributors involved.
10. Scientists who have a substantive scientific role in the proposed research do not have any financial interests that could affect the objectivity of the research.
11. Any material in the grant application/protocol that is a verbatim reproduction of other persons' writings has been identified by quotation marks and properly attributed.
12. If I will be unable to direct this research personally, as when on sabbatical leave or vacation, I will arrange for a co-investigator to assume direct responsibility in my absence.
13. Study personnel have completed the mandatory educational compliance training on human research.
I certify that I have reviewed this application and will carry out the proposed research in compliance with the principles stated above.

Signature of Principal Investigator: [Signature]
Date: 8/2/05

XIV. REQUIRED SIGNATURE(S) OF THE PARTICIPATING DEPARTMENT ADMINISTRATIVE DIRECTOR(S) AND THE DEPARTMENT CHAIR STATEMENT OF ASSURANCE

The following departmental administrative director(s) agree to departmental participation in the study:

<table>
<thead>
<tr>
<th>Name of Department</th>
<th>Administrative Director Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family Medicine Center</td>
<td>Richard Hines, MD</td>
</tr>
</tbody>
</table>

I have reviewed this protocol and evaluated the scientific merit and potential value of the proposed study as well as the plan for protecting human subjects involved and approve it for submission to the Institutional Review Board.

Signature of Department Chair: [Signature]
Date: 7/4/05

Typed / Printed Name: James Cross, MD

REVISED ORRA: 6/11/05
APPENDIX D

INFORMED CONSENT FORM

SUMMA HEALTH SYSTEM
PATIENT CONSENT FOR INVESTIGATIONAL STUDIES
Principal Investigators: Nancy Burzinski, EdD, Everett Logue, PhD, William Smucker, MD
Improving the Health of Patients with Diabetes
(Pilot Study: Medical Nutrition Therapy in a Chronic Care Model)

Doctors at the Family Medicine Center and researchers at Kent State University and the University of Akron are working together on a research project to improve the health and nutrition of patients with diabetes.

Purpose
The purpose of the study is to compare two ways (Method A and Method B) of talking with patients to help them control their blood sugar, blood pressure, and blood cholesterol. The “talking” will be about the medicines prescribed by your doctor, eating a healthy diet, getting more exercise, and maybe losing some weight. A total of forty adults will be invited to be in the study.

Procedures for all patients
All patients will be asked to fill out a questionnaire asking about diet and diabetes, another questionnaire asking about your diabetes care at home and at the clinic, talk to a nurse about medicines and your diabetes care, record food and beverage intake for four days, talk to a dietitian about eating and exercise habits, and have a new “basal metabolic rate” (BMR) test. The questionnaires will take a total of about 10 minutes to complete; the meeting with the nurse will take about 20 minutes.

To do this BMR test, you need to sit quietly for a few moments and then breathe in and out through your mouth into a tube for 10 minutes while a clip holds your nose shut. The clip may be a little uncomfortable. The BMR test will tell you how many calories your body needs when your body is resting. Then the dietitian will add some more calories to figure out how much food you should eat when you are awake. The BMR test and the advice from the dietitian may help you and your doctor plan your diet and manage your weight.

After the dietitian explains what the BMR test results mean for you, you will paid $10, and you will be randomly assigned (like flipping a coin) to study Group A or Group B.

Once you have agreed to participate in the study, research assistants will also use your Family Medicine Center chart and Summa electronic systems to collect information about your visit history at the Family Medical Center, your diabetes diagnosis date, your diabetes type, current treatment, treatment history, other health problems, smoking status, blood sugar logs, height & weight, blood pressure, labs (blood cholesterol, urinary microalbumin, creatinine, HBA1C), and a record of foot exams, ophthalmic referrals, and immunizations.

Procedures for Group A patients
If you are a Group A patient, you will meet one time with the nurse to complete medical information (about 20 minutes) and then be asked to set up one appointment with the dietitian (about 20 minutes), who will ask you about your dietary and activity habits and provide you with dietary guidelines for people with diabetes. Your doctor and nurse will get a
report from the diettian that describes your dietary and exercise habits and the BMR test results. The report may help your doctor, nurse, and diettian work with you to plan your care.

Over the next six months you may get one or more telephone calls from a nurse, a diettian, or a social worker who will ask how you are doing. They will ask if there is anything that they can do to help you improve your health. You will be invited back to the Family Medicine Center for a free 6-month study-related check-up. The 6-month check-up you will be like the first study visit and you will be asked to fill out the same paperwork. You will be paid $15 at the end of the six-month follow-up visit.

Procedures for Group B patients
If you are a Group B patient, you will meet one time with the nurse to complete medical information (about 20 minutes), and then you will be asked to set-up two, one-hour long visits with a diettian over the next three weeks. During these the visits the diettian will talk about your blood sugar, your diet, your exercise habits, your weight and what you and the Family Medicine Center can do keep you healthy. These visits are called "medical nutrition therapy (MNT)". We do not know whether the extra MNT visits will improve your health or not.

After the last MNT visit your doctor and nurse will get a report from the diettian that describes your health habits, your health goals, and any roadblocks to good health. The report may help your doctor, nurse, and diettian plan your care.

If you are a Group B patient, you will also be asked to participate in two, two-hour group-visits. Other patients with diabetes will be present. At the group-visit the nurse will check your blood pressure, blood cholesterol, blood sugar, and your feet. There will also be time to talk to other patients with diabetes about how you take care of yourself. All patients at the group-visit agree to keep information about other patients private. We do not know whether the extra group-visits will improve your health or not.

Over the next six months you may get one or more telephone calls from a nurse, a diettian, or a social worker who will ask how you are doing. They will ask if there is anything that they can do to help you improve your health. You will be invited back to the Family Medicine Center for a free 6-month check-up. This 6-month check-up you will be like the initial study visit and asked to fill out the same paperwork. You will be paid another $15 at the end of the six-month follow-up visit.

Alternative treatment. If you do not want to be in the study you will have the standard exams, tests, and treatments ordered by your doctor or the Summa Health System. Whether you choose to be in the study or refuse to be in the study will have no effect on the other medical care that you will receive from your doctor or Summa Health System.

Patient Risks. There are no known risks from being in this study. In other words, the risks are minimal (almost zero). The nose clip for the BMR test may be uncomfortable. If you are a group B patient you may feel a little uncomfortable at the start of your first group-visit because it is new. There may be unforeseen risks to your participation in this study. If new information becomes available which might affect your participation in this study, you will be given this information as soon as possible.
Procedures to Reduce Risks. Nurses and dietitians are trained to respect the privacy and wishes of patients according to standards set by Summa Health System.

Confidentiality. All information collected about you will be kept secret. Identifying information (name, address etc) will be kept separately in secure files. Summa Health System’s patient protection committee (Medical Research Committee) may look at the study records. You will not be personally identified in any way when the pilot study results are reported.

Patient Benefits. Direct benefits to study patients like you include more attention to your eating and exercise habits. You will get a free diet analysis and BMR test. Future patients like you may adopt healthier habits because of your part in the study. All participants who complete the study will receive a total of $25.

Research-Related Injuries. Medical care will be provided for any injuries occurring while you are in this study, but you or your insurance company must pay the cost of treatment. Payment for lost wages or other losses will not be provided. If you have questions about payment for losses while you are in the study, you can call Summa Health System’s Medical Research Committee (330-375-4045).

Questions About Research. You can ask more questions about the study at any time. To ask further questions, you can contact Dr. Everett Logue or Dr William Smucker (330-375-4049) at Summa Family Medicine or Dr. Nancy Burzminski at Kent State University (330-672-2064). If you have any questions about your rights as a study member you can call the Summa Medical Research Committee (330-375-4045), the Kent State University Institutional Review Board (330-672-3012) or Dr. John West, Kent State University Vice President of Research and Graduate Studies (330-672-2851).

Voluntary Participation. Your participation is completely voluntary. You can refuse any part of the study if you choose. You can withdraw from the study at any time. Your withdrawal from the study will have no effect on the other medical care that you will receive from your doctor or Summa Health System. Your doctor or the study doctors will remove you from the study without your consent if leaving the study would be better for you.

By signing this consent form you do not give up any of your legal rights. Your signature does not relieve the investigators, Summa Health System, Kent State University, or the University of Akron of liability, but indicates that you have been informed about the study and agree to be a study member. A copy of this signed consent form will be provided to you.

Signature Lines. By signing this form, I indicate that I have read the form and have had a chance to have my questions about the study answered to my satisfaction.

Participant Signature __________________________ Date _____________

Witness __________________________ Date _____________