The Effect of Diabetes Self-Management Education Using Simulation for Persons Diagnosed with Type II Diabetes

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Abstract

Many educational programs are available for self-management of type II diabetes; however, there have been few studies conducted to examine the effect of a simulation-based educational intervention. Diabetes is an ever-growing health issue that impacts millions of Americans and is associated with many serious, long-term complications. This study aims to examine the effect of a simulation-based educational intervention on self-care management. Specifically, the research question is as follows: In adults diagnosed with type II diabetes, how does diabetic education delivered by simulation, compared to educational handouts, affect the diabetes self-management questionnaire (DSMQ) score within 6 weeks? The second research question includes if the time since diagnosis affects the DSMQ score for either group. A literature search was performed using CINAHL to identify studies regarding diabetic education interventions for patients with type II diabetes. These studies are discussed and critiqued in detail to establish the current evidence. The sample for this study consisted of adults that have been diagnosed with type II diabetes with a recent glycosylated hemoglobin in the past 6 months greater than eight. This study was an experimental design that uses a two-group pretest-posttest method. The mean DSMQ score was obtained for both the educational handout and simulation groups before and 6 weeks after the simulation-based intervention. Low enrollment in this study prevented any formal comparisons from being completed through statistical tests. Frequencies and percentages of the raw data is shared. Immersive educational activities may be beneficial for patients with type II diabetes to enhance their self-care management.

Keywords: diabetes, simulation, self-management, patient education, HbA1c, self-care deficit

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The Effect of Simulation for Persons Diagnosed with Type II Diabetes

Over 30 million Americans are diagnosed with diabetes (Centers for Disease Control and Prevention [CDC], 2021b). Type II diabetes is the most common form of diabetes, with 90-95% of Americans diagnosed with diabetes having this type (CDC, 2021b). It is a chronic condition that can cause long-term complications and frequent hospitalizations. Diabetes is somewhat unique in that management of the condition is largely handled through self-care activities. Many patients diagnosed with diabetes are unable to adequately control their glycemic levels, and many do not enroll in diabetic education programs (Fan & Sidani, 2018). The purpose of this study is to provide an effective educational intervention for self-care management of type II diabetes through simulation. Self-care management will be measured using the Diabetes Self-Management Questionnaire (DSMQ). The DMSQ score has been validated to correlate with glycemic control, an important indicator of successful diabetes management (Schmitt et al., 2013).

Problem and Significance

Many types of educational strategies have aimed to improve diabetes, but this serious health issue continues to cause significant associated mortality and morbidity (Ebrahimi et al., 2016). Unfortunately, the prevalence continues to be on the rise, with significant increases in incidence from 9.5% in 1999 to 12% in 2016 (CDC, 2020). According to the CDC (2020), diabetes was the seventh primary cause of death for Americans in 2017. It is a frequent contributor to hospitalizations, with approximately 7.8 million hospitalizations attributed to the disease and 16 million emergency department visits with diabetes listed as a diagnosis in 2016 (CDC, 2020). Serious comorbidities are also associated with diabetes, including cardiovascular disease, amputation of a lower extremity, diabetic ketoacidosis, hyperosmolar hyperglycemic syndrome, chronic kidney disease, and vision problems (CDC, 2020).

It was estimated that 1.5 million new cases of diabetes were diagnosed in 2018 (CDC, 2020). The CDC (2020) reported that incidence of type II diabetes is highest in people over 45 years of age. Additionally, regarding ethnicity, in adults aged 18 years and older, American Indian/Alaskan natives have the highest incidence of diabetes followed by Hispanics and non-Hispanic Blacks (CDC, 2020). The incidence in men is higher than in women—7.2 per 1,000 compared to 6.3, respectively (CDC, 2020). In the United States, the CDC (2020) reported that prevalence fluctuates by education level and those adults with less than a high school education have a higher rate of diagnosis. Many more Americans remain undiagnosed or are living with prediabetes (CDC, 2020). Additionally, the incidence of type II diabetes is on the rise in children and adolescents (CDC, 2020).

Furthermore, diabetes is associated with a significant financial burden to the United States healthcare system, calculated to be over 327 billion dollars in expenses just in 2017 (CDC, 2020). Expenses have been increasing since 2012 and are likely to continue to rise. With a problem of this magnitude, more effective educational interventions are needed for successful self-management of type II diabetes to achieve improved blood glucose control.

Diabetes is a chronic disease that requires self-management on behalf of the patient. Diabetes self-management education (DSME) is recognized to be an evidence-based and effective way to help patients suffering from diabetes to achieve better glycemic control, thus decreasing the likelihood of serious complications from the disease (CDC, 2021a). DSME involves activities that foster "the knowledge, skill, and ability necessary for diabetes self-care" (Powers et al., 2015, p. 1372). The American Diabetes Association (ADA) supports that patients should receive DSME at diagnosis and then at least annually, with complications, and with transitions (Powers et al., 2015).

Unfortunately, less than 10% of patients receive these educational interventions, despite the evidence supporting DSME being a cost-effective intervention (CDC, 2021a). Utilization of DSME is particularly low in rural areas with limited healthcare access (Powers et al., 2015). Furthermore, Powers et al. (2015) noted that most patients report not being offered such services.

Simulation is an effective educational technique used in several healthcare professions to mimic realistic clinical experiences to decrease the risk of errors in real clinical settings (Galloway, 2009). Simulation involves immersion in a realistic scenario in a controlled and safe environment with the use of an interactive instructor to achieve the intended objectives (Galloway, 2009). Lioce et al. (2020) stated that simulation is "a technique that creates a situation or environment to allow persons to experience a representation of a real event for the purpose of practice, learning, evaluation, testing, or to gain understanding of systems or human actions" (p. 44). However, upon review of the literature, this learning method is not well-utilized among patient populations for self-management of chronic illnesses. Many studies have examined various other types of education interventions on glycemic control and self-care management, such as lecture and discussion-style delivery of information, active skills training, psychological skills, and a combination of interventions (Fan & Sidani, 2018).

Self-management is largely measured by glycemic control throughout the literature. Glycated hemoglobin (HbA1c) is an important indicator of successful diabetes management, as it measures glycemic levels over a 2- to 3-month time span (Little & Sacks, 2009). However, the DSMQ is a validated tool that is closely associated with the patient's HbA1c (Schmitt et al., 2013).

The COVID-19 pandemic has brought about additional importance to ensure that patients can adequately self-manage type II diabetes. According to data from March 2020, almost 90% of adults hospitalized with COVID had at least one chronic condition, such as type II diabetes (Riley et al., 2021). Riley et al. (2021) also reported that approximately 66% of Medicare recipients have two or more chronic conditions, so this population is significantly affected by prolonged illness. Furthermore, due to the nature of the pandemic, many patients with these chronic diseases are having their regular medical care services delayed or interrupted altogether (Riley et al., 2021). However, routine management is crucial to prevent disease progression and complications. Policy changes have recently allowed more access to telemedicine, outpatient services, and home-based care (Riley et al., 2021). Tertiary prevention methods, such as educational programs, that are intended to slow disease progression and prevent patients from needing acute care due to disease complications are timelier than ever before.

Purpose of the Project

The purpose of this study is to specifically examine the effect of simulation as an educational technique for self-management in adult patients diagnosed with diabetes. The aim is for simulation to be employed as an effective strategy to improve outcomes for patients, ultimately decreasing the morbidity and mortality associated with the disease. Based on an assumed knowledge deficit in patients with diabetes, the plan is to target such participants to examine the effect of simulation on their self-care abilities. Despite the vast amount of research on self-care education interventions for diabetes in the literature, a clear gap exists specific to using simulation. However, simulation is a well-established educational technique that allows opportunity to practice new skills in a safe environment (Galloway, 2009). It is of interest whether the effectiveness of simulation applies to patient education as it does in the education of healthcare providers. The ability of participants to self-manage their diabetes will be evaluated by the DSMQ score.

Research Questions and Hypotheses

The specific question that this study will aim to answer is: In adults with newly diagnosed type II diabetes, how does diabetic education delivered by simulation, compared to educational handouts, affect the DSMQ score within 6 weeks? A secondary question is: Will the time since diagnosis impact the effectiveness of the interventions on the DSMQ?

The hypothesis of the primary research question predicts that a simulation-based education intervention for persons with diabetes will have an effect on the DSMQ score within 6 weeks compared to groups that receive educational handouts only. Alternatively, the null hypothesis states that the simulation-based education would not have an effect on the DSMQ score within 6 weeks. The primary research question aims to answer whether the simulation intervention group will have a change in the DSMQ score, compared to the handout comparison group.

The hypothesis of the secondary research question is that the time of diagnosis will have no effect on the DSMQ score for both groups. This would suggest that either educational method could still be beneficial for healthcare management, regardless of how long the patient had diabetes. The alternative null hypothesis is that there is an effect on the DSMQ score in one or both groups when comparing the time since diagnosis. This would suggest that one of or possibly both interventions are not effective for self-care management beyond a certain timeframe regarding length of diagnosis.

Conceptual Framework

The variable of type II diabetes will be defined as a chronic disease state characterized by the gradual development of insulin resistance in adults (CDC, 2018a). The ADA guidelines further define type II diabetes as an HbA1c of greater than 6.5 (ADA, n.d.). Higher HbA1c levels indicate poor glycemic control.

The diabetes self-management questionnaire was developed by Schmitt et al. (2013) to “assess self-care activities” that resulted in successful diabetes self-management. The 16-item questionnaire can be used for those with both type I and type II diabetes and has four main categories including glucose management, dietary control, physical activity, and healthcare use. It also has a sum scale to total the four aforementioned categories (Schmitt et al., 2013). The instrument has been validated to be consistently associated with the patient’s HbA1c level, indicating their glycemic control, and ultimately their ability to successfully self-manage their chronic illness.

Orem’s self-care deficit theory steered the development of this study because the patient’s self-care agency, or ability to maintain their functioning and development, represented the nature of diabetes management. Orem defined self-care as the “maintenance of life, health, and well-being” (Berbiglia & Banfield, 2018). A diagnosis of type II diabetes clearly represents a self-care deficit, which means that the agency is inadequate to meet the current health-related requirement. Self-care requisites are “the reason self-care is undertaken” (Berbiglia & Banfield, 2018, p. 201). Furthermore, the concept of normalcy is defined by Orem as “in accordance with the genetic and constitutional characteristics and talents of individuals” (Berbiglia & Banfield, 2018, p. 201). Because of a diagnosis of diabetes, these patients have a new normalcy to manage, resulting in the self-care deficit and the need for interventions to aid in successfully achieving this new state.

Health deviation self-care requisites are those required in a state of illness including the ability to effectively perform the recommended actions, acquiring appropriate medical attention, and an awareness and responsiveness to manage the effects of the disease (Hartweg & Pickens, 2016). There becomes a demand for nursing assistance when people can no longer provide the level of self-care required due to a state of decreased health. To address this need from an outpatient approach, it would be appropriate to utilize the supportive-education system of nursing practice for self-care and to "regulate the exercise and development of self-care agency" (Berbiglia & Banfield, 2018, p. 202).

The self-care activities in the intervention specifically addressed managing medications, selecting a proper diet, and glucose testing. Additionally, basic conditioning factors (age, gender, developmental state, health state, sociocultural factors) can be used to guide demographic data to be obtained. Specific requisites to be addressed in the simulated interventions would include balance between activity and rest, prevention of hazards to human life, human functioning, human well-being, and promotion of development within social groups in accordance with human potential, known human limitations, and the human desire to be normal (Berbiglia & Banfield, 2018).

Surucu and Kizilci (2012) use Orem's self-care deficit theory as a conceptual framework to research the effect of an educational intervention on self-management of type II diabetes. They identified the basic conditioning factors of the patient in this case including age, gender, developmental state, health state, sociocultural orientation, healthcare system factors, family system factors, pattern of living, environmental factors, and resource availability and adequacy. Next, they determined the universal self-care requisites and self-care deficits (Surucu & Kizilci, 2012). The authors determined the patient was not lacking in the universal self-care requisites of air, water, food, excretion, activity and rest, or promotion of normalcy. Considering potential deficits of this patient's universal self-care requisites, the authors did identify that she used glasses and lived alone, which may ultimately impact her self-care abilities (Surucu & Kizilci, 2012). Next, they examined her developmental and health deviation self-care requisites and determined that she maintained self-care deficits for lacking knowledge related to her condition, which led to ineffective self-management of treatments, lack of realization of some aspects of her diagnosis, and decreased knowledge of the benefits of care. These deficits were then used to plan and prioritize goals of care and interventions for educational needs (Surucu & Kizilci, 2012). Last, the researchers evaluated the patient's response to the interventions by questioning if she could perform teach-back, and if she implemented any of the suggested interventions (Surucu & Kizilci, 2012).

Additionally, the stages of learning described in Kolb's experiential learning theory (ELT) contributed to the development of the simulation-based education intervention. According to the ELT, learners have a more enhanced understanding through realistic scenarios and experiences (Williams & Spurlock, 2019). The ELT suggests there are four specific, cyclical stages of learning—concrete experience, abstract conceptualization, active experimentation, and reflective observation. Knowledge is obtained through this holistic process of understanding an experience (Reed, 2020).

The concrete experience stage emphasizes that the learner should be actively engaged in the educational activity, such as in a simulation (Reed, 2020). Kolb's theory suggests reading and/or observation are not sufficient methods to fully learn, as it requires active participation (Williams & Spurlock, 2019). Next, the reflective observation stage is about debriefing, or reviewing what happened during the experience. This is where the connections are made by the learner identifying and linking patterns and themes (Williams & Spurlock, 2019). It may even lead to altered reflections on a concept or new thoughts and ideas. This is considered the most crucial stage for learning when using simulation as an education method (Reed, 2020). In the abstract conceptualization stage, the learner then starts to make sense of their experience and associate meaning to what they observed (Williams & Spurlock, 2019). Last, the active experimentation stage is where the learner would apply and practice these learned concepts and ideas.

Review of the Literature

A literature search was performed through CINAHL to identify appropriate quantitative studies and systematic review articles regarding diabetic education interventions for patients with type II diabetes. Interventions involving patient education to promote the self-management of diabetes are well researched in the literature. A large variety of interventions have been used by multiple disciplines, examining the effect of many different outcomes—largely glycemic control and psychological measures. The interventions included online and multimedia types of education, compared to the standard of care of educational handouts and/or provider instruction, but few have included simulation.

Education Interventions

Simulation

A randomized controlled trial (RCT) by Ji et al. (2019) examined the effect of simulation education and case management interventions on diabetic control for patients with diagnosed type II diabetes. The control group received group sessions focused on the

> knowledge and skills required for a healthy diet, exercise education, self-monitoring of blood glucose levels, and drug management specifically for insulin injection participants,

> problem solving related to diabetes, and changes in lifestyle to facilitate a reduction in the risks and complications associated with diabetes. (p. 3)

The intervention groups received both simulation education and care management interventions. The simulation education invited household members to join with patients and included "role playing and problem solving" techniques following an educational video (Ji et al., 2019, p. 3). The case management intervention was led by a nurse to follow up both individually and through group sessions with patients, focusing on diet, exercise, goal setting, and troubleshooting challenges. The sample size was 100 participants, though nine did not complete the study or were lost to follow up and no further discussion was provided on these participants or their characteristics (Ji et al., 2019). Therefore, 91 participants were included for data analysis. There was no explanation provided on how the sample size was reached. The authors do note, however, that one of the limitations of the study is that the sample size is small (Ji et al., 2019).

The tools used in the study by Ji et al. (2019) include established laboratory tests such as HbA1c, glucose levels, total cholesterol, triglycerides, high-density lipoproteins (HDL), and low-density lipoproteins (LDL), as well as other well-accepted vital signs including blood pressure and body mass index (Ji et al., 2019). No measures of validity or reliability were established for these types of tests. However, a diabetes self-management self-efficacy scale was also used, and this was tested for validity and reliability using Cronbach's alpha, retest reliability, and content validity (Ji et al., 2019). While the main outcome examined was HbA1c, other outcomes included the additional laboratory tests and vital signs previously noted. Additionally, secondary outcomes regarding self-care management were included, which were categorized as balanced diet, exercise, blood glucose monitoring, medication management, troubleshooting, and risk reduction (Ji et al., 2019). These outcomes were obtained as a baseline prior to the intervention and again upon conclusion of the intervention at 6 months. Furthermore, demographic information was obtained from the patients and an analysis was performed to examine these characteristics between the control and intervention groups (Ji et al., 2019).

In the study by Ji et al. (2019), the continuous variables were expressed as means plus or minus the standard deviation and t-tests, either Student's or Mann-Whitney U, were used for comparisons between groups. Nominal variables were compared using a chi-squared test. Both statistical tests were two-tailed with a level of significance of $p < 0.05$ (Ji et al., 2019). The results demonstrate, perhaps not surprisingly, that all groups had an improved HbA1c. However, the experimental group had a significantly better HbA1c than the control group. In terms of other outcomes for the experimental group, the systolic blood pressure was also significantly improved, as well as scores for diet, exercise, glucose monitoring, risk reduction, and problem-solving (Ji et al., 2019). The authors referenced a previous meta-analysis that also supported that case management improved glycemic control. Furthermore, they mentioned that diabetic self-management education alone has been well-demonstrated to improve HbA1c in diabetic patients (Ji et al., 2019). The authors did not discuss previous studies using simulation as an educational intervention in their literature review. The authors recognized that it had been used as a patient education technique, though it is better recognized for its use in training those pursuing the healthcare field interventions to improve glycemic control.

Strengths of the study by Ji et al. (2019) included the use of validated and reliable tools, a high-level study design, and largely homogenous groups. A few limitations of the study are noted, specifically the small sample size and lack of acknowledgement regarding the cost of the intervention. Also, results were obtained immediately following the completion of the intervention, and therefore long-term effects are not able to be determined.

Penneçot et al. (2020) assembled a consensus conference to determine the skills and conditions in patient education that could be delivered using simulation. The authors used a modified Delphi process with a panel of experts from a variety of disciplines including nursing, medicine, nutrition, health engineering, and research. The expert panel was also comprised of caregivers and patients (Penneçot et al., 2020). Several important recommendations regarding the use of simulation in patient education were noted from this process. These recommendations included that simulation can be used regarding patient education to increase the motivation to take care of oneself, learn techniques or procedures through repetition, reinforce self-efficacy, and learn how to manage a crisis or emergency (Penneçot et al., 2020). Additionally, the panel suggested that simulation should be used as soon as possible in the course of the illness.

Written Materials Versus Multimedia Education

Moghadam et al. (2018) examined the effect of self-care education for diabetic patients on their levels of emotional intelligence (EI) and the HbA1c in an RCT (p. 41). The educational intervention for self-care was delivered via video over 8 weeks, in approximately one and a half hour sessions (Moghadam et al, 2018). The control group received written materials and instruction as the standard of care. EI was measured by the Bar-On questionnaire, which was demonstrated to be a reliable and valid tool (Moghadam et al., 2018, p. 41). In this repeated-measures design study, results suggested that there was a significant difference between the mean HbA1c before and 2 months after the self-care intervention. Also, EI was demonstrated to be higher in the intervention group (Moghadam et al., 2018, p. 41). However, the duration between the data collection points was rather brief, as the post-intervention measure was directly after the intervention and then again 2 months after.

The effect of another type of educational intervention for patients with diabetes was studied by Ebrahimi et al. (2016). The intervention in this RCT included an empowerment approach training based on Bandura’s self-efficacy construct and the Health Belief Model (p. 131). The control group received the standard of care, and results suggested that there was a significant difference in the intervention group compared to the control group in HbA1c. The demographics in the population in this study were homogenous, so results may not be generalizable to patients with various sociocultural, economic, and clinical characteristics (Ebrahimi et al., 2016, p. 131).

A study by Huang et al. (2017) explored the effect of multimedia education for patients with type II diabetes using insulin pen injections on several different variables. These variables included knowledge of diabetes and insulin, insulin injection skills, self-efficacy, satisfaction with health education, and HbA1c and creatinine. The control group in this experimental study received the standard of care, which included written handouts and instruction from a certified diabetes educator (Huang et al., 2017). The participants were assigned to the groups by randomization. While the experimental group had significantly higher scores for insulin injection knowledge and skills, self-efficacy, and satisfaction, the authors found no significant difference in HbA1c and creatinine in the control and experimental groups (Huang et al., 2017). The study was a repeated measures design, as data was collected before the intervention and four other points after the intervention (Huang et al., 2017). The final data collection point, however, was 13 weeks after the intervention, so one could question if this was a long enough duration to see the intervention’s actual impact. A noteworthy concern the researchers addressed was that 30 participants received alternative education from an outside source in addition to what was provided in the study, so their data was not included in the analysis (Huang et al., 2017).

Self-Care Management Indicators

HbA1C

Cheng et al. (2017) analyzed 16 randomized controlled trials (RCTs) with 3,545 participants in which interactive self-management interventions were associated with a significant reduction in the HbA1c of type II diabetic patients. The collaborative interventions found to be associated with significant decrease in HbA1c included goal-setting, feedback, problem-solving, action planning, and motivational interviewing. Though a reduced HbA1c was the main outcome examined, secondary outcomes were also positively affected, and these included increased knowledge, increased self-efficacy, and decreased psychological distress (Cheng et al., 2017, p. 69). Unfortunately, sustainability of the interventions was not supported by the review, as the effects of the interventions were reported to diminish after 12 months. The authors suggested that these interventions should be prioritized for patients with poor glycemic control (Cheng et al., 2017, p. 71). The authors did not provide explanations or definitions for any of the interactive self-management interventions.

Fan and Sidani (2018) did a cross-sectional study that explored the relationships between demographic influences and clinical factors on the preferences for types and dosages (or intensity and frequency) of educational interventions for patients with type II diabetes. The interventions the authors examined included a variety of delivery methods, such as active skills training. The results suggested that several factors significantly affected the participants' preferences. Specifically, older participants and those with a lower HbA1c were more likely to select a combination of interventions. Participants with a higher education level and a lower HbA1c were more likely to prefer interventions that allowed for open discussion (Fan & Sidani, 2018). Furthermore, participants with higher education levels and longer duration of type II diabetes diagnosis were more likely to choose lecture-style interventions. Women were more likely to choose face-to-face interventions; and also, women who did not have a history of receiving prior diabetes education with poor glycemic control preferred to attend more frequent sessions (Fan & Sidani, 2018).

The Fan and Sidani (2018) study could be used to further develop algorithms to customize educational interventions based on patient preferences, which are influenced by their demographics and clinical status. While their research has great importance, several limitations must be considered. The sample size was 100 participants, and though some eligible patients refused to participate, no diagram was included to depict the flow of attrition (Fan & Sidani, 2018). Furthermore, the researchers used convenience sampling, which could limit the generalizability of the results. The authors also were concerned that participants could have had a desire for in-person interactions for the social benefit, which is a source of potential bias (Fan & Sidani, 2018).

Other types of educational interventions for type II diabetic patients that examined the effect on HbA1c were observed by Whitehead et al. (2017) in an RCT. The authors looked at two different intervention groups and a control group. The control group received the standard of care, but the intervention groups received a 1-day nurse-led educational intervention that used acceptance and commitment therapy (ACT) (Whitehead et al., 2017). Whitehead et al. (2017) found that there was a significant reduction in HbA1c 6 months after the intervention groups received the nurse-led educational sessions. The HbA1c in the control group increased, and there was no significant difference in the intervention group with ACT compared to both the education-only group and the control group (Whitehead et al., 2017, p. 826). One strength of this study was that it measured the impact at 6 months post-intervention, which was longer than other studies reviewed. Also, an important consideration the authors noted was that the time since diagnosis of type II diabetes may have some impact on the outcomes, as some participants had been diagnosed with diabetes for more than 10 years (Whitehead et al., 2017).

A notable study by Radcliff et al. (2020) aimed to examine the cost-effectiveness of three different dosages (categorized as high, medium, and low) of nutritional education and behavioral coaching compared to low-dosed nutritional education without coaching. Additionally, the study examined the effect of the interventions on HbA1c for patients with or at risk of having type II diabetes in rural areas. Cost effectiveness was determined by comparing total costs of the interventions and quality adjusted life years (QALYs). Additionally, this study was built on the Rural LITE trial, which looked at cost and outcomes of patients with type II diabetes (Radcliff et al., 2020). Data was extracted from this earlier trial and utilized to further analyze overall cost-effectiveness. This study, therefore, used a subsample of the original 612 participants in the prior trial, ultimately using 317 participants for this analysis (Radcliff et al., 2020). Gender, age, and body mass index were compared and were consistent among the participant groups collectively. It is likely that further sample size details were discussed in more detail in the prior study (Radcliff et al., 2020). The participants were randomly grouped to receive one of the three dosages of education in the experimental group or to receive the control intervention of the education without behavioral coaching. This study also was specific to individuals in rural settings, and the educational interventions were provided using a cooperative extension service, which already are equipped in providing training programs (Radcliff et al., 2020).

The validity and reliability of the measures in the study by Radcliff et al. (2020) were not explicitly mentioned in this analysis. Costs for the sessions were previously obtained from the prior study, as well as data for weight and HbA1c (Radcliff et al., 2020). Additionally, other factors of financial estimates including annual healthcare costs were used from previous studies, though the authors noted this to be "rigorous" and "peer-reviewed" (Radcliff et al., 2020, p. 1166). Furthermore, estimates for QALYs were based on national benchmarks. The cost-effectiveness analysis was completed by using ratios for annual healthcare costs and QALYs through a third-party source (Radcliff et al., 2020).

Results of the study by Radcliff et al. (2020) found that the low and moderately dosed educational and coaching interventions in the experimental groups were the most cost-effective compared to the control group. The moderately dosed intervention, while costlier than the low-dose intervention, produced higher QALYs (Radcliff et al., 2020). This was an important finding to guide future studies regarding dosages for interventions from a cost-effectiveness standpoint.

In reviewing the literature, Radcliff et al. (2020) discovered an important finding that only eight other studies involving diabetic education interventions examined the cost and financial impacts of the intervention. This is clearly a gap in the current literature that is likely crucial to the buy-in of stakeholders and to sustain such educational programs. Strengths of this study include the aim to examine a needed research area of cost-effectiveness of diabetic education interventions (Radcliff et al., 2020). The authors employed a high-level randomized trial designed to analyze financial data. Limitations include using data based on findings from the literature and only one measure of glycemic control to examine diabetic disease progression (Radcliff et al., 2020). Furthermore, no power analysis was provided for this study.

A systematic review on online self-management interventions for type II diabetes by Celik et al. (2020) examined the primary outcome of HbA1c. A search strategy using three databases of Medline, Embase, and CINAHL was implemented. The authors included details regarding the time frames in which the search was conducted and included the search terms and operators used. Additionally, they discussed the inclusion and exclusion criteria for studies to be considered (Celik et al., 2020). Inclusion criteria required that the study was a randomized controlled trial with type II diabetic patients and had to be written in English (Celik et al., 2020). Additionally, the review only incorporated online self-management interventions that also facilitated communication between the patient and provider.

The systematic review by Celik et al. (2020) did not specifically describe the validity for individual studies. The authors did, however, use specific tools for quality assessment including Cochrane Collaboration's tool for assessing risk of bias and the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system. Additionally, many features were collected from the studies including, but not limited to, study design, comparison, follow-up, and results (Celik et al., 2020). The combined results from the eight RCTs in this review showed a statistically significant improvement in HbA1c values, but the study did not address the results in the individual studies separately. This review also included secondary outcomes including blood pressure, lipids, depression and diabetes distress, and self-efficacy—all of which had mostly inconclusive findings. The pooled mean difference reported was -0.35%, 95% confidence interval (CI) (-0.52 to -0.18) and $p < 0.0001$ (Celik et al., 2020). The authors explained that the results suggest a "small effect size but significantly high levels of heterogeneity" (p. 269).

The mean patient age in the studies in the systematic review by Celik et al. (2020) was 50 to 65 years of age, which is consistent with the average age of the population affected by type II diabetes and most likely will represent future research participants. The authors explained that the financial impact of the online interventions in these studies was not included. Also, considerations for lack of other resources, such as broadband access, were not discussed (Celik et al., 2020). However, the advantages of the online interventions in this study include better participation than live, in-person education sessions, continually updated information, and less time requirement for providers.

Strengths in this review include the use of high-level randomized controlled trials. Additionally, many of the studies were powered, and therefore the effect estimate "was moderately confident" (Celik et al., 2020, p. 271). Limitations of the review include the potential for missed studies in other databases and languages. Furthermore, the potential for bias was present in some of the included studies due to lack of blinding and variations in the control interventions or standard of care (Celik et al., 2020).

Self-Efficacy

A double-blinded controlled clinical trial conducted by Torabizadeh et al. (2019) aimed to examine the impact of resiliency skills training on self-efficacy in management of type II diabetes. The sample size was obtained by using a formula and results based on a prior study. Based on the calculations and accounting for a 30% rate of attrition, it was determined that 150 total participants would be needed to randomly sort into the control and intervention groups (Torabizadeh et al., 2019). Initially, 162 participants were reviewed for appropriateness to be included in the study. Exclusion criteria required a self-efficacy pre-intervention score of above 134 and a resilience preintervention score of above 52, which excluded nine patients (Torabizadeh et al., 2019). Three other patients were lost to attrition, so there was a total of 150 participants.

In the study by Torabizadeh et al. (2019), the tests for resilience and self-efficacy were both assessed for reliability and validity and retested after the tools were translated. The resilience score was obtained using the Conner and Davidson Resilience questionnaire and was tested for reliability by Cronbach's alpha and for validity by factor analysis (Torabizadeh et al., 2019). The self-efficacy score was obtained using the Diabetes Management Self-Efficacy Scale (DMSES), which was tested for validity by the "content validity ratio" and "factor analysis" (Torabizadeh et al., 2019, p. 214). Reliability of the DMSES was tested by Cronbach's alpha.

The outcome data that Torabizadeh et al. (2019) specifically looked at were self-efficacy scores before the intervention, immediately after the intervention, and 1 month post intervention. An independent t-test was used, and results suggested that there were significant differences in the control group and the intervention group regarding the DMSES scores (Torabizadeh et al., 2019). Additionally, a repeated measures ANOVA found that the time post-intervention was a significant influence in the self-efficacy scores of the intervention group versus the control group. Demographic information was also obtained and examined between the study groups (Torabizadeh et al., 2019). There were seven participants that did not remain in the study, but the authors did not discuss the demographic information of these participants. However, a CONSORT flowchart is included in the article to provide details on why the patients were not included (Torabizadeh et al., 2019). Listed reasons include hospitalization for four participants and lack of involvement for three other participants.

Torabizadeh et al. (2019) did clearly state that research is quite limited regarding the impact of resilience on self-efficacy and overall diabetic self-management, though it has been examined with other conditions. More studies need to be done to better determine what skills and interventions can be taught to build resilience in patients. Results like those obtained in this study have been found in examining the effect of resilience on other chronic conditions, suggesting this construct could be a very important factor for diabetic self-management (Torabizadeh et al., 2019). Limitations of this study include that both the intervention and control groups were predominately female. Also, the post-intervention period was brief at only 1 month (Torabizadeh et al., 2019). Strengths include large effect sizes and limited bias due to the double-blinded design (Torabizadeh et al, 2019).

Michiels et al. (2019) examined the effect of a pharmacist-delivered diabetic education intervention on treatment compliance and HbA1c. However, the study also examined the ability of the participants to self-manage and their overall knowledge levels (Michiels et al., 2019). Self-management abilities were evaluated by a Test d'Observance Pharmaceutique (TOP) questionnaire (Michiels et al., 2019). This RCT had an experimental group of participants receiving the intervention of three 30-minute sessions over 6 months that focused on nutrition, medications, and disease progression. The educational interviews were based on the information-motivation-behavioral model (Michiels et al., 2019). The control group received the standard of care of counseling.

First, pharmacies were recruited and selected based on the eligibility criteria and pharmacists received training prior to the execution of the interventions (Michiels et al., 2019). The pharmacies were then randomly selected to the control group or the experimental group. A power analysis was performed to reach the needed sample size of 167 patients per group (Michiels et al., 2019). A total of 377 patients were included in the analysis with 189 participants in the experimental group and 188 participants in the control group. A flowchart is included in the article with details about reasons for exclusion including missing data, patients declining to participate, and ineligibility based on the inclusion criteria (Michiels et al., 2019).

Evaluated outcomes included medication adherence, which was measured by a medication possession ratio, defined as the "ratio of the number of pills taken by the patient to the number of pills that should have been theoretically taken within a time interval" (Michiels et al., 2019, pp. 1293-1294). Glycosylated hemoglobin, low-density lipoprotein levels, and blood pressures were reportedly obtained per the patient, and the authors did not elaborate if any measures were taken to verify this data (Michiels et al., 2019). Also, the authors did not account for the validity and reliability of the TOP questionnaire in their discussion. Additionally, the patients' knowledge level was assessed by another questionnaire that had no validity or reliability data reported to support its use. Demographic data were obtained from the participants for analysis (Michiels et al., 2019). Demographic details for participants in this study included a predominately male gender, approximately 65 years of age (Michiels et al., 2019). Additionally, it is important to note that the participants in this study had been diagnosed with diabetes for over 10 years (Michiels et al., 2019). The average baseline HbA1c for participants was mildly elevated at 7.8%.

The statistical analysis performed in this study includes the use of the Fisher-Snedecor test for analyses of variance, comparing the means between groups (Michiels et al., 2019). Also, a paired t-test or chi-squared test was used for comparisons within groups. Interestingly, the medication adherence ratio was found to be quite high at above 90% in both the experimental and control groups, with no significant difference in either group post intervention (Michiels et al., 2019). Results for HbA1c revealed that, while both groups decreased throughout the duration of the study, the experimental group had significant decrease from baseline at both 6 and 12 months (Michiels et al., 2019). No significant changes were noted for LDL level and blood pressures. Also, knowledge levels and self-management scores were noted to be significantly better in the experimental group (Michiels et al., 2019).

Strengths of the study by Michiels et al. (2019) include that it examined results up to 12 months after the intervention. Additionally, medication adherence was examined, a potential factor not consistently examined in other studies in the literature. Furthermore, changes in medication treatment were also accounted for in this study as a factor that might contribute to improved glycemic control. Limitations of the study include that it only had participants on oral medications (Michiels et al., 2019). Despite the high-level design of this study, opportunities for the introduction of bias were also noted, especially considering the high medication adherence rate of participants at baseline. This study provided an excellent example of the need to incorporate other disciplines to assist in the management of diabetes to bring additional perspectives to the research being conducted regarding patient education.

In summary, there are a vast number of high-level studies that have examined educational interventions for diabetic patients. The findings overall seem to be consistent across various settings. Many studies were done at large care centers; however, the rurally set study by Radcliff et al. (2020) also found benefits in the educational interventions. Unfortunately, the systematic review of online self-management interventions by Celik et al. (2020) did not provide details on setting, which would have been particularly interesting regarding access being a potential barrier. Access can be a barrier in many areas concerning transportation for in-person interventions and for broadband in rural areas. Also, the inclusion of studies from various healthcare disciplines can contribute additional considerations that otherwise might have been overlooked.

These studies suggest that participation in educational activities, regardless of method, has a significant effect on lowering HbA1c. Many included studies used written materials and even provider instruction as the standard of care, or control group. These written materials were found to be generally ineffective. Research that examines self-efficacy, self-care management, and diabetes knowledge are also prevalent in the literature. However, these outcomes are seemingly more inconclusive than glycemic control.

Research Design

This study was intended to investigate the effect of simulated patient education, compared with educational handouts, on the DSMQ after 6 weeks in adult persons with type II diabetes. As previously discussed, the specific hypothesis of this study included a proposal that the simulation-based educational intervention for patients with type II diabetes will have an effect on the DSMQ score compared to groups that receive the educational handout. Also included is an examination of the relationship between time since diagnosis and the DSMQ scores. Therefore, the research design was a prospective, interventional design due to the specific simulation-based education planned for this investigation (Aggarwal & Ranganathan, 2019a). More specifically, the type of prospective, interventional design proposed is an experimental design. Both the intervention group and the comparison group were tested before and after the intervention (pretest and posttest design). Data collection occurred 6 weeks after receiving the intervention or standard of care.

Project Sample

All participants were diagnosed with type II diabetes and had an HbA1c obtained within 6 months that was greater than or equal to eight. Furthermore, participants were adults 18 to 70 years of age. The study excluded participants that are non-English speaking, have severe cognitive impairment, are physically disabled, blind, or severely hearing-impaired, have a terminal illness, or are criminally institutionalized. Eligible subjects were recruited from Carilion Clinic family medicine practices in Rocky Mount, Virginia after the Carilion Health Analytics Research Team (HART) identified them through electronic medical record review. The practice managers also reviewed the list and approval was obtained to proceed with contacting the patients. Due to time limitations for this particular project, and the one-on-one interventional nature, a feasibility study is a reasonable option with a small sample size. This sample size goal to obtain statistically significant results and plan for attrition was 40 participants—20 in the intervention group and 20 in the comparison group.

Approval for this study was obtained from the Carilion Clinic Institutional Review Board (IRB), which was subsequently reviewed by the Radford University IRB. The sample was not considered a vulnerable population (Polit & Beck, 2017), and written consent was waived. A recruitment letter was mailed either electronically or physically (or both) to potential participants that were identified based on eligibility criteria. The recruitment letter explained the study's purpose, risks, and benefits. Additionally, it provided information on how safeguards were taken to protect the participants' information and privacy. Data was identifiable; however, it was entered and utilized in a secure platform, REDCap. The Carilion HART member served as an honest broker to the data and blocked the ability to download the data. Only aggregated and de-identified data was shared.

A total of 448 participants were deemed to meet the eligibility criteria through the Carilion HART electronic medical record review. Subsequently, the researcher sent recruitment materials via both mail and electronic mail means (if an e-mail address was available). The risks and benefits of participating in the study were thoroughly explained to all participants in an information sheet, which was distributed with the recruitment letter. Additionally, this was reviewed verbally upon contact with the participant by the researcher. Risks were minimal and mostly resulted in a loss of the participant's time. Increased stress, frustration, or anxiety were also possible risks due to gaining new knowledge of recommended lifestyle changes and disease complications. Breach of confidentiality is always a potential risk, but measures were in place to limit this. Identified potential benefits included increased levels of knowledge regarding self-management of diabetes, improved glycemic control, and decreased future disease complications. Additionally, incentives for participation included a medical alert card, a blood glucose log, and a grocery store gift card—valued at $10. Furthermore, the participant contributed to an area of research in which gaps currently exist.

Pretest data that were analyzed included a baseline HbA1c, which was the most recent value in the electronic medical record within the past 6 months. Additional pretest data included descriptive demographic information, specifically the participant's age, gender, race and ethnicity, education level, employment status, annual income, duration of diagnosis, address, phone number, indication of previous receipt of formal diabetic education, time since diagnosis of diabetes, and comorbidities. Demographic information was obtained via the medical record and phone interview.

Instrumentation

The outcome being examined and measured in this study was diabetes self-management. This was measured using the DSMQ, which is a standardized, validated tool. It assessed self-care interventions required for glycemic control specifically regarding diet, physical activity, medications, and self-monitoring of blood glucose (Schmitt et al., 2013). The DSMQ utilized a 16-item 4-point Likert scale for participants to self-rate their own self-management ability. The DSMQ has been demonstrated to have an overall good reliability (Cronbach's alpha) of 0.84 (Schmitt et al., 2013). Originally developed by Schmitt et al. (2013) in Germany, many other studies have also used the tool cross culturally. It has been validated in other languages. The DSMQ was administered by the researcher via phone interview prior to the intervention (pretest). After the interventions were completed, the information for the DSMQ was obtained via phone interview again for both groups at the 6-week mark.

The DSMQ has also been assessed in regard to its consistency with glycemic control, specifically in comparison with HbA1c (Schmitt et al., 2013). Results of the study by Schmitt et al. (2013) suggest that it is superior to a similar type of diabetes self-management scale in correlating with one's HbA1c. The DSMQ score will be an interval level of measurement. It is obtained by adding the points per the participant's responses. It does require reversal of negatively worded responses (Schmitt et al., 2013). Additionally, if one of the behaviors does not apply, it requires a transformed score based on a provided scale. The possible range of scores are from zero to 10, with 10 being the highest score indicating an excellent ability to self-manage diabetes (Schmitt et al., 2013).

Procedure

The participants were recruited using a consecutive sampling method from both family practice offices. Potential subjects were sent a recruitment email/letter regarding information about the study, with the researcher's contact information. Additionally, they received an information sheet explaining the study in more detail. Once the potential participant reached out to the researcher indicating their interest, the researcher then reviewed the study and obtained consent over the phone after providing an opportunity for the potential participant to ask questions. Upon obtaining consent, eligible participants were assigned to receive either the intervention or the educational handouts using simple, computerized randomization procedures.

Next, the participant completed the DSMQ, and provided demographic information via phone interview. Subsequently, those that were randomized to the simulation group were scheduled for an appointment to complete the simulation activity, in which they experienced an unfolding simulated scenario that provided realistic experiences to educate them on how to navigate self-management of diabetes. The simulated activity involved a one-on-one interaction between the researcher and the participant. The scenario took approximately 20 minutes to complete, followed by a 40-minute debrief session that reviewed the intended objectives. The intervention was completed in a single session that was scheduled upon obtaining consent and took place at the family practice office setting in Rocky Mount, VA. The simulation group participants were contacted 6 weeks after the intervention to complete the DSMQ as a posttest.

Eligible participants randomized to the comparison group also completed the DSMQ and provided demographic information via phone interview. They received an educational handout via mail for their diabetes management. Six weeks after the handout was mailed, the participant was contacted again to complete the posttest. Participants in the handout group were also provided the opportunity to participate in the simulation if they wished, scheduled at the discretion of the researcher.

Participants from both groups that completed the study were provided the $10 gift card, medical alert card, and blood glucose log via mail. Participants were either mailed or hand-delivered their incentives. Furthermore, the protocol defined a limited points of contact that the researcher could attempt reaching a participant of only three attempts leaving a voicemail each time.

Intervention

The intervention was developed through the guidance of a simulation expert and with the approval of the Carilion Clinic Center for Research, Patient Safety, and Simulation. The information provided in the simulation and education was based on ADA guidelines. Diet and blood glucose monitoring was covered specifically through the simulated interventions. Pathophysiology, medications, complications, coping, risk-reduction, and problem-solving were covered during the debrief session as it relates to the simulated scenarios.

Psychomotor skills required of participants prior to simulation included writing and manipulating lancets and the blood glucose monitor. Cognitive activities required of participants prior to simulation included understanding the goal of the scenario and how it will be facilitated, recognizing and recording blood sugar readings, and reading nutrition labels. Learning objectives of the simulation included:

- The patient will state causes, signs, and symptoms of hypoglycemia and hyperglycemia.
- The patient will be able to perform the appropriate actions to manage blood sugar after recognizing signs and symptoms of hypoglycemia and hyperglycemia.
- The participant will be able to choose appropriate portion sizes based on the diabetes plate method.
- The participant will state the important components related to blood sugar on a nutrition label have increased knowledge of interpreting a nutrition label.
- The participant will be able to identify at least one nonstarchy vegetable, protein food source, and one carbohydrate food source

A prebriefing was held to discuss the roles, expectations, fiction contract, assumptions of the scenario, and orientation to the simulation, which took approximately 5 minutes. The unfolding scenario was 15 minutes in length. Finally, 40 minutes was dedicated to debriefing with the participant to encourage their reflection on the activity and address the participants' actions based on the ADA guidelines.

Data Management and Statistical Analysis

The data for this project were analyzed by the Carilion HART biostatistician using the SAS Enterprise Guide. No questionnaires were missing data. One participant was lost to posttest follow up but was still included in the pretest results due to the small sample size. Descriptive statistics were used to examine and describe the demographics of the participants. Individual items in the DSMQ for the intervention group and the comparison group were reported by frequencies and percentages.

The participants' DSMQs were scored and reported for both groups for the pretest and again for the posttest. Mean scores were examined for total DSMQ score and the DSMQ categories of scores (dietary control, glucose management, glucose monitoring, medication adherence, physical activity, and physician contact). However, it was determined that statistical analyses were of no value due to the very small sample size in this study. Therefore, no formal comparisons were made between the pretest scores versus posttest scores for either group. Furthermore, the DSMQ items were unable to be compared by time since diagnosis due to the low sample size, and only three participants providing a definitive answer to this question.

Results

The purpose of this study was to specifically examine the effect of simulation as an educational intervention for adult patients diagnosed with diabetes. The aim was for simulation to be used as a method of patient education to ultimately improve the patient's self-management of the condition, evaluated by the DSMQ score. The primary research question for this study was: In adults with newly diagnosed type II diabetes, how does diabetic education delivered by simulation, compared to educational handouts, affect the DSMQ score within 6 weeks? A secondary question was: Will the time since diagnosis impact the effectiveness of the interventions on the DSMQ?

Demographics

All the participants met the inclusion criteria to participate. This study had a very low recruitment of only six subjects of 448 that were recruited. All six participants spoke English as their primary language. All were able to perform activities of daily living without difficulty. Interestingly, all six participants reported some extent of visual impairment, but this was corrected with glasses for each subject. One subject also reported hearing impairment, but this was corrected with the use of a hearing aid. This patient was in the simulation group, and they did wear their hearing aid for the scenario and had no difficulty hearing during data collection obtained via phone. One subject reported either learning disability or needing assistance in school, but this was determined to not be severe enough to exclude them from participating. Similarly, one patient reported suffering from mental illness and/or mood disorder but was not experiencing any current exacerbation during the study period and was therefore deemed eligible to participate.

The subjects were randomized by a computer program to the handout and simulation groups. The number of participants was three in each group. The subject lost to follow up was in the simulation group, so posttest data for the simulation group was obtained from only two participants. However, all six subjects completed the demographic survey, which took about 5 minutes to complete over the phone. The mean age was similar for both the simulation and the handout group and ranged from 46 to 69 years. The simulation group mean age of participants was 58 years, and it was 54 years in the handout group.

The handout group consisted of one female and two male participants. Alternatively, the simulation group consisted of two female participants and one male participant. Five of the participants reported that they were of Caucasian ethnicity and one participant reported to be of a Black/African American background (simulation group).

Additional demographic data obtained included that most subjects were married. Two reported that they were single as their marital status, both of which were in the handout group. The demographic survey further explored the participants' education level and work status. One participant reported less than a high school degree (handout group), while the remaining participants had either some college and/or technical school or a college degree. Most subjects were working full-time, two participants in the handout group and two in the simulation group. Otherwise, one subject reported they were on disability (handout group) and the other reported working part-time (simulation group). Incomes of all participants varied greatly, as they ranged from $10,000 - $24,999 to $100,000 - $150,000. Demographic data for both groups is summarized in Table 1.

Table 1

Demographic Data

Variable	n	%
	Handout	
Marital Status		
Married	1	33.3
Single	2	66.7
Work Status		
Working full-time	2	66.7
Working part-time	0	0.0
Disabled	1	33.3
Biological Sex		
Male	2	66.7
Female	1	33.3
Race/Ethnicity		
White/Caucasian	3	100.0
African American	0	
Education Level		
Less than High School	1	33.3
Some College or Technical School	1	33.3
	1	33.3

College Degree		
Income	1	33.3
$10 000 - 24 999	1	33.3
$25,000 - 49,999	0	0.0
$50,000 - 74,999	0	0.0
$75,000 – 99,999	1	33.3
$100,000 - 149,999		
	Simulation	
Marital Status		
Married	3	100.0
Single	0	0.0
Work Status		
Working full-time	2	66.7
Working part-time	1	33.3
Disabled	0	0.0
Biological Sex		
Male	1	33.3
Female	2	66.7
Race/Ethnicity		
White/Caucasian	2	66.7
African American	1	33.3
Education Level		
Less than High School	**0**	**0.0**
Some College or Technical School	**1**	**33.3**
College Degree	**2**	**66.7**
Income		
$10 000 - 24 999	**0**	**0.0**
$25,000 - 49,999	**0**	**0.0**
$50,000 - 74,999	**2**	**66.7**
$75,000 – 99,999	**1**	**33.3**
$100,000 - 149,999	**0**	**0.0**

The health status of the participants was mostly rated as good or very good. However, one participant in each group did rate his or her health status as poor. Comorbidities and risk factors reported among the subjects included hypertension (n = 4), heart disease (n = 1), tobacco use (n = 1), anxiety (n = 1), depression (n = 1), joint pain (n = 1), history of stroke or clot (n = 1), sleep apnea (n = 1), and other (n = 2). Comments from participants that selected "other" for comorbidities included high cholesterol and vascular disease.

Regarding previous receipt of diabetic education, most patients reported a variety of different methods. These include previous use of educational handouts (n = 2), education from their healthcare provider (n = 2), and from self-study or online resource (n = 2). Interestingly, only one participant reported prior formal instruction from a diabetic educator. Receipt of previous diabetic education is summarized in Table 2.

Table 2

Receipt of Previous Diabetic Education

Variable	n	%
	Handout	
No previous education	2	66.7
Educational handouts	1	33.3
Provider-led education	0	0.0
Diabetic educator	1	33.3
Self-study/online resources	1	33.3
	Simulation	
No previous education	0	0.0
Educational handouts	1	33.3
Provider-led education	2	66.7
Diabetic educator	0	0.0
Self-study/online resources	2	66.7

Study Variables

Due to the low participant enrollment, the initial plan for data management had to be adjusted. Every data point had to be used, so responses that were lost to follow up in the posttest were noted with a frequency missing table. Formal statistical tests were not possible due to the low sample size. Therefore, data points were evaluated for frequency and percentage only.

Item 1, “I check my blood sugar levels with care and attention,” for applies “very much” increased from 66.7% to 100% in the simulation group. However, it also increased from 33.33% to 66.7% in the handout group. In the posttest, no participants felt it only applied to them to “some degree”; they responded either to a “considerable degree” or “very much.”

For Item 2, “The food I choose to eat makes it easy to achieve optimal blood sugar levels,” no participants responded that this applied to them “very much” in the pretest. However, one participant from the posttest responded “very much” (n = 1) from the simulation group.

For Item 5, “Occasionally, I eat lots of sweets or other foods rich in carbohydrates,” the simulation group had a variety of responses including that this applied to them “some degree” (n = 1), “very much” (n = 1), and “does not apply” (n = 1) in the pretest. However, in the posttest 100% of participants in the simulation group reported that it applied to them “some degree.” One person in the handout group reported that this still applied for them “very much.”

For Item 6, “I record my blood sugar levels regularly (or analyze the value chart with my blood glucose meter),” 100% of the simulation group in the posttest reported that this applied to them “very much” whereas only 66.7% of the handout group reported this.

The posttest responses decreased for Item 13, “Sometimes I have real ‘food binges’ (not triggered by hypoglycemia),” from three participants that rated it applying to them “very much” to just one participant (handout group).

For Item 16, “My diabetes self-care is poor,” the number of those that replied “very much” was three at the pretest and this decreased to zero responses at the posttest. Two participants did reply at the posttest that it applied to them some degree, but of note they were in the handout group.

The DSMQ was scored for both groups for the pretest and posttest. Mean total scores were examined for the pretest for the simulation group and handout group. Additionally, mean total scores were examined for the posttest for the simulation group and handout group. Mean scores were also examined for individual items on the DSMQ for pretest versus posttest for both groups. Again, no formal comparisons could be made between pretest versus posttest for simulation versus the handout group due to low enrollment, so only the mean was reported. Table 3 shows the mean total scores, as well as mean scores for individual items, for pretest versus posttest for both groups.

Table 3

DSMQ Scores

Variable	Mean Handout	Mean Simulation
	Pretest	
DSMQ Total	5.9	7.6
Dietary Control	2.5	5.6
Glucose Management	6.9	8.7
Glucose Monitoring	5.9	7.8
Medication Adherence	8.3	10.0
Physical Activity	7.0	9.3
Physician Contact	8.9	7.8
	Posttest	
DSMQ Total	7.5	9.1
Dietary Control	5.3	7.1
Glucose Management	8.9	10.0
Glucose Monitoring	8.5	10.0
Medication Adherence	9.4	10.0
Physical Activity	7.4	8.9
Physician Contact	8.1	10.0

Unfortunately, three participants were not able to provide length of time since diagnosis data. This is largely since this data point was not planned to be obtained in the original study protocol and these patients were already enrolled after the approved protocol change took place. Therefore, the assumption their diagnosis was less than 1 year at the point of data collection was made. The three participants that did provide this data reported 6 months (n = 1), 1 year (n = 1), and 8 years (n = 1).

Analysis of Research Questions

Unfortunately, little could be determined regarding the effect of the two interventions on the DSMQ due to the low sample size. However, small improvements in the DSMQ for the simulation group noted above on certain items suggest that simulation could be helpful in improving self-care management for diabetes. Overall, the increase in mean DSMQ for the posttest group in both the simulation and handout group suggests that both types of education were beneficial. Furthermore, it was unclear without formal statistical tests if the time since diagnosis impacted the effect of simulation on self-care management.

Discussion

The purpose of the study was to examine the effect of simulation versus educational handouts on self-care management of type II diabetes. Additionally, the time since diagnosis of type II diabetes was an additional variable of interest to examine the effect on the DSMQ score. For example, is simulation only effective for those diagnosed in the past year, or beyond? However, only six participants were enrolled in the study and one was lost to follow up for the posttest. Therefore, only raw numbers were reported including frequencies and percentages. No formal comparisons could be made; however, there are still some valuable insights to consider upon the completion of the project.

Relationship of Findings to Prior Research

The outcome of self-care management was measured by obtaining the DSMQ, a validated tool with 16 Likert-scale items. A secondary aim was to investigate if length since diagnosis affected this outcome. The goal was to have a sample size of 40 participants—20 in the intervention group and 20 in the comparison group. This seemed reasonable as 448 participants were sent recruitment materials based on meeting eligibility criteria as identified by Carilion HART. Unfortunately, this study had a low enrollment of only six participants, one of which was lost to follow up, and therefore formal statistical tests had no real value when applied to analyze the results. The age of the participants in this study was consistent with those most affected by type II diabetes, which typically occurs in adults 45 years and older (CDC, 2020). However, race and ethnicity were not well represented in this small sample, as most participants were Caucasian. Biological sex was well distributed across both the handout group and simulation group.

There are few studies on the use of simulation in patient education, and the enrollment in this study was too low to be able to make sound statistical analysis of the results from these participants. More research with a larger sample size is needed to further explore this topic. Previous studies that were conducted on various educational activities for patients with diabetes had largely positive results, especially those examining the effect on outcomes such as HbA1c, self-efficacy, and other health indicators. Other studies have suggested some mixed results, and those that were effective in lowering the HbA1c did not assess the results long-term. However, most educational activities have little risk and if they do provide some level of benefit to the patient and their ability to self-manage their condition, they may be worthwhile. It is also important to note that all the studies in the literature review included in this study were performed prior to the COVID-19 pandemic.

Observations

It is important to note that originally, this project had stricter eligibility criteria to include patients only diagnosed with type II diabetes in the past year. However, upon obtaining the list of eligible patients from the Carilion HART analyst and contacting them, it was learned by the researcher that the patients did in fact have a longer time since diagnosis. Some patients reported a diagnosis as long as 12 years in the researcher's initial contact with them. The issue was discussed with the stakeholders involved in the project. To put efforts in place to try to ensure adequate subject enrollment, the shared decision was reached to include all willing participants that were originally recruited and eliminate the 1 year since diagnosis criteria. An added benefit to this approach was the opportunity to investigate if the interventions could be beneficial for patients with a longer time since diagnosis. The COVID-19 pandemic was also taken into consideration into this decision and how that may have affected fewer people to be diagnosed during the study's time frame. Additionally, it may have limited educational programs or opportunities for persons newly diagnosed with diabetes.

The proper procedures were taken to resolve the issue with the Carilion IRB by submitting an event report and revisions to the protocol. Revisions included removing the 1 year since diagnosis from the eligibility criteria and recruitment and consent materials. Participants that were originally recruited via email were sent updated recruitment information to inform them of the change, in case not meeting criteria had kept them from contacting the researcher when the original materials were distributed. Participants that had originally contacted the researcher for interest in participating but did not meet criteria due to the time since diagnosis were also recontacted by the researcher. Suggested changes were approved by the Carilion IRB and the procedures followed in this manner.

Observations and discussion with patients over phone interview provided noteworthy information that contributes to the project. Specifically, upon asking the subjects about their receipt of previous diabetic education, one participant that reported online/self-study was because they were recently diagnosed but had not yet had any formal education from their provider or other sources. They went on to explain that their provider had left shortly after the diagnosis was made and nothing else had yet been offered to them for patient education. Interestingly, the seasonality of the phone interviews impacted the participants elaborating on the survey items. For example, when discussing physical activity, cold weather was brought up as a barrier to physical activity. Furthermore, the holidays and the temptation to indulge in sweets during this period came up when discussing diet.

Observations from the one-on-one simulation session with the participants provided additional insight for this study. Most patients that participated in the simulation found the scenario and nutritional education from the debrief most helpful. Many were already checking their blood sugars and were familiar with how to perform this self-care activity and reported that they were performing it regularly. Interestingly, only one participant chose to assess their blood sugar during the hypoglycemia scenario.

Evaluation of Theoretical Model

The patients involved in this research study were very motivated to improve their self-care management of their diabetes. They clearly saw value in the utilization of the supportive-education system of nursing practice for self-care and to "regulate the exercise and development of self-care agency" (Berbiglia & Banfield, 2018, p. 202). They had accepted their new normalcy and desired to close the gap on their own self-care deficits. Furthermore, while the results were unclear whether the simulation or handouts had any effect on the DSMQ, the simulation and handouts were both aimed to provide knowledge to meet the healthcare demands of the patient. The education for both learning methods were specifically targeted to increase knowledge in the areas of glucose monitoring and management and nutrition.

The simulation successfully provided a concrete experience for learning according to Kolb's theory. Most patients reported already having previous concrete experience in obtaining blood sugars, but not necessarily on performing the activity at the appropriate times. It was evident that prior learning methods were not effective for them regarding nutrition, as several participants were familiar with the dietary information but were not able to properly apply that knowledge in the scenario. It was also challenging at times to keep the participants in the simulation to adhere to the fiction contract; many of them wanted to comment about their reasons for certain decisions made during the scenario. It was possible to redirect them, however, and hold off on debriefing and discussion for later stages of the simulation experience.

They were active participants in the reflective observation stage, asking questions and engaging in the debriefing session. Comments from some of the participants revealed that they had entered the abstract conceptualization stage: "Oh that makes sense now." Additionally, many of the participants in the simulation group mentioned what a difference it made in their level of understanding for their nutrition to prepare appropriate portion sizes on the plate provided in the scenario.

It was unclear based on the results of the study whether the active experimentation stage was activated by learners in this intervention. Some of the results did suggest there were improvements within the DSMQ on several of the items for the simulation group, especially regarding those specific to the simulation scenario.

Limitations

Clearly, the largest limitation of the study was the small sample size. This was confounded by the time constraints of a scholarly project, so additional time or recruitment efforts were not possible. This was an unexpected outcome, considering that 448 participants were contacted for recruitment. However, the issue of an initial inaccurate list of eligible participants likely was a large contributing factor to the low response to recruitment materials. The original recruitment materials that were distributed included the original eligibility criteria of being diagnosed with type II diabetes within the past year. However, many patients notified the researcher that they did not meet this criterion, leading to the investigation with the list with the Carilion HART data analyst. Despite the eligibility criteria being adjusted to include all participants, this was only done through means of e-mail and may have still created confusion for potential subjects.

Furthermore, two of the patients mentioned participating in an alternative research study, so there may have been a sense of burnout from the participants in the recruitment setting. Additionally, the timing of the enrollment and participation period may have caused concerns for patients. This could include concerns about exposure to COVID-19 and influenza. Also, timing around holiday festivities could have been a possible factor.

Another limitation was the convenience sample including only two family practices in Rocky Mount, Virginia. The sample could potentially have been expanded to include a larger sampling area, such as the Roanoke, Virginia region to recruit more potential subjects. This could have opened up for many more Carilion family practice offices to participate, but again additional time would have been needed for this additional approval as well as additional resources for more recruitment material and postage.

Implications for Future Research

Replication of this study with a higher enrollment of subjects is clearly needed. One recommendation for future studies would be to verify the accuracy of eligible patients based on the inclusion and exclusion criteria. It also might have been helpful to involve the staff at the recruitment setting to help advertise and support the study. The influence from providers at the family practice offices suggesting and encouraging the subject's participation might have aided in recruitment efforts. Also, researchers should be aware of any other concurrent studies being conducted that may contribute to study fatigue in the sample population.

Continued research on this topic should also explore cost-effectiveness of these interventions. There is little research regarding the cost of educational interventions for diabetes in the literature. Considerations should be made of the potential savings if the interventions are beneficial and suggest positive outcomes for the patients. Sustainability of the outcomes at longer data points than 6 weeks in this study, and the typical 3 months in the literature should additionally be explored.

The education in this project focused on diet and nutrition, glucose management, and glucose monitoring. Further studies could include education topics such as indoor physical activities due to noted barriers of weather and cold temperatures. Nutrition education seems to be lacking and should continue to be further studied.

Additional strategies to expand on this research study include a virtual option for the simulation so that participants do not have to attend in person. This could help negate some of the potential concerns about exposure to illness. Unfortunately, the intent with simulation is to get a more hands-on practice with skills, so this may negatively impact the simulation experience for this educational intervention.

Implications for Practice

Only one participant reported prior diabetic education from a diabetic expert. This is consistent with the literature revealing that patients may not be receiving appropriate, thorough education on self-care management of diabetes. Diabetic educators may also be able to provide more hands-on training for patients, which may have some degree of efficacy. When providers do use educational handouts, measures should be taken to ensure the material is at an appropriate reading level, in the patient's primary language, and it should be reinforced with verbal education at each visit. Specifically, the participants in this study most desired nutritional information. Primary care providers should ensure appropriate referrals to registered dietitians for patients to gain the necessary tools to make appropriate dietary choices. Furthermore, it may be best to not solely target newly diagnosed persons with diabetes but consider those also with a longer time since diagnosis for diabetic education. This is especially considering the stagnant effect on healthcare needs created by the COVID-19 pandemic.

Conclusion

Type II diabetes is a prevalent condition that has serious health complications for patients and is associated with significant healthcare costs. This disease is largely managed by self-care and multiple interventions have been studied in the literature to promote self-management using a variety of educational techniques. However, little is known about simulation as an educational strategy for patients despite its effectiveness in healthcare education. Additionally, there have been few studies that have examined the cost-effectiveness of these educational interventions, which is likely a top priority for many stakeholders. This is especially important when considering the sustainability of the intervention as a standard in patient care. Also, many studies have only examined outcomes within three months of the intervention; therefore, long-term effects are largely unknown.

The research proposed in this paper aims to address some of the gaps in the literature and to explore an effective strategy to improve glycemic control in patients with diabetes. Due to the importance of self-management in this disease, Orem's self-care deficit theory was used as a foundational basis to guide the research. Additionally, Kolb's experiential learning theory guided the development and utilization of the simulation experience for the participants. The DSMQ was a validated tool used to measure the self-care abilities of the participants before and after the educational interventions. While the results were not statistically of value due to the low sample size, important takeaways were obtained from this project. Results do suggest that an immersive learning experience through simulation may be an effective method to increase one's self-care management of type II diabetes. Furthermore, simulation-based interventions may be helpful regardless of the time since a diagnosis of diabetes was established. The significant gap in the literature along with these findings warrants further investigation into this topic with a larger sample size. This research will contribute to the body of work already established for patient education and may impact future interventions addressing diabetic self-care management.

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Appendix A

Hierarchy of Evidence for Selected Studies

Studies Referenced	Type of Evidence	Level of Evidence
Celik, A., Forde, R., & Sturt, J. (2020). The impact of online self-management interventions on midlife adults with type 2 diabetes: A systematic review. *British Journal of Nursing*, *29*(5), 266–272. https://doi.org/10.12968/bjon.2020.29.5.266	Systematic review	I
Ji, H., Chen, R., Huang, Y., Li, W., Shi, C., & Zhou, J. (2019). Effect of simulation education and case management on glycemic control in type 2 diabetes. *Diabetes/Metabolism Research & Reviews*, *35*(3), 1-7. https://doi.org/10.1002/dmrr.3112	Randomized controlled trial	II
Michiels, Y., Bugnon, O., Chicoye, A., Dejager, S., Moisan, C., Allaert, F.-A., Hunault, C., Romengas, L., Méchin, H., & Vergès, B. (2019). Impact of a community pharmacist-delivered information program on the follow-up of type-2 diabetic patients: A cluster randomized controlled study. *Advances in Therapy*, *36*(6), 1291–1303. https://doi.org/10.1007/s12325-019-00957-y	Randomized controlled trial	II

Radcliff, T. A., Côté, M. J., Whittington, M. D., Daniels, M. J., Bobroff, L. B., Janicke, D. M., & Perri, M. G. (2020). Cost-effectiveness of three doses of a behavioral intervention to prevent or delay type 2 diabetes in rural areas. *Journal of the Academy of Nutrition & Dietetics*, *120*(7), 1163–1171. https://doi.org/10.1016/j.jand.2019.10.025	Randomized controlled trial	II
Torabizadeh, C., Poor, Z. A., & Shaygan, M. (2019). The effects of resilience training on the self-efficacy of patients with type 2 diabetes: A randomized controlled clinical trial. *International Journal of Community Based Nursing & Midwifery*, *7*(3), 211–221. https://doi.org/10.30476/IJCBNM.2019.44996	Randomized controlled trial	II

Appendix B

National League for Nursing

Simulation Design Template

Diabetes Education Simulation

Date:	**File Name:**
Discipline: Nursing	**Student Level:**
Expected Simulation Run Time:	**Guided Reflection Time:** Twice the amount of time that the simulation runs.
Location:	**Location for Reflection:**
Today's Date:	

Psychomotor Skills Required of Participants Prior to Simulation

Writing
Manipulating lancet and blood glucose monitor

Cognitive Activities Required of Participants Prior to Simulation

Understand the goal of the scenario and how it will be facilitated
Recognize and record blood sugar readings
Reading nutrition labels

Simulation Learning Objectives

General Objectives

1. Participant will utilize provided tools and knowledge of diabetes to promote healthful meal planning that will improve glycemic control.
2. Participant will be able to monitor blood sugars and manage appropriately.
3. Participant will have increased knowledge and ability to perform diabetic self-care.

Simulation Scenario Objectives

- The patient will state causes, signs, and symptoms of hypoglycemia and hyperglycemia.
- The patient will be able to perform the appropriate actions to manage blood sugar after recognizing signs and symptoms of hypoglycemia and hyperglycemia.
- The participant will be able to choose appropriate portion sizes based on the diabetes plate method.
- The participant will state the important components related to blood sugar on a nutrition label.
- The participant will be able to identify at least one nonstarchy vegetable, protein food source, and one carbohydrate food source.

For Facilitators: References, Evidence-Based Practice Guidelines, Protocols, or Algorithms Used for This Scenario:

ADA Nutrition Guidelines

American Diabetes Association. (2020, February). Ask the expert: What is the diabetes plate method? https://www.diabetesfoodhub.org/articles/what-is-the-diabetes-plate-method.html#:~:text=The%20Diabetes%20Plate%20Method%20is,you%20need%20is%20a%20plate!

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American Diabetes Association. (n.d). Eating well: Fats. https://diabetes.org/healthy-living/recipes-nutrition/eating-well/fats

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Setting/Environment

☐ Emergency Room ☐ Medical-Surgical Unit ☐ Pediatric Unit ☐ Maternity Unit ☐ Behavioral Health Unit	☐ ICU ☐ OR / PACU ☐ Rehabilitation Unit X Home ☐ Outpatient Clinic ☐ Other:

Equipment/Supplies

Simulated Equipment Needed:
Blood glucose Test Trainer

Hybrid simulation case with study participant as patient + task trainers (simulated glucometer & simulated glucose stick finger)

Food and Drink:
Orange Juice
Soda
Water
Milk
Beer
Wine
Pie
Ice cream
Hamburger buns
Hamburger
Cheese
Lettuce
Tomato
French Fries
Condiments
Spaghetti with meat sauce
Garlic bread
Salad
Baked chicken
Canned Green beans
Corn on the cob
Chips
Fish
Broccoli

Rolls
Bananas
Apples
Peanut butter
Potato
Rice
Cereal
Plates
Cups

Roles

- Patient (Participant)
- Facilitator (Researcher)

Guidelines/Information Related to Roles

Learners in role of patient (self) will also be responsible for decision-making regarding nutrition choices. He or she will also be recording blood sugar levels on the provided blood glucose log.

The facilitator will explain the scenarios and observe the participant's self-care decisions. The facilitator will also be prompting as needed with cues to aid in the unfolding of the scenario. The facilitator will not be able to assist the participant in making self-care decisions.

Pre-briefing/Briefing

Participants will be welcomed to the session and ensure they are comfortable. An opportunity for using the restroom will be offered prior to the start of the session.

Fiction Contract
The scenarios in this session will have realistic self-care situations that you could potentially encounter in your daily life. This is a safe environment in which to practice the skills and behaviors involved with diabetic self-care. Your role is to participate in the scenarios provided as if they were the actual reality--as if you were at home. Also, you

will be asked not to seek help from the facilitator as this would disrupt the realistic environment that is intended for this session.

Assumptions

The assumption upon your participation is that you are intelligent, skilled, and willing to make improvements to your ability to manage your diabetes. This is intended to be a learning environment in which you will receive feedback and education regarding your performance in the session.

Objectives and Expectations

Objectives of the session include:

1. Participant will be provided tools and knowledge to promote healthful meal planning to improve glycemic control.
2. Participant will be able to monitor blood sugars and manage appropriately.

If you experience emotional or physical distress during the session, you must notify the simulation facilitator immediately. An attempt to relieve the distress will be made upon notification. If the source of distress cannot be resolved, the session will end prematurely, and you will be withdrawn from the study at that time.

Orientation to Environment and Logistics

Participant will be oriented to simulated kitchen and food/drink products. They will be instructed on how to plate their meal with the simulated food products. The facilitator will explain that they will be provided scenarios and should respond accordingly based on the information they are given, which may include checking their blood sugar. Additionally, they will be oriented to the blood glucose test trainer. They will be provided a log on which to record their blood sugar readings.

Role Assignment

The participant will be instructed that they will be role playing themselves in their home environment. They should make food and portion size selections as if they were at home preparing dinner, based on the available options. They should also make self-care decisions as they would in their home environment based on the blood glucose monitoring scenarios provided to them.

Scenario Progression Outline

Timing (approx.)	Manikin/SP Actions	Expected Interventions	May Use the Following Cues
0-5 min	Facilitator explains scenario: It is 5pm on a Friday and you just got home after running errands since noon. It's been a busy day! You had to make several stops, but you spent the most time going up and down the aisles at Walmart because you could not find where they moved the paper products since they recently rearranged the store. You were so busy you forgot to eat lunch while you were out. Good thing you got a few items for dinner at the store, because you are very hungry!	**Learners should begin by:** • Check their blood sugar (blood sugar would result 55-hypoglycemic) and record on log • Eat a snack or consume a drink with 15g of carbohydrates • Recheck blood sugar 15 minutes after food or drink consumption and record on log (result is normoglycemic)	**Role member providing cue: Facilitator** **Cues:** **If participant begins meal preparation with an appropriate self-care intervention, start describing symptoms of hypoglycemia including: headache, shakiness, feeling sweaty/clammy, lightheadedness/dizziness** **May need to allow 15 minutes to elapse for participant to have opportunity to recheck blood sugar**
5-15 min		**Learners are expected to**: • Selecting food and drink items from the options provided • Review nutrition labels • Plate their meal • May or may not choose to check their blood sugar after their meal and record on log	**Role member providing cue: Facilitator** **Cue:** **Assist participant with food "preparation"**

		(result would be normoglycemic)	
15-20 min	Facilitator explains scenario: You are feeling much better after you ate dinner. You are tired from the day, so you decide to put your feet up in your recliner. You start to reflect on how you felt earlier when your blood sugar was low, and it makes you feel somewhat nervous. You have been very stressed with work lately and this is just making you feel more overwhelmed. To make matters worse, you've had sinus congestion and a cough for two days now. You want to assure you don't get a low blood sugar again, and you can't remember if you took your medicine today or not. You decide not to take it, just in case you took it earlier. After such a busy day and skipping lunch, you decide to treat yourself to a piece of pie and some ice cream.	**Learners are expected to**: • Check their blood sugar and record on log (result would be hyperglycemic-300) • Consider physical activity, call provider, eating better, improve their medication management (pill box or logging)	**Role member providing cue: Facilitator** **Cue:** **Patient begins thinking they may have a fever and feels very thirsty.**

Debriefing/Guided Reflection

Themes for this scenario:

- Signs and symptoms of hypoglycemia
- Management of hypoglycemia
- Diet and nutrition, portion sizes, reading food labels
- Hyperglycemia symptoms and causes

We do not expect you to introduce all of the questions listed below. The questions are presented only to suggest topics that may inspire the learning conversation. Learner actions and responses observed by the debriefer should be specifically addressed using a theory-based debriefing methodology (e.g., Debriefing with Good Judgment, Debriefing for Meaningful Learning, PEARLS).

1. How did you feel throughout the simulation experience?
2. What were the main problems that you identified?
3. Discuss the signs and symptoms that were in the scenario that guided your thinking surrounding these main problems.
4. How did you arrive to the decisions to select the food and drink choices you made during this scenario?
5. If you were able to do this again, how would you handle the situation differently?
6. What did you learn from this experience?
7. How will you apply what you learned today to managing your diabetes?
8. Is there anything else you would like to discuss?

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