Motivational Interviewing for Diabetes Medication Adherence in Type 1 Diabetes and Type 2 Diabetes Patients

by

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Abstract

Objectives: Medication adherence is vital towards achieving adequate glycemic control in diabetes management. Workplace Wellness Programs (WWPs) for chronic disease management offer a unique setting for employers to offer behavior change interventions towards improving employees' health and wellbeing. Motivational Interviewing (MI) is a patient-centered counseling approach that is effective towards helping patients adopt and sustain health behaviors for chronic disease self-management. Although, studies have documented the impact of MI in diabetes management, the effectiveness of an integrated, pharmacist-delivered approach using MI-based communication tools to modify medication-taking behavior remains unknown among diabetes patients enrolled in a WWP. This study assessed a brief pharmacist-delivered MI-based intervention for diabetes medication adherence among patients with type 1diabetes (T1D) and type 2 diabetes (T2D) in a hospital-based WWP.

Methods: A quasi-experimental, longitudinal, one-group study design was implemented. Pharmacists trained in MI delivered three face-to-face sessions of brief MI-based counseling using conversation tools that support patient-selected conversation topics/reasons for medication nonadherence. The three sessions were delivered over a 12-week timeline in a diabetes outpatient clinic. Study duration was six months and primary data were collected at baseline, post-intervention (3 months after baseline), and at follow-up (3 months after post-intervention) using self-report and Electronic Health Record (EHR) data. The primary outcome was change in medication adherence which was measured using self-report at each MI session (based on the Medometer) and at each primary data collection time point using the Summary of Diabetes Self-care Activities (SDSCA) medication subscale. The secondary outcomes included change in clinical outcomes (hemoglobin A1C, blood pressure, and depressive symptoms), humanistic outcomes (health-

related quality of life and patient satisfaction with treatment), and economic indicators (emergency department visits and hospital admissions).

Results: Of the 170 eligible participants in the WWP, 53 consented to the study (31.2%); most were female 30(56.6%), average age was 54 years, and T2D was the predominant diagnosis 48(90.6%). Medication adherence based on the Medometer showed a statistically significant change from baseline to post-intervention, $t_{(35)} = -4.485$, $p < 0.00$; the SDSCA medication adherence measure result showed improvement but it was not statistically significant. Among the clinical variables, diastolic blood pressure showed a statistically significant improvement, $F_{(2, 70)} = 3.57$, $\rho = 0.034$. All other clinical outcomes did not change significantly. The Physical Component Summary (PCS) score and Mental Component Summary (MCS) score on the Short Form-12 measure for health-related quality of life increased significantly from baseline to follow-up; PCS, $F_{(2, 58)} = 7.53$, $p = 0.003$ and MCS, $F_{(2, 58)} = 3.92$, $p = 0.025$. Diabetes treatment satisfaction and economic indicators (emergency department visits and hospital admissions) did not change significantly.

Conclusions: The intervention was effective towards improving medication adherence and participants' quality of life. These findings add to the literature on the clinical utility of MI in modifying health behaviors. Although other target variables increased after the intervention, the observed changes were not sustained through the follow-up phase. Future research activities need to employ effective strategies to sustain intervention effects during follow-up or between patient visits in clinical settings. Study findings are useful for organizational decision-making on implementing a brief, patient-centered communication strategy to modify patient health behaviors.

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List of Abbreviations

MIDMA	Motivational Interviewing for Diabetes Medication Adherence
SMIT	Structured Motivational Interviewing Tools
WWP	Workplace Wellness Program
MISCHE	Motivational Interviewing Skills in Health Care Encounters
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
DANC	Diabetes and Nutrition Center
EAMC	East Alabama Medical Center
MI	Motivational Interviewing

CHAPTER I

INTRODUCTION

Part I – Background

The rising prevalence of diabetes and its expensive risks and complications signal the need for interventions that promote positive changes to patient health behaviors in the self-management of Type 1 Diabetes (T1D) and Type 2 Diabetes (T2D). Motivational Interviewing (MI) is a communication skill set aimed at evoking the intrinsic motivation of the individual to initiate decision-making for behavior changes including diabetes self-management. The effectiveness and clinical utility of MI in promoting health behaviors has been documented in diverse health conditions.[1]

According to the American Diabetes Association (ADA), about 30 million of the US population is diagnosed with diabetes, and 8.1 million people are estimated to be undiagnosed.[2] Furthermore, 86 million people are estimated to have blood glucose levels that are in the ranges for prediabetes, and T2D accounts for 90-95% of diabetes diagnosis in US adults.[2] According to the Centers for Disease Control (CDC), diabetes is the 7th leading cause of death in the US and the cost to treat diabetes is about 200% higher than the cost of treating non-diabetic patients.[3] The total estimated cost of treating diagnosed diabetes in the US according to a report by the ADA was $327 in 2017, indicating a 26% increase from the 2012 estimated annual cost of $245 billion.[2]

The treatment and management of diabetes involves pharmacotherapy and health behavior changes. The primary behavior changes needed in diabetes management include dietary changes, medication adherence, increased physical activity, and blood glucose monitoring, among others.[4] Pharmacotherapy greatly impacts diabetes outcomes and adherence with prescribed medication(s) plays a

foundational role in the long-term control and prevention of diabetes-related complications, such as neuropathy, nephropathy, and retinopathy.[5]

Medication Adherence and Motivational Interviewing in Diabetes Self-Management

Medication adherence is defined as the extent to which patients take medications as prescribed by their health care provider. This includes medication strength, dosing frequency, duration, and other factors needed for optimal medication adherence. Adherence includes the broad domain of factors that influence the ability of patients to follow treatment recommendations and these includes, dosage and time schedules.[6] Furthermore, adherence is influenced by components of patient-centered care, such as support for patient autonomy and preferences and for the patient-provider relationship. Responsibility for the outcomes of care is optimally shared between the patient and provider in the context of adherence.[7]

Motivational Interviewing (MI) is a patient-centered communication approach. Evidence indicates MI-based interventions can modify health behaviors including medication adherence.[8] However, there are only a few published studies of MI-based medication adherence interventions for T2D patients, and none for T1D patients.[8] This research study primarily builds on two prior initiatives aimed at addressing diabetes outcomes through pharmacist-delivered interventions. The first is the Asheville project in which pharmacists delivered diabetes disease management in a worksite wellness program for employees of the city of Asheville, North Carolina.[9] The second includes the pilot study jointly developed and implemented by the American Pharmacist Association (APhA) and the APhA Foundation, known as the Discussions on Taking Medications (DOTx.MED) diabetes pilot program.[10] The DOTx.MED study evaluated the impact of pharmacist-delivered MI-based structured communication interventions (SCIs) among T2D patients. The SCIs were designed as quick conversation guides for pharmacists in a community pharmacy setting. The tools were designed based on MI techniques and language as well as health literacy considerations. The intervention goals intended to improve provider-patient communication, diabetes medication adherence, and patient satisfaction.

The DOTx.MED primary outcome of medication adherence, based on the proportion of days covered (PDC), improved for the intervention group by 6.55% after 180 days, while the control group improved by 3.75%. These results support the potential for MI in helping patients engage in medication-taking behavior and suggests that further investigation is needed to explore the effectiveness of structured MI counseling for diabetes medication adherence among T1D and T2D patients. Our study is referred to as the Motivational Interviewing for Diabetes Medication Adherence (MIDMA) study. This MI-based intervention focused on medication-taking behavior and incorporates support components to strengthen patient self-efficacy towards achieving medication-taking goals and improves pharmacist confidence for engaging in MI-based conversations in patient encounters.

Workplace Wellness Programs for Diabetes Management

The Centers for Disease Control and Prevention (CDC) defines workplace wellness programs (WWP) as "a coordinated and comprehensive set of health promotion and protection strategies implemented at the worksite that include programs, policies, benefits, environmental supports, and links to the surrounding community designed to encourage the health and safety of all employees".[11]

The objectives of implementing a WWP are to promote healthy lifestyle, prevent disease, and/or provide support in the self-management of existing chronic health conditions.[12] In recent years, WWPs are reported in the literature as effective platforms to deliver behavior change interventions to improve employee health, boost productivity, and reduce health care costs. In addition, several studies have reported increased productivity and reduced health care costs for chronic disease management using WWP as the intervention setting.[13-15]

There are different types of WWP models and these are often modified to fit work settings and their health promotion needs.[12 15] The Patient Protection and Affordable Care Act (ACA) emphasizes health promotion and disease prevention among other targets. Also, the ACA encourages and supports WWPs by providing startup grants for new programs and incentives to bolster existing programs.[16] From

the perspective of the employers, the overarching goals of implementing WWPs are to improve the health of employees and reduce health care cost for organizations. However, WWPs must be appropriately designed and possess certain characteristics to ensure program effectiveness. Features of successful WWPs include evidence-based best practices, adequate resource allocation, and programs that support/fit organizational culture.[17] The study setting and target participants for the MIDMA study are enrollees of an existing WWP at the East Alabama Medical Center (EAMC) Diabetes Disease Management Program. Employees and employee dependents with T1D and T2D are encouraged and incentivized, with waived co-pays for medications and supplies, to join the program.

Problem Statement

Pharmacotherapy and health behavior change are critical in the treatment and management of diabetes; however, the initiation and maintenance of behavior change can be difficult. Health behavior modification interventions have been employed in various settings to help people change different health behaviors.[18 19] Adherence with prescribed medication(s) and lifestyle changes are important targets in the management of diabetes.[20] Recent data reported an average 51% adherence rate with prescribed medications among T2D patients, and several studies have reported significant findings for the impact of adherence with non-insulin medications on improved health outcomes among T2D patients.[21 22] Evidence from the landmark Diabetes Control and Complications Trial (DCCT) suggested a significant relationship between insulin adherence and improved glycemic control among T1D patients in the study.[20]

Comprehensive medication adherence counseling based on Motivational Interviewing (MI) is an approach with an evidence base for helping patients improve medication adherence in chronic disease management.[10] MI is a patient-centered counseling skill set and way of being which explores patient ambivalence while eliciting internal motivation for behavior change.[8] The effectiveness of MI was first observed in treating addictions, and gradually, MI has been utilized in helping patients engage and sustain self-care behaviors needed for managing chronic conditions. The target population for the study includes

employee and employee dependents with T1D or T2D, and who are enrolled in the EAMC diabetes management WWP.

A comprehensive review of the literature reveals a need to evaluate the effectiveness of MI on medication taking behavior among diabetes patients, particularly in the population of adults with T1D and T2D in the unique setting of WWP for chronic diabetes management. No studies using MI and including these parameters in T1D and T2D medication adherence and pharmacist-delivered intervention were reported in recently published evidence and gaps review of rigorous studies.[8]

Overall Objective

The overarching objective of the MIDMA study was to assess the effectiveness of a pharmacist-delivered semi-structured MI intervention for modifying medication taking behavior. Secondary outcomes included assessing changes in clinical indicators, humanistic outcomes (quality of life and patient satisfaction with treatment), and economic (utilization) outcomes. The study design was a single-site, one group, pre-post intervention study.

Significance and Innovation

The MIDMA study seeks to improve outcomes by impacting medication taking behavior. Diabetes management involves patient engagement, yet, health behavior change is difficult and overwhelming for most patients. The innovative feature of the MIDMA is focused on the pharmacist-delivered MI and communication components using the Structured Motivational Interviewing Tools (SMIT) which offer support structures to strengthen self-efficacy towards using MI communication strategies for the pharmacist and working towards medication-taking goals for the patient.

Purpose and Specific Aims

The purpose of this study was to evaluate the effectiveness of pharmacist-delivered MI-based counseling intervention to modify medication taking behavior among patients with T1D and T2D.

A. Aim 1: To examine changes in medication taking behavior for a worksite MI-based behavioral modification intervention and to determine factors related to changes in medication taking behavior post intervention.

This aim examined changes in medication taking behavior at baseline, post-intervention (3 months after baseline), and follow-up (3 months after post data collection). Changes in medication adherence were assessed based on a self-report measure the Summary of Diabetes Self-care Activities (SDSCA) medication subscale.[23] Medication adherence was examined across patient demographics, clinical variables, psychosocial variables, and health-related quality of life, to identify a possible relationship between factors and medication taking behavior. Further, medication adherence was evaluated at each pharmacist-patient meeting using a self-report measure, the Medometer.[24]

B. Aim 2: To evaluate changes in clinical parameters (hemoglobin A1C, blood pressure, and presence of depressive symptoms), and determine factors related to changes in glycemic control.

Target clinical variable were hemoglobin A1C, blood pressure, and presence of depressive symptoms. Indicator for glycemic control, hemoglobin A1c was collected from the Electronic Health Records (EHR) based on one to three months pre-intervention records. Blood pressure was collected from the hospital EHR and the presence of depressive symptoms was collected prospectively based on a validated self-report measure, the Patient Health Questionnaire (PHQ-9).[25] Furthermore, significant association between glycemic control and target variables were identified. Target variables also included demographic variables, medical history variables, treatment type, and comorbid conditions.

C. Aim 3: To assess changes in economic indicators (health care utilization), health-related quality of life and patient satisfaction from baseline to follow-up among participants.

This aim examined: (1) healthcare utilization, and (2) health-related quality of life (HRQoL) and (3) patient satisfaction with the intervention. All data for aim 3 was based on self-report. Healthcare utilization for the MIDMA study was assessed based on r emergency department (ED) visits and hospital admissions.

Patient-reported outcomes for HRQoL were assessed with a generic measure (Medical Outcomes Study Short Form-12)[26] and a diabetes-specific measure (Audit for Diabetes Dependent Quality of Life).[27] Patient satisfaction was measured using the Diabetes Treatment Satisfaction Questionnaire (DTSQ),[28] which assesses patients' perception of diabetes treatment/intervention. Patient satisfaction and HRQoL was measured at each data collection time point, baseline, post-intervention, and follow-up.

Data and Measures

Patients who consented to participate in the study completed surveys for self-report data; in addition, diabetes self-management knowledge was assessed using the EAMC Diabetes and Nutrition Center knowledge survey.

The Marlowe-Crowne Social Desirability Scale (MC-SDS) was also collected to evaluate possible association with self-report data of social desirability bias.[29]

Conceptual Framework

The conceptual framework for the MIDMA study was derived from the American Association of Diabetes Educators (AADE) framework for assessing diabetes education outcomes. [30] The AADE framework evaluates diabetes outcomes for seven target behaviors relevant to diabetes management. These are healthy eating (diet), blood glucose monitoring, medication adherence, increased physical activity (exercise), healthy coping, problem solving, and reducing risks. The AADE diabetes self-management outcomes framework was modified to focus on medication adherence as the target behavior for the MIDMA study.[31]

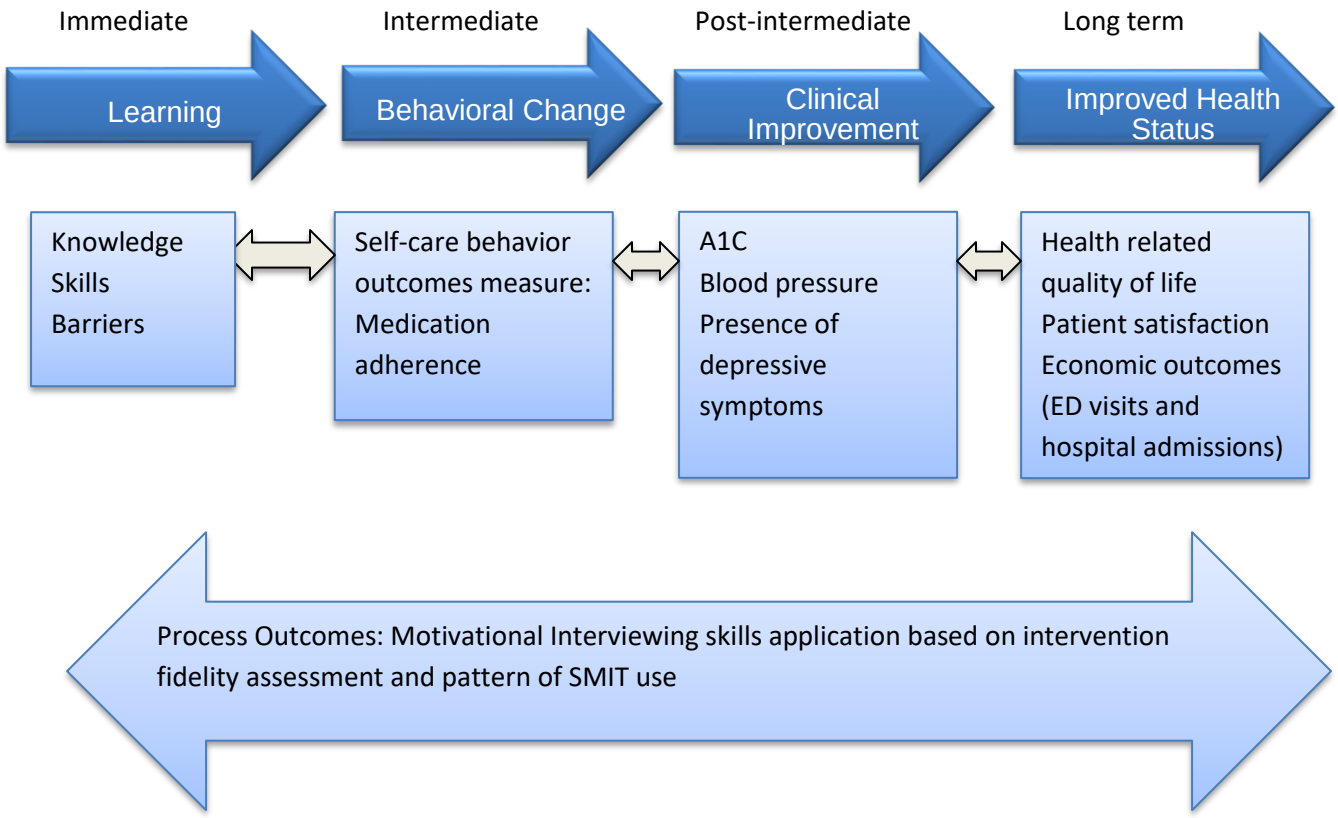

Fig 1: MIDMA Study Outcomes Continuum for Medication Adherence

Source: Adapted from the Diabetes Self-Management Education Outcomes Continuum. [31]

In addition, the dissertation study utilized communication tools, the Structured Motivational Interviewing Tools (SMITs) to engage participants' commitment towards behavior change. A needs assessment was performed in the target population to identify reasons for medication nonadherence. The SMITS were designed based on the patient-specified reasons for medication nonadherence, and six target topics were applied in the study. A behavior-specific SMIT was signed at each encounter and a copy was

given to the patient to keep as a reminder and reinforcement of the commitment towards target behavioral goals. At each subsequent meeting after the first encounter, the interventionist followed-up with the participant on goals outlined in the previous encounter. The principle of supporting autonomy was further expressed in the patient's choice of discussing medication adherence goals.

Applying Motivational Interviewing Skills

The fundamental objective of MI encounters is to elicit personal motivation and overcome ambivalence towards changing a target behavior. This requires the interventionist to express the spirit of MI, which is a clinical "way of being" that is based on three primary elements: collaboration (between the interventionist and the patient), evocation (eliciting motivation for change), and emphasizing the autonomy of the patient.[32] In addition, the interventionist must engage the principles of MI which are expressing empathy, supporting self-efficacy towards behavior goals, rolling with resistance/avoiding argumentation, and developing discrepancy (between present circumstances and patients' specified desires or goals).

There are micro skills considered important for implementing the Spirit of MI. Eliciting change talk is a pivotal micro skill in MI encounters because it engages the patient in reflecting his/her internal motivations for changing the target behavior.[32] Change talk occurs when the patient talks about change by verbalizing the pros or benefits for change. Change talk is further strengthened when the pros outweigh the cons for change. Miller proposed four pre-commitment category types for change talk narrative. These indicate desire, ability, reasons, and need (DARN) for change on the target behavior.[32] The linkage between change talk and behavior change was extensively explored by Miller and Rose, and findings from other studies confirmed that the DARN framework was not directly predictive of change, rather, the strength of commitment associated with the change talk words was more indicative of eventual behavior change.[33]

Expected Contributions

The overall objective of the project was to assess the effectiveness of a brief structured MI-based counseling intervention on changes in medication taking behavior, clinical indicators, and health status outcomes. A systematic search of the literature revealed a gap for future research focused on MI interventions for medication adherence in diabetes.[8 10]

Potential contributions of the MIDMA study towards research includes: (1) examining the usefulness of MI counseling strategies for diabetes medication adherence and insulin use among adults with T1D and T2D. (2) Evaluating the clinical impact and economic benefits of engaging pharmacists in brief, evidence-based health behavior change conversations aimed at impacting specific health behaviors. (3) Assessing the utility of the SMITs as conversation aids for gaining commitment to goal setting for a specific target behavior, medication adherence.

Practice implications include: (1) examining adequate training of providers in MI skills and methodology has the potential to impact patient health behaviors through the various processes involved in patient-provider communication; (2) focusing on a single health behavior (diabetes medication adherence) could potentially improve outcomes; (3) examining evidence for pharmacist-delivered brief MI encounters in WWP settings.

Part II – Literature Review

Types of Worksite Wellness Programs

There are various types of wellness programs with varying areas of focus on organizational health needs and culture. These programs were grouped into seven subsets: health promotion, disease prevention, and wellness programs; fitness/exercise programs; disease management programs; employee assistance and behavioral health; worksite medical clinics; disability management programs; and combination programs.[15] Most wellness programs are designed to incorporate disease prevention

measures such as screening and health education/counseling. This frequently results in several "combination-type" wellness program designs.

Worksite Wellness Programs as Part of the Healthcare Continuum

In recent years, WWPs have gradually evolved into a strategy to support employees' health and management of chronic conditions.[34 35] Employers implement WWPs for various reasons and could be motivated by the prevailing economic, organizational, or policy climate in the workplace.[16 36 37] Witt and Ablah (2013) identified three goals that motivated employers to adopt WWPs.[38] These motivators were to lower heath care costs, address human relations objectives, and improve employee productivity. The economic burden of managing chronic diseases among employees can create a salience among employers to implement WWPs and return on investment (ROI) is certainly a motive for employers' hopes for the full spectrum of outcomes from WWPs.

Several studies have conducted cost-benefit analyses for WWPs and reported varying but mostly positive results for ROI.[15 17 39 40] Dement and colleagues evaluated an academic WWP, and reported an average savings of $35 per month for participants in the wellness program compared with the control group, and ROI was estimated at $2.53 for every dollar spent on the program.[14] Another study aimed to estimate long-term potential medical care cost savings for WWPs observed that attributable Cost of Illness (COI) which was the measure for savings was significantly lower in all age groups compared to Total Medical Care Expenses (TMCE).[41] The cost savings for the three most expensive disease conditions among working-age adults were cardiovascular disease ($163.39 or 4.5% of TMCE), cancers ($126.68 0r 3.6%), and diabetes ($94.00 or 2.7%). The potential savings for all medical conditions included in the study was 18.4% of TMCE.

The chances of recording positive results for WWPs increase where program designs are evidence-based and theory driven. The blueprint for Healthy people 2010 proposed five fundamental elements in the design and implementation of a comprehensive WWP, and these are: (1) health education

targeting health behavior change and awareness, (2) workplace environment with social and physical support structures that promote health behaviors, (3) incorporation of the WWP into the organization's framework, including human resources, employees benefits, and health-related initiatives, (4) structures that bridge the wellness initiative with other organization's programs, and (5) routine health screenings with follow-up counseling and education on health care utilization.[42] Several studies that recorded the effectiveness of WWPs identified strategies that aligned with the framework proposed in the Healthy People 2010 recommendations.[43-45]

Facilitators and Barriers to Participation in WWPs

Participation in wellness programs is imperative to evaluate the process, impact, and outcomes measures.[46] Various strategies are employed to enhance employee engagement in WWPs, and these includes motivators (e.g. incentives and benefits), education (e.g. counseling and informational resources), and penalties for non-involvement.[38]. However, several barriers still exist and negatively impact voluntary participation in WWPs.[47-49] Certain factors impact participation positively (such as the presence of incentives/benefits), while some factors negatively influence participation (e.g. participation cost and high job demands).

Types of barriers towards implementing a successful WWP were grouped by Linnan and colleagues into three broad categories; interpersonal (e.g. peer support, perception of organizational support, personalized recruitment, and social ties), institutional (e.g. incentives/benefits, size of organization, access to facilities at work, company allocated time to participate, cost of participation, and job demands), and intrapersonal (e.g. stage of motivational readiness, self-efficacy, intention, health status, knowledge, attitudes, and beliefs).[47]

Targeting Chronic Disease Management in Worksite Wellness Programs

Chronic diseases account for seven of 10 deaths each year in the United States, and the cost of treating patients with chronic conditions is projected at 86% of the healthcare expenditure.[50] Well-

designed WWPs offer a promising strategy to improve employee health, boost productivity, and reduce healthcare cost.[51] WWPs are often designed to target/modify health behaviors such as increased physical activity, dietary changes, and other self-care management behaviors. Furthermore, condition-specific wellness programs (e.g. diabetes, hypertension, and weight management) tend to improve health outcomes, sustain self-management behaviors, and reduce health care cost compared to generalized lifestyle management program.[52-54]

Provider-led Worksite Wellness Programs for Chronic Disease Management

Health care personnel are important in implementing various types of wellness programs. Worksites that employ full-time or part-time personnel responsible for the wellness program activities are more likely to offer a comprehensive program.[55] In addition, the absence of certification requirements for wellness personnel and the plethora of wellness interventions create a fluid setting for various health professions to be involved.[56] Overall, intervention requirements and design dictate the type of personnel (occupational doctors, medics, nurses, dieticians etc.) suitable for the particular wellness program intervention.[51 57]

A collaborative care model has been implemented in some work sites where health care professionals in two or more fields deliver different components of care.[52 58] Lenz and colleagues, reported a comprehensive diabetes management WWP, where the pharmacist served as the inter-professional team leader.[59] The collaborative team was comprised of five pharmacists, a dietitian, an exercise physiologist, a health educator and a licensed mental health practitioner. Consultants to the team include a physician, a wellness coordinator and a human resources healthcare benefits specialist. Several studies have reported favorable outcomes for WWPs where a collaborative model was utilized. [52 58 60-62]

In light of the preceding section, pharmacists are involved in WWP in various capacities and these include patient-centered medication management (PCMM), which include education and counseling for medication use/adherence, self-management behaviors (e.g. glycemic monitoring), addictive

behaviors (e.g. smoking cessation), and several other health behaviors.[63] The Asheville project and other similar studies report the impact of pharmacist-led WWPs that were effective for various chronic conditions.[52 58 60 62 64 65]

The Asheville Project

The Asheville project was a landmark study that assessed the effectiveness of Pharmaceutical Care Services (PCS) on clinical, economic, and humanistic outcomes among patients with diabetes.[9] The study design was a quasi-experimental, longitudinal, cohort-with-comparison group study. Two employer groups provided PCS for employees and dependents in 12 community pharmacies in Asheville, North Carolina. The program was part of the organization's wellness program initiative towards improving health outcomes for employees with diabetes. Participants were offered scheduled PCS consultation by pharmacists at no cost. Pharmacists collaborated with patients to set and monitor treatment goals, provide training on home glucometer use, and provide counseling and information on medication adherence. Pharmacists provided physical examinations for patients' feet, skin, blood pressure, and weight. When needed, patients were referred to their physician or the diabetes education center that collaborated with the research team on the study.

Results showed a significant reduction in A1C and satisfaction with pharmacy services after seven to nine months. There was a significant increase in diabetes costs ($52 per patient per month) primarily based on PCS fees and diabetes prescriptions. Long-term (5 years) outcomes evaluation showed sustained improvement in A1C with an increase in the proportion of patients with A1C < 7.0%, and there was a mean reduction in direct medical costs compared with baseline where costs shifted from physician services to prescriptions.[9] Results from the Asheville project suggest support for the utility of PCS and collaborative health care for improving employee health outcomes for WWPs.

Different WWPs have used portions of the Asheville project model for chronic conditions among employees. Portions of the EAMC diabetes disease management (WWP) program are based on the

Asheville project model. This dissertation seeks to modify the current PCS consultation implemented for the EAMC WWP using MI principles and methods to elicit patients' motivation and strengthen self-efficacy for medication taking behavior.

Motivational Interviewing (MI) in Health Behavior Change

The utility and effectiveness of MI in addressing intrapersonal and interpersonal challenges for health behavior change has been explored across various health behaviors for more than three decades. The first description of MI was published in 1983 by the psychologist Dr. William R. Miller.[66] Miller described his findings while working with clients who had a problem drinking behavior, and observed that empathy was the therapist's most effective skill in reducing alcohol consumption among patients. His findings lead to the conceptualization of MI principles, clinical processes, and theoretical underpinnings. Later, Miller collaborated with Dr. Stephen Rollnick to write a book with a detailed description of MI as a communication skill set for health behavior change.[67]

Motivational Interviewing in Health Behavior Change

MI is a patient-centered communication skill set and way of being with proven effectiveness in helping patients decide to modify problem behaviors/adopt health behaviors. Historically, patient counseling was based on a paternalistic and advice-giving mode of communication that assumed a directive and information-giving style. This communication style assumed an authoritative role for the provider and a submissive role for the patient. MI is an alternative, adaptive approach which utilizes a guiding style, explores patients' strength and aspirations, elicits their own internal motivations for changing a target behavior, and supports patient autonomy in the decision-making process.[68]

The process of behavior change is fraught with ambivalence, indecision, apathy, and resistance. The basis of MI involves eliciting the inner motivation of the individual towards a verbal expression for change, and this is referred to as "change talk".[69] Change talk is the verbal expression of the patients' need, reasons, and desire for change. The effectiveness of change talk is hinged on the proposition of the

Self-Perception Theory, that self-motivational statements could influence our behavior decision-making by strengthening self-efficacy for modifying a target behavior.[32]

Theoretical Background of Motivational Interviewing

The concepts of MI were drawn from the intuitive clinical experiences of psychologist, Dr. William R. Miller, while also incorporating components from several established psycho/social/behavioral theories into MI skills and processes. The concepts of MI include or were supported by the following theories: (1) Leon Festinger's theory of Cognitive Dissonance - that there is psychological discomfort and a gravitation towards balance when people are faced with internal contradictions about their thoughts, beliefs, or behavior; (2) Daryl Bem's reformulated Theory of Self-Perception - that people are influenced by observing their own behavior and the words they say aloud; (3) Albert Bandura's Self-Efficacy theory - that the probability of accomplishing a task is increased among people who believe in their ability to succeed in the given task; and (4) Carl Roger's person-centered approach to psychotherapy which emphasizes empathy, collaboration, and positive regard.[70]

The Self-Determination Theory (SDT) has been used recently to understand how MI works at eliciting internal motivation.[71] The SDT embodies the processes of MI such as eliciting patients' verbalizations about his/her reasons or needs for change (intrinsic motivation), and encouraging the patient to assume responsibility for change and outcomes. SDT reflects the core MI principles of supporting autonomy and collaboration in a patient-centered and non-judgmental approach. The close alliance of SDT and MI has proven useful in guiding the MI framework for health behavior change interventions.[70]

Motivational Interviewing Skills in Patient-centered Communication

The application of MI encompasses patient-centered communication skills and a way of being which is referred to as the 'spirit of MI'. This "way of being" is characterized by relating with people in a purposeful, genuine, and person-centered way. There are four elements that reflect the 'Spirit of MI' and

these are collaboration or partnership, acceptance, compassion, and evocation.[32] The primary principles of MI are expressing empathy, developing discrepancy, rolling with resistance/avoiding argumentation, supporting self-efficacy and patients' autonomy. [32] Accurate empathy encompasses verbal and nonverbal communication that reflects compassion and genuine interest in the well-being of the patient, and is a purposeful way of communicating with patients with the primary aim of fostering a collaborative relationship which is needed for health behavior change conversations. These elements embody the true essence of MI and are useful in provider-patient encounters.

The framework for MI includes three core communication styles, directing, guiding, and following and three general communication skills, which are, informing, asking, and listening. The guiding style incorporates the three communication skills equally, and most successful MI encounters lean more towards the guiding style. MI involves four processes, engaging, focusing, evoking and planning.[70] The processes of MI also require the interventionist to apply MI micro skills which include asking open-ended questions, affirmations (praise), reflections, and summaries.[70] These skills are applied with the sole aim of eliciting intrinsic motivation, sustaining and strengthening change talk, and consolidating specific action plans in partnership with the patient.

Diabetes Management and Haelth Behaviors

The American Association of Diabetes Educators (AADE) created a framework for patient-centered diabetes self-management education and training (DSME/T), referred to as the AADE7 Self-Care Behaviors™. The AADE seven key behaviors in the management of diabetes include medication taking, healthy eating, physical activity, blood glucose monitoring, diabetes self-care-related problem solving, reduction of acute and chronic complication risk, and healthy coping.[72] Other self-care behaviors that are important in general health are also important with diabetes (e.g., smoking cessation, reducing alcohol intake, and eye and foot exams). The AADE7 self-care behaviors framework shifts diabetes education and management from a content-based practice to an outcomes-driven care model. The

framework includes goal setting and assessment of behavior change, clinical indicators, and health status through a continuum of outcomes.

Motivational Interviewing in Diabetes Management

Various intervention types have been utilized to support healthy behaviors in diabetes management and range from patient education to behavior modification strategies.[4 72-74] MI has received significant attention in research and practice in recent years since the evidence base for its positive impact has grown. MI is a communication skill set and way of being aimed at evoking the intrinsic motivation of the individual to develop the behavior changes needed to manage T2D.[75 76] The effectiveness and clinical utility of MI in promoting health behaviors have been documented in diverse health conditions and populations and in many different target behaviors such as healthy eating, physical activity, smoking cessation, and blood glucose monitoring.[77-79]

Ambivalence towards behavior change often results in a state of indecision and lack of action.[76] To overcome ambivalence, MI employs communication principles such as expressing empathy, rolling with resistance/avoiding argumentation, developing discrepancy, and supporting self-efficacy along with strategies for eliciting change talk.[76]

The ADA treatment guidelines specifically recommend patient-centered communication as an intervention strategy for lifestyle behavior changes in the management of diabetes.[80] MI has been applied exclusively or as an add-on strategy in various diabetes interventions aimed at improving treatment outcomes for people living with diabetes, however, few studies have examined the impact of MI on medication adherence for diabetes.[81] Several studies of MI-based interventions aimed at diabetes self-management behavior change have yielded heterogeneous results, typically stemming from varied training intensities, limited follow-ups, brief study designs, limited measures of intervention fidelity, small sample sizes, and heterogeneous measures of outcomes.[82-85]

Medication Adherence in Type 1 Diabetes Management

T1D is a disorder characterized by autoimmune-mediated destruction of β-cells resulting in a lack of insulin production and absolute dependence on external supply of insulin for optimal metabolic activity.[86] An American Diabetes Association survey found that "21% of adults with T1D never checked their blood glucose level; for those with insulin-treated T2D, 47% never monitored, and among those with T2D who were not using insulin, 76% never checked". Glycemic control in diabetes management reduces the risk of developing micro- and macro-vascular complications. The hemoglobin A1C test is recommended in clinical practice to assess glycemic control based on a regular 3-month visit to the clinician.[87] Patients with T2D and stable glycemic control may test twice a year.[88] Recommended A1C goal for most nonpregnant adults is <7% (53 mmol/mol). The guideline is more flexible for patients with long-standing diabetes, history of severe hypoglycemia, limited life expectancy, or extensive complications, where the recommended A1C is <8% (64 mmol/mol).[88]

Medication nonadherence in T1D is often unintentional due to the severity of the disease and absolute dependence on insulin doses.[89] Several factors have been reported to potentially hinder insulin adherence and Blood Glucose Monitoring (BGM) among T1D patients who are often children, adolescents, and young adults. These barriers could be intrinsic or extrinsic such as fear of needles/pain, stigma, inconvenience, frustration with/avoidance of high blood glucose readings, the perception that BGM was only for insulin titration, lack of motivation, inadequate knowledge/skills, and lack of self-efficacy.[90] Barriers to insulin adherence in T1D have been broadly categorized into: (1) psychosocial factors (peer influence, perceptions of social support, forgetfulness), (2) clinical factors (anxiety, depression, eating disorders, fear of hypoglycemia), and (3) external factors (treatment cost, patient-provider communication, interference from activities which could lead to forgetting).[91 92] The primary reason specified by patients for non-adherence to insulin use was forgetting to administer doses at the right time or forgetting dosing schedule and units.[89 92]

Facilitators for enhancing patient engagement for BGM have also been reported; these include the desire to see improved health outcomes or effects of dietary changes or physical activity, the desire to please the health care provider, and family motivations.[90] Other factors or aids for supporting BGM include mobile health applications, charts/logs for inputting readings, computerized logbooks, and visual reminders in the patients' immediate environment.[90 93]

Behavioral interventions like MI could impact insulin adherence among patients living with T1D. Stanger and colleagues assessed the effectiveness of motivational interviewing on glycemic control among adolescents living with T1D.[79] The study design incorporated MI with family-based Contingency Management (CM). The CM component was a reward system, where the parents gave incentives for BGM behavior. The pilot study enrolled 17 participants (aged 12-17 years) with uncontrolled (mean A1C = 11.6%) T1D. Participants and their parents received 14 weeks of MI, clinic-based CM, and parents-directed CM for BGM. Statistically significant improvement in BGM and A1C was observed post intervention ($p<0.001$) among the study participants.

Medication Adherence in Type 2 Diabetes Management

T2D is characterized by insufficient production of insulin by the islet of Langerhans in the pancreas and low cell uptake of insulin due to changes in metabolic processes in the body. The treatment regimen for T2D involves lifestyle changes, medication taking (oral and/or injectable), and/or insulin use depending on the severity of the disease.[94] Health behavior change and adherence to recommended regimens are important targets improving health outcomes diabetes management.[20 66 95]

Various T2D pharmacotherapy regimens have their accompanying facilitators and barriers to adherence. Guenette and colleagues assessed beliefs about taking oral antidiabetic drugs among T2D patients.[96] Facilitators for medication adherence identified in the study were beliefs that pharmacotherapy will reduce complications and improve glycemic control, perceived support from family members, carrying medication at all times, keeping the medication in sight (visibility), and having a structured routine for

taking medications.[96] Barriers were forgetting medication at home, denial of disease severity, and lack of confidence in providers.[96]

A review by Tiktin and colleagues evaluated barriers to poor adherence to diabetes medications among T2D patients and reported that common barriers were depression, polypharmacy, difficulty with administering medication, cost, patient motivation and education.[97] Spain and colleagues evaluated barriers for injectable antidiabetic medications among T2D patients.[98] The barriers reported by participants (N=2000) included adverse event/side effects, lack of perceived need, the cost of medication and injection concerns (pain, aversion to needles or needle size). Datye and colleagues reported the most common reason for insulin nonadherence was forgetting.[92] Other reasons for sub-optimal insulin adherence included weight gain, pain at injection site, and fear of hypoglycemia, cost and interference with daily activities.[91]

Motivational Interviewing Interventions for Medication Adherence

Palacio and colleagues compared the efficacy of phone-based MI interventions to the traditional educational video at improving medication adherence to antiplatelet medications among minorities.[18] The study population was made up of Hispanics and African Americans, and the 452 participants were randomized into the MI group to receive four phone calls in 12 months (quarterly) by interventionist trained in the Motivational Interviewing Network of Trainers (MINT) network. A video DVD was mailed to participants in the control group. Outcome measures were adherence to antiplatelet medications measured by the Medication Possession Ratio (MPR) and the Morisky for the self-reported measure. At 12 months, adherence in the intervention group was statistically significantly higher from the control group ($p<0.05$) for both self-report adherence and MPR. Findings support the efficacy of phone-based MI for improving medication adherence in the minority population. Furthermore, a systematic review of phone-based MI intervention for medication adherence showed significant improvement in the intervention group compared to controls in seven of the nine studies retained.[99]

A meta-analysis was conducted on the impact of MI-based interventions on medication adherence and the effect of the intervention delivery method. Other parameters assessed were intervention fidelity, fidelity-based feedback to the MI interventionists, MI exposure time and the educational background of the interventionists.[100] Disease conditions included were rheumatoid arthritis, HIV, osteoporosis, depression, multiple sclerosis, and hypertension.. Studies that used fidelity assessment tool and provided fidelity-based feedback recorded superior results for MI. Background of interventionists with favorable outcomes was reported for nurses and research assistants. MI exposure time did not impact adherence significantly, however, other studies have indicated otherwise.[8]

Motivational Interviewing as Brief Structured Communication Tools

The American Pharmacists Association (APhA) and the APhA Foundation jointly developed and implemented the Discussions on Taking Medications for Diabetes (DOTx.MED) pilot program.[66] The pilot program was designed to evaluate the impact of Structured Communication Interventions (SCI) on diabetes medication adherence. The primary outcome of Proportion of Days Covered (PDC) was calculated based on the date of prescription fill and pick up. Medication adherence improved for the intervention group (6.55% improvement in overall PDC after 180 days) compared with the control group (PDC increased by 3.75%).

The MIDMA study sought to evaluate the impact of an adaptation of the DOTx.MED project using Structured Motivational Interviewing Tools (SMITs) as an MI-consistent conversation tool for diabetes medication taking behavior. Findings from the literature support the need for investigations that assess the impact of MI-based interventions on medication adherence in diabetes. Furthermore, at the time of this work, the DOTx.MED pilot program was the only published study that examined medication adherence among diabetes patients using tools based on MI principles.[66] This dissertation builds on and modifies the DOTx.MED pilot study towards examining the effectiveness of MI on medication taking behavior among T1D and T2D patients.

CHAPTER 2

SYSTEMATIC REVIEW OF THE LITERATURE

Manuscript 1

Title: Motivational Interviewing and Outcomes in Adults with Type 2 Diabetes: A Systematic Review

Journal: Patient education and counseling

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Abstract

Objectives: The management of type 2 diabetes (T2D) requires complex behavior changes and treatment regimens to achieve optimal outcomes. Interventions including Motivational Interviewing (MI) have been explored to help patients achieve these outcomes; this study aimed to systematically explore evidence and gaps in the literature for the impact of MI on outcomes in adults with T2D.

Methods: A modified Cochrane method structured the search strategy among databases including MEDLINE, CINAHL, PsycINFO, and others. Inclusion criteria included randomized controlled trials that assessed the effects of MI on behavioral and clinical outcomes in adults with T2D.

Results**:** Of the initial 159 studies identified, 14 were eligible for retention. Behavior targets in the retained studies included dietary changes, physical activity, smoking cessation, and alcohol reduction. MI had significant impact on some dietary behaviors and on weight loss. MI intervention structures were heterogeneous across studies; fidelity assessment was infrequent.

Conclusion: The effects of MI interventions on outcomes in T2D showed promising results for dietary behaviors. Clinical change outcomes from MI-based interventions were most favorable for weight management in T2D.

Practice implications: Behavior-specific MI interventions may positively influence study outcomes. Assessment of MI intervention fidelity will enhance treatment integrity and claims for validity.

Introduction

The treatment and management of diabetes mellitus is a continued life experience that requires the development of behavioral self-management to achieve optimal outcomes. The International Diabetes Federation (IDF) estimates that 387 million people worldwide are living with diabetes with 4.9 million deaths attributed to diabetes in 2014.[1] The Centers for Disease Control and Prevention (CDC) indicates the U.S. prevalence of diabetes is at 9.3%. About 90 - 95% of these cases are diagnosed as type 2 diabetes (T2D) [2]. Suboptimal diabetes self-management increases the risk of diabetes-related complications[3 4]. As such, a substantial number of people living with diabetes are at risk for hyperlipidemia, hypertension, and microvascular complications [5]. Diabetes treatment and care are associated with considerably higher lifetime treatment costs, particularly when treatment involves poor adherence to self-management behaviors [3 6]. The rising prevalence of T2D and its expensive risks and complications signal the need for interventions that promote positive changes to patient health behaviors in the self-management of T2D.

The American Association of Diabetes Educators (AADE) identifies seven key behaviors in the management of diabetes. These include medication taking, healthy eating, physical activity, blood glucose monitoring, diabetes self-care-related problem solving, reduction of acute and chronic complication risk, and healthy coping [7]. Other self-care behaviors that are important in general health are also important with diabetes (e.g., smoking cessation, reducing alcohol intake, eye and foot exams, etc.). Various intervention types have been utilized to support healthy behaviors in diabetes management and range from patient education to behavior modification strategies [7-10]. Motivational Interviewing (MI) has received significant attention in research and in practice in recent years since the evidence base for its positive impact has grown. MI is a communication skills set aimed at evoking the intrinsic motivation of the individual to develop the behavior changes needed to manage T2D [11 12]. The effectiveness and clinical utility of MI in promoting health behaviors have been documented in diverse health conditions and populations and in many different target behaviors. [13-15]

MI is designed to elicit the inner motivation of the individual by using the communication styles of guiding, following, and directing. It is a patient-centered communication skills set that involves, among other things, open-ended questions, reflective listening, and support for patient autonomy. The state of ambivalence in a person often complicates behavior changes for the individual [12]. To overcome ambivalence, MI employs communication principles such as expressing empathy, rolling with resistance/avoiding argumentation, developing discrepancy, and supporting self-efficacy along with strategies for eliciting change talk [12].

Recent American Diabetes Association (ADA) treatment guidelines (2014) specifically recommend patient-centered communication as an intervention strategy for lifestyle behavior changes in the management of diabetes [13]. MI has been applied exclusively or as an add-on strategy in various diabetes interventions aimed at improving treatment outcomes for people living with diabetes [14]. Several studies of MI-based interventions aimed at diabetes self-management behavior change have yielded diverse results for the impact of MI, with inadequate MI training and/or the presence of heterogeneous study designs and measures often cited as reasons for the differences in study findings [15-18]. To clarify those discrepancies, it would be useful to conduct a systematic review of rigorous, controlled study designs to examine how MI performs as compared to controls with regards to its impact on target behavioral and clinical outcomes.

The objectives of this review are to systematically examine empirical evidence for the impact of MI on behavioral and clinical outcomes in adults with T2D, and to report evidence and gaps in the literature in relation to factors with implications for research and practice.

Methods

Inclusion criteria

This study employed a modified Cochrane method of systematic review. In contrast to a typical Cochrane review which compares specific outcomes surrounding a narrowly defined research question between two interventions in a specific population, this systematic review used the rigorous systematic search-and-review approach applied to a more exploratory research question regarding evidence and gaps in the literature for MI as an intervention for behavior change in adults with T2D.

The selection criteria for eligible studies were based on the PICOS format (Participants, Intervention, Comparators, Outcomes, and Study design) recommended by the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) guideline. The inclusion criteria for retaining studies were:

Population: Adults (18 years and older) with T2D

Intervention: Motivational interviewing alone or MI-based intervention

Comparators: Usual care or a non-MI intervention

Outcomes: Assessment of changes in relevant health behaviors for diabetes management and any targeted clinical outcomes

Study design: Randomized controlled trials (RCTs)

Retained studies only included RCTs that assessed the effects of MI-based interventions on behavioral and/or clinical outcomes of adults with T2D. Studies were excluded if there was no comparator group to the MI-based intervention group. In addition, cross sectional studies, literature reviews, preventive studies in pre-diabetes, and studies of gestational or type 1 diabetes were excluded.

Search strategy and review process

A systematic search of the literature was performed to identify all studies published in the English language through October 2014 that investigated the effects of MI or MI-based interventions on outcomes for T2D. The electronic database search was conducted among relevant databases, including Medline, CINAHL, PsycINFO, PsycARTICLES, Academic Search Premier, Alt Health Watch, Health Source: Consumer Edition, and Health Source: Nursing/Academic Edition. Additional articles were found by manual searching of reference lists of relevant published papers, reviews, and published MI books, including the bibliography of the Motivational Interviewing Network of Trainers.

Search terms or combinations included: “motivational interviewing,” “MI,” “type 2 diabetes,” “diabetes mellitus,” “non-insulin dependent diabetes mellitus,” “adult onset diabetes,” “outcomes,” “health outcomes,” and “behavioral outcomes.”

Data extraction and review of studies

The database retrieval process for eligible studies was initially performed by one researcher, and independently assessed by both authors at each search and review tier of the process. A study with differing retention/rejection opinion was settled to consensus by a critical evaluation of the study based on the review eligibility criteria. A standardized data extraction form was used to extract relevant information from all full-text studies reviewed. The following information was included: first author’s name, study design, characteristics of the study sample, study setting, intervention methodology, study duration and number of follow-ups, training/fidelity assessment, behavioral outcome targets, and clinical outcome targets.

Assessment of methodological quality

It is important to evaluate the methodological quality of retained studies in a systematic review. All included studies were analyzed for methodological rigor in order to support summative conclusions from the results. Study quality assessment was conducted using the Cochrane method for assessing methodological quality; the Cochrane method assesses the risk of bias in several characteristics of the design of retained studies [19]. Bias domains evaluated per study included participant recruitment/selection, allocation, blinding, attrition, reporting, and other potential threats to validity. Each of the domains was given a judgment of high, low, or unclear risk based on methods and analyses reported in the study.

Results

Retaining studies for review

The detailed literature search process and rejection rationale are illustrated in the PRISMA flow diagram in Figure 1. The initial search revealed 155 citations from the databases and four citations from manual

searching of reference lists from other relevant sources. After removing duplicates, 138 studies were retained for further screening. The next tier involved analysis of titles and elimination of those that were not relevant (n=110). Abstracts were then screened and were excluded (n=7) if they did not meet the inclusion criteria for this review as specified in the PRISMA diagram.

The seven full-text reviewed papers were excluded for the following reasons: one contained only baseline data, one assessed diabetes prevention and reducing risk in patients with pre-diabetes, one did not have a comparator group, one reported for a combined population of type 1 and 2 diabetes patients, and three did not measure behavioral outcomes. The remaining 14 studies were retained for the review [18 20-32]. All retained studies were randomized controlled trials. The characteristics of retained studies, their settings, and their MI-related methods are summarized in Table 1.

Methodological quality assessment

Table 2 reports the methodological quality of the 14 retained studies based on the Cochrane method for assessing risk of bias in randomized controlled trials [19]. Methodological strengths of the retained studies include that they were all randomized and controlled and sample sizes ranged from 22 participants to 940. Each bias domain was judged based on the Cochrane criteria for low, high, or unclear. Reporting bias had the lowest bias while a judgment of unclear was given to some studies for selection bias and blinding. All the studies reported randomization of participants and/or interventionists; however, the randomization method was not described in all studies.

Motivational Interviewing intervention structures

The MI sessions were delivered as part of the study intervention or the intervention itself was designed based on the principles of MI. Intervention sessions were delivered by trained medical professionals including general practitioner physicians, psychologists, pharmacists, nurses, diabetes educators, and dieticians. As seen in Table 1, studies had varying length and frequency of MI delivery episodes. Intervention design could be broadly categorized into three types: (1) MI-based tailored intervention, (2) MI counselling only, and (3) MI added to diabetes education or usual care.

Length of MI encounter ranged from 30 to 90 minutes, with frequency of MI sessions ranging from one to five times during a study period. An individual face-to-face or group delivery of MI was applied in all 14 studies for one or more MI sessions; some studies included telephone follow-up session(s). The 14 studies had been carried out in a variety of outpatient settings such as primary care clinics, doctor's offices, and community health facilities.

Motivational interviewing training and intervention fidelity assessments

Reporting a description of the training of interventionists is important to understanding the validity of the actual intervention being delivered and its fidelity to the intended intervention, particularly when the intervention involves a complex skills set and way of being, like MI. Among the 14 retained studies, MI training procedures and duration were described by eight studies. Reported areas of focus specified for MI trainings included exploration of patient ambivalence, reflective listening, asking open-ended questions, and agenda-setting. Reported training period durations ranged from 10 to 80 hours among the eight studies reporting training details [22-26 28 31 32]. Five studies did not detail the training of interventionists, but simply stated that they were MI trained [18 20 21 27 29]. One study did not include any references to training details or duration [30].

Intervention fidelity assessment is important to determine whether the interventionist's delivery was actually MI-consistent. Six studies directly reported how ongoing intervention fidelity was assessed; namely, that assessment was conducted by recording MI sessions and analyzing them for MI consistency [18 23 24 28 29 31]. The recordings were either audiotapes or videotapes of intervention sessions which were coded and evaluated by MI experts for feedback purposes. Three studies reported specific measures used in measuring MI fidelity assessments [24 28 29]. Measures included in these intervention fidelity assessments were the Motivational Interviewing Treatment Integrity (MITI), the Motivational Interviewing Treatment

Code (MISC), and the Behavior Change Counseling Index (BECCI), which is primarily a global communication/counseling assessment instrument that also includes some of the MI principles and/or strategies. The remaining studies reported no methods for assessment of MI intervention fidelity.

Behavioral and clinical outcomes

Table 3 summarizes the results and significance testing of target behavioral and clinical outcomes for the fourteen retained studies. It can be seen that the most frequently targeted self-management behaviors included one or both of the lifestyle changes related to healthy eating (n = 7) or being active (n = 6). Some studies included smoking cessation and/or alcohol reduction (n = 4) in diabetes patients. All behavior measures used self-reporting. Most of the studies (n = 11) used measures that were specific to the targeted health behaviors being studied. Three of the fourteen studies applied a compound measure that reported behavioral outcomes as a global "self-management behaviors" concept that reported a single, global score for the aggregate (multiple behaviors perception in one measure) outcomes that were self-reported.

Five of the seven studies that assessed eating changes reported significant group differences between the MI intervention group and usual care group. Two of the five studies showing significant group differences assessed specific target eating behaviors including reduction of saturated fat intake or increased fruit or vegetable intake [23 29]. Brug, et al. (2007) reported a significant difference in reduction of saturated fat intake for the MI group compared to the usual care group; however, fruit and vegetable intake had non-significant results in both groups. Among the three studies that reported a global measure for diabetes self-management behaviors, only Chen, et al. (2011) reported a significant difference for the MI group compared to control [24 27 28]. No significant differences were reported for the MI group versus the usual care group for physical activity, smoking cessation, and alcohol reduction in the studies that examined these behaviors (n = 7).

Clinical outcomes

Target clinical outcomes included in retained studies were glycemic control (n=14), blood pressure (n=6), waist circumference (n=2), BMI (n=8), weight loss (n=2), and cholesterol (n=5). Clinical variables were measured using recommended methods relevant to the particular clinical indicators. Smoking cessation and alcohol use were measured with self-reporting as noted above; self-report was also compared with a biochemical test in some studies [22 23 25 31 32]. The type of biochemical test used was not specified.

All retained studies measured blood glucose levels; the methods used were A1C (n=13) and current blood glucose level with a standard meter (n=1). A significant difference for the MI group compared to control was reported in three of the thirteen studies that measured A1C and in the study that measured blood glucose level with a standard meter. Moreover, two studies reported a reduction in A1C, but it was not significant [18 21]. In addition, Hokanson and colleagues (2006) reported A1C level reductions to below the 7.0% guideline for both the intervention and control groups after the intervention.

Significant weight loss in the MI group compared to the control group was reported by West and colleagues [18]. Another study with duration of 18 months reported significant weight loss in the MI group compared to the control at the 6 months follow-up, but not at the end of the study [21]. Wattanakorn and colleagues found a significant reduction in BMI for the MI group [20]; while Chen and colleagues reported similar findings for systolic blood pressure [27]. Non-significant differences between the MI intervention group and the control/usual care group were reported for other anthropometric and clinical outcomes such as waist circumference and cholesterol.

Discussion and Conclusion

Discussion

This systematic review culminated in an examination of fourteen randomized controlled trials assessing MI as an intervention for targeted self-management behavior changes in adult patients with T2D. Positive effects of MI were observed in four of seven studies that targeted dietary changes, one of two for weight loss interventions, four of fourteen for glycemic control, and one of eight studies for body mass index. Systolic blood pressure reduction was also significant in one study among studies assessing blood pressure. Three studies reported self-management behaviors as a global behavior summary score and one of these was significant for the MI group. MI did not show a statistically significant effect on physical activity, waist circumference, cholesterol, alcohol reduction, and smoking cessation in any of the studies retained in this review. The behavioral change category targeted most focused on various eating behaviors and a majority of these had significant changes in the MI group. This supports the potential for MI as an intervention for diet modification in T2D patients; however, conclusions should be drawn with caution due to heterogeneity in study designs, settings, and intervention type.

Most of the retained studies focused on health behaviors that directly impact T2D glycemic control outcomes; however, four studies evaluated the effectiveness of MI on substance abuse/addiction behaviors like alcohol intake and/or cigarette smoking [22 25 31 32]. These behaviors are frequently addressed in diabetes self-management because of their contribution to increased risk of cardiovascular comorbidities or events. The studies in this review that targeted alcohol reduction and smoking cessation did not report significant results for the MI group compared to control/usual care. These findings for the targeted addiction behaviors were not congruent with original work with MI that impacted addictive behaviors [33-35]. A possible factor could be the addition of these challenging addictive behavior changes to the already complex set of diabetes self-management behaviors required for glycemic control. The reduction of habituated, physiologically addictive behaviors is complex and can be considered a big change for which many patients may not have the motivation or self-efficacy to achieve [36].

It is important to note that medication taking behavior was not evaluated as a target behavior in any of the retained MI-based intervention studies. Medication adherence rates have been reported as poor in chronic disease management including diabetes and since medication taking is a diabetes self-management behavior that is particularly impactful on glycemic control, further research in this realm is warranted [37 38]. One study not retained in this review was the Discussions on Taking Medications (Dotx.MED) diabetes pilot program conducted by the American Pharmacists Association. Data were collected from ten varied pharmacy practice sites across the US on the impact of MI-trained pharmacists and pharmacy residents on medication adherence in non-adherent patients (proportion of days covered). The pharmacists had brief MI-based conversations with patients each month for six months when the patient returned to the pharmacy for his or her medication refill. Results were modestly, but significantly impactful on the target behavior of adherence with diabetes medication-taking [39].

Limitations

The care settings in the retained studies were all outpatient sites, which is similar to the majority of real world encounters for behavior change interventions. Some of the retained studies were multi-site trials and while this is an opportunity to collect additional and comparative data, using multiple sites adds variability that impacts outcomes and could produce challenges to intervention fidelity among interventionists because of the varying nature of sites. External validity is limited due to the unique characteristics of the study populations. Potential bias could exist in this summary due to the exclusion of some studies based on the review inclusion criteria, unpublished manuscripts, and potentially eligible publications in other languages. Another potential source of bias is the heterogeneous designs, methods and measures used in retained studies. MI implementation was variable and 57% of retained studies did not document ongoing intervention fidelity measures. Measures of behavioral outcomes, patient baseline control level, and patient recruitment also varied significantly and impact outcomes and comparisons. In addition, as an MI originator recently reported in reflecting back on a few decades of MI, adequate training and practice is a key to skills development. His recommendation was that at a minimum, persons require at least two days of training with multiple opportunities to role-play with MI expert feedback and

that follow-up training and/or practice is critical for reinforcing skills development and progression [40 41]. MI impact is not seen or is not significant in a study, it is often found that the study reported minimal training of interventionists in MI or did not report training in the article. Health literacy was not addressed within the retained studies; in addition, other outcomes of interest like humanistic outcomes (i.e., satisfaction, quality of life) and financial outcomes (e.g., return on investment) were also not targeted within the studies retained in this review and should be considered as areas for future research with MI as an intervention for behavior change in adults with T2D.

Comparison to other studies

The results of this review contribute to the body of literature that supports MI as an evidence-based, patient-centered communication skill set that is promising, when appropriately trained and applied, in addressing ambivalence. Some findings in this review are similar those from other reviews on the effects of MI in changing health behaviors [14 41 42]. It is important to note that, as in other studies, a common thread suggests that higher frequency of MI-based encounters are associated with more significant improvements in patient target outcomes [40 43]. This is congruent with recent commentaries by Miller, an MI originator [40 43].

As noted in the previous section, the quality of MI training received by interventionists has also been implicated as a factor that influences rigor of outcomes in MI studies [32 44 45]. Madson and colleagues (2009) concluded in their review of MI training that a lack of standard measures for MI assessments on knowledge, attitudes, and self-confidence contributes to challenges in comparing studies and validating MI-based interventions and their impact [45 46]. Measures used in evaluating MI proficiency and MI intervention fidelity should be implemented and reported in studies to support claims for validity of the actual intervention as being MI-consistent. MI training delivered by one trainer has been indicated as a possible influence on uptake of MI strategies by interventionists [32]. This could influence outcomes based on the methods emphasized by the trainer.

Copeland and colleagues examined possible mediators for MI outcomes in a previous general review of the mechanisms of MI in interventions [47]. MI spirit and change talk had been indicated as mediators for favorable outcomes [47]. A mediation analysis showed a positive association where an effective MI spirit increased change talk and behavior change was found in participants who engaged more frequently in change talk [47 48]. The lack of significant results in some behavioral outcomes such as physical activity and addiction could possibly be associated with a lack of these mediators and or study design and methods concerns noted previously.

Mulimba and Byron-Daniel recently published a review of MI in the diabetes literature published up through March, 2010 [49]. The inclusion criteria included type 1 or 2 diabetes and included less rigorous study designs than this review. Eight studies were retained and the authors found minimal impact of MI on diabetes outcomes. Some of the studies retained in that review were rejected for this review due to less rigorous study designs and measures. It is clear that studying a complex intervention set like MI requires rigorous methods for training, implementation, and assessment.

Practice Implications and future directions

Results among retained studies suggest that MI, when appropriately trained and applied, has potential to impact changes in health behaviors, thereby, improving outcomes. The treatment and management of T2D requires sustained change for self-management behaviors such as healthy eating, being active, medication taking, and blood glucose monitoring. Patients who adhere with recommended regimens often have better disease prognosis and reduced risk of microvascular and macrovascular complications. Assessment of patient understanding and behavioral and motivational readiness is important to helping a provider make patient-centered decisions about directions to take in guiding a patient on goal setting for behavior change.

For the outcomes targeted among retained studies in this review, the behavioral change needed for addictive behaviors such as smoking and alcohol use requires behavior-specific interventions for favorable results. A focus of MI suggests that building self-efficacy for change can be achieved by goal-setting where incremental changes are the focus for those who may be resistant or ambivalent for the

change (e.g., initial focus on cutting back on cigarettes smoked in a day rather than quitting altogether). In addition, the studies that did show significant impact on behavior change for the MI group versus control were often those which focused on a singular behavior (e.g., dietary intake), which has important implications for research and practice. Focus on many changes at once for a complex chronic disease like diabetes may prove overwhelming for individuals. A premise of MI includes the support of self-efficacy and one means of supporting confidence for change is to focus on incremental change [50]. This includes setting goals within behaviors that start with small changes with a plan for progression, which can also have implications for advising patients to focus on one behavior at a time if their self-efficacy for major change is low or the complexity of change is beyond their health literacy level.

The heterogeneous nature of MI interventions creates a significant challenge for comparing methods and outcomes across studies, and certainly does not reveal a "gold standard" for MI intervention study design. This is true of behavioral interventions in general. In addition, the way behavior change/achievement was measured across studies varied significantly, limiting meaningful comparisons. This is problematic across behavioral interventions research, with theory-based, established measures often producing more valid results, but not always being a standard of measure in practice settings beyond a research study. This is also problematic because often studies do not measure behavior change to a defined, specific behavior for a participant to respond for in self-report. The use of global measures to summarize diabetes self-management behaviors does not capture the adherence or change on any particular behavior. Participants may be adherent with one behavior but unsuccessful in another, and the changes could be significant if measured individually.

Another important research design factor to consider is the presence of motivation and incentives/compensation that will help attract more poorly controlled patients to a study in order to be able to show impact of an intervention. Smith and colleagues reported higher dropout rate among younger and poorer controlled participants [21]. Participant motivation has been indicated as a potential mediator for outcomes in MI interventions [47]. One retained study had provided compensation up to $65 for travel expenses [26]. Future studies may benefit from strategies to recruit participants with poorer disease control,

since patients who are already adherent or well-controlled tend to show less impact from an intervention, because there is less room for significant improvement in the target outcome. This may have contributed to insignificant findings in some of the studies retained in this review and elsewhere.

Adequate training in MI has been implicated as a favorable factor in outcomes from MI interventions. Miller (2013) described the importance of adequate MI training and trainee feedback as factors in achieving competence with MI skills [51]. Most studies retained in this review did not adequately report training of the MI interventionists and MI intervention fidelity assessments. This calls into question the validity of those interventions since it has not been substantiated that what was actually done in the encounter was MI-consistent. Retained studies that evaluated intervention fidelity utilized the method of pre and post- assessments and/or MI expert evaluation of sample(s) of audio or video recorded intervention encounters with study participants. Providers who hope to impact outcomes of adult patients with T2D should consider extensive healthcare-based training that includes at least two days, MI expert feedback, and includes opportunities for follow-up training and/or practice. Future studies should at the very least conduct a pre and post-assessment of trainee knowledge, attitudes, and skills for MI and at best could employ intervention fidelity assessments in the study design to ensure that the intervention delivered was MI-consistent [44 46 52].

Conclusion

This review reports the evidence and gaps in the literature for the effectiveness of MI in the unique patient population of adults living with T2D. Among targeted behavioral outcomes, the most frequent category of impacted behavior change included dietary changes. This associates with the clinical outcome of weight reduction which had a 50% success rate among the studies evaluating this clinical target. Heterogeneity of measures and methods makes it difficult to compare the evidence and identify best-practice strategies, but one factor that was found among most of the studies showing MI impact had to do with frequency of encounters; the more MI encounters a patient experienced, the more likely he or she was to change behavior and achieve improved outcomes. Further research is needed due to the variability across studies for MI implementation and outcomes measurement. Overall, findings from this review support the

potential effectiveness of MI-based interventions in patients living with T2D when optimally applied by trained interventionists.

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Conflict of interest

None

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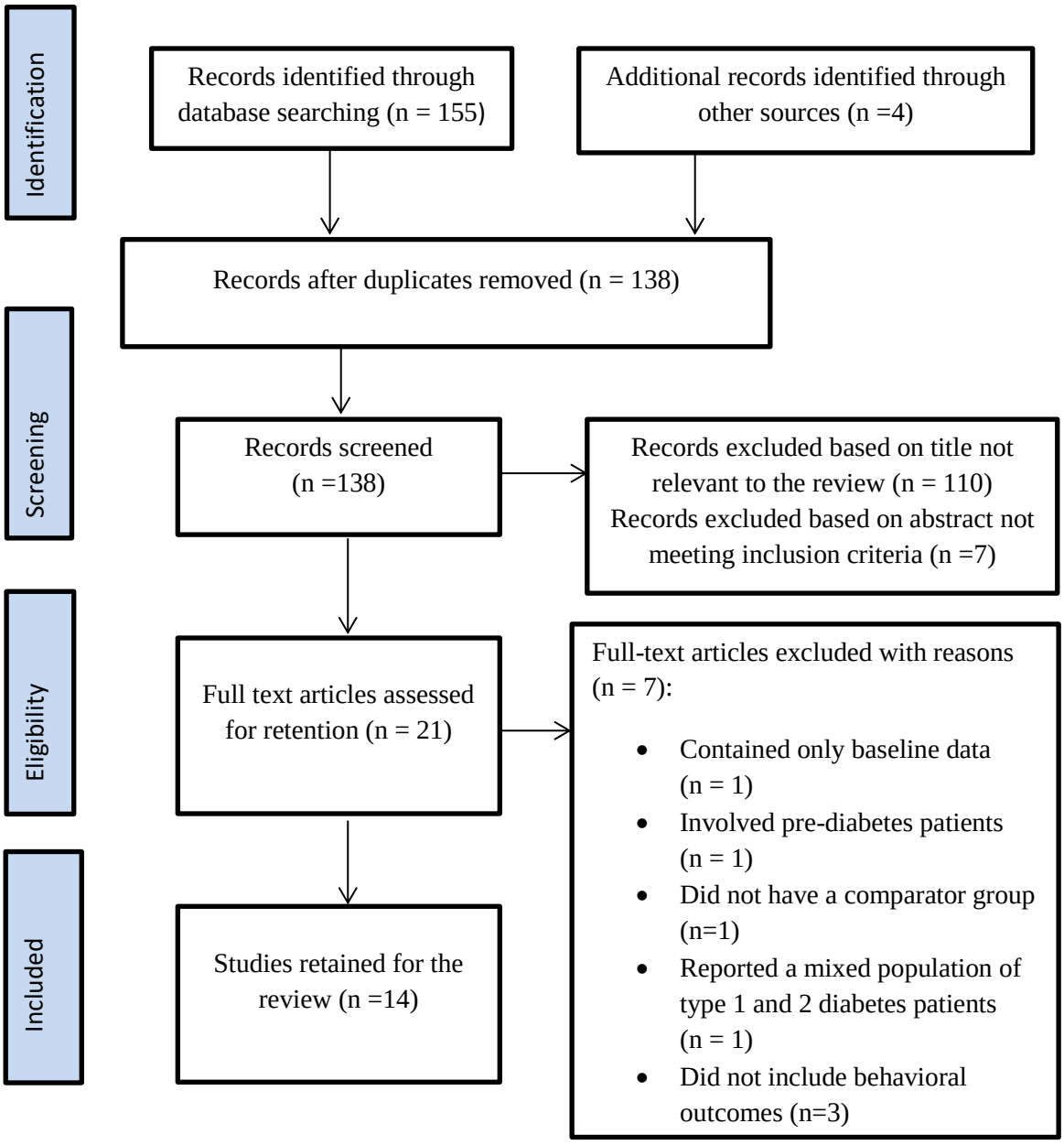

Fig1. PRISMA flow diagram of study retention process for the systematic review

Table 1

Randomized controlled trials evaluating MI in T2D

Source	Design, Settings	Sample	Method	Duration (months)	Clinical indicators	Behavioral targets
Wattanakorn et al. Thailand, 2013 [20]	RCT; single site	76 obese T2DM patients.	I: MI - based Eating Behavior Modification Program (EBMP) C: DM health education	13 weeks	BMI, waist circumference, blood sugar levels	Diet, physical activity
Jansink et al. Netherlands, 2013 [31]	RCT; multi site	940 uncontrolled and overweight T2DM patients	I: MI -based lifestyle counseling C: Usual care	14	HbA1C, BP, BMI, and cholesterol levels.	Diet, alcohol, physical activity
Gabbay et al. USA, 2013 [28]	RCT; multi site	545 high-risk (A1C > 8.5%) T2DM patients	I: MI-based behavior change counselling C: Usual care	24	A1C, BP, and LDL	Self-management behaviors
Chen et al. Taiwan, 2012 [27]	RCT; single site	250 T2DM patients	I: MI (45-60 minutes) + hospital based educational	3	HA1C	Self-management behaviors

			sessions + "Diabetics Club" C: Hospital based educational sessions + "Diabetics Club"			
Rubak et al. Denmark, 2011 [32]	RCT; multi site	628 newly diagnosed T2DM patients	I: MI-based DM counseling C: Usual DM counseling	12	HbA1C, BP, BMI, and cholesterol levels.	Physical activity, smoking
Heinrich et al. Netherlands, 2010 [23]	RCT; multi site	584 T2DM patients	I: MI based counseling C: Counseling based on usual care	24	HbA1C, BP, BMI, cholesterol and triglycerides	Diet (fat, vegetable & fruits), smoking, and physical activity
Welch et al. USA, 2010 [24]	RCT; single site	234 poorly controlled (A1C >7.5%) T2DM patients	Grp 1: DSME alone Grp 2: DSME + DM self-management barriers report Grp 3: MI alone Grp 4: MI + DM	6	HbA1C	Self-management behaviors

			self-management barriers			
Osborn et al. USA, 2010 [26]	RCT; single site	118 T2DM patients	I: MI - based Information-Motivation-Behavioral (IMB) skills intervention C: Usual care	3	HbA1C	Diet, physical activity
Brug et al. Netherlands, 2007 [29]	RCT; multi site	209 newly diagnosed T2DM patients	I: MI counseling sessions C: Usual care	NA	A1C, BMI, waist circumference	Diet (Saturated fat, fruit, vegetable intake)
West et al. USA, 2007 [18]	RCT; single site	217 overweight and uncontrolled (AIC >12%) female T2DM patients	I: MI + weight management program C: weight management program	18	A1C, BMI, and weight change	
Hokanson et al. USA, 2006 [22]	RCT; single site	114 patients with T2DM	I: MI-based counselling for smoking cessation + diabetes	6	A1C, BP, and weight reduction	Smoking cessation

			education C: Diabetes education			
Clark et al. UK, 2004 [30]	RCT; single site	100 overweight T2DM patients	I: MI-based personalized program C: Usual care	12	HbA1C, BMI, LDL, HDL, triglycerides, and waist circumference	Diet, physical activity
Pill et al. UK, 1998 [25]	RCT; multi site	252 T2DM patients	I: MI-based DM counseling C: Usual DM counseling	16	Glycemic control (% GHb), BMI, blood pressure	Smoking, and alcohol
Smith et al. USA, 1997 [21]	RCT; multi site	22 obese female T2DM patients	I: MI + behavioral weight control program C: Behavioral weight control program alone	4	Glycemic control (% GHb) and weight loss	Diet, physical activity

I: intervention group, C: control or usual care group

Table 2

Risk of bias assessment for included studies (Cochrane method).

Source	**Random Sequence Generation**	**Allocation Concealment**	**Blinding of Participants and**	**Blinding of Outcome Assessment**	**Incomplete Outcome Data (Attrition Bias)**	**Reporting Bias**	**Other Bias**
Wattanakorn, 2013	+	+	?	?	+	-	+
Jansink, 2013	?	?	?	?	-	+	+
Gabbay, 2013	?	?	?	?	+	+	+
Chen, 2012	+	+	+	+	+	+	+
Rubak, 2011	+	+	-	-	+	+	+
Heinrich, 2010	+	+	+	+	+	+	+
Welch, 2010	?	?	?	?	-	+	+
Osborn, 2010	+	+	+	+	+	+	+
Brug, 2007	?	?	+	+	+	+	+
West, 2007	+	+	+	+	+	+	+
Hokanson, 2006	+	+	?	?	-	+	+
Clark, 2004	+	+	+	+	+	+	+
Pill, 1998	+	+	+	+	-	+	+
Smith, 1997	?	?	+	+	-	+	+

‘+’: Low risk of bias in study design, “-’: High risk of bias in study design, ‘?’: Unclear or insufficient detail

Table 3

Behavioral and clinical outcomes based on tests of significance between the MI and control group.

	Behavioral Targets					Clinical Targets					
Source	Healthy eating	Physical activity	Alcohol reduction	Smoking cessation	Self-management behaviors	A1C/Glycemic levels	BP	BMI	Weight reduction	Waist Circumference	Cholesterol levels
Wattanakorn et al. Thailand, 2013 [20]	Sig	NS				Sig		Sig			
Jansink et al. Netherlands, 2013 [31]	NS	NS	NS			NS	NS	NS			NS
Gabbay et al. USA, 2013 [28]					NS	NS	Sig#				NS

Chen et al. Taiwan, 2012 [27]					Sig	Sig					
Rubak et al. Denmark, 2011 [32]		NS		NS		NS	NS	NS			NS
Heinrich et al. Netherlands, 2010 [23]	NS					NS	NS	NS			NS
Welch et al. USA, 2010 [24]					NS	NS					
Osborn et al. USA, 2010 [26]	Sig	NS				NS					

Brug et al. Netherlands, 2007 [29]	Sig*					NS		NS		NS	
West et al. USA, 2007 [18]						Sig[α]			Sig		
Hokanson et al. USA, 2006 [22]				NS		NS	NS	NS			
Clark et al. UK, 2004 [30]	Sig	NS				NS		NS		NS	NS
Pill et al. UK, 1998 [25]			NS	NS		NS	NS	NS			
Smith et al. USA, 1997 [21]	NS	NS				Sig			NS		

Sig = significant at $p < 0.05$; NS = not significant at $p < 0.05$. * = Reduced saturated fat. # = systolic blood pressure. [α] =6 months follow-up.

CHAPTER 3

METHODS

Manuscript 2

Title: Motivational Interviewing for Diabetes Medication Adherence (MIDMA): Study Protocol, Lessons Learned, and Implications for Research with Implementation

Citation: Ekong G, Fox, B., Chou, C. E., Hunt, C., Lakin, J & Kavookjian, J. Motivational Interviewing for Diabetes Medication Adherence (MIDMA): Study Protocol, Lessons Learned, and Implications for Research with Implementation. *Manuscript in final preparation*

Abstract

Objectives: Diabetes self-management requires behavior change to attain adequate disease control. Medication nonadherence has been shown to negatively impact health outcomes, leading to increased risk of long-term complications, morbidity and mortality. Motivational Interviewing (MI) is an evidence-based, patient-centered approach for health behavior change with relevance for provider-patient communication in clinical settings. Motivational Interviewing (MI) is an evidence-based, patient-centered approach for health behavior change with relevance in clinical settings for provider-patient communication. This article describes the protocol and development phases for a study that assessed a brief semi-structured pharmacist-delivered MI-based intervention for diabetes medication adherence, using MI-based conversation tools among type 1 diabetes (T1D) and type 2 diabetes (T2D) patients in a hospital-based workplace wellness program (WWP).

Methods: A single-site, one-group pre-post intervention study with 3-month follow-up assessment examining the effectiveness of MI trained pharmacists using a semi-structured conversation tool on self-reported medication adherence. MI-trained clinical pharmacist (n=1) and PharmD resident (n=1) will deliver three sessions of MI-based counseling for medication adherence over 12 weeks using conversation tools adapted from the APhA Foundation DOTx.MED project. The study will include three phases for development, recruitment, and implementation.

Phase one activities include needs assessment for medication adherence barriers in the target population and MI training for the interventionists (pharmacist and PharmD resident). A needs assessment was conducted to identify the six most prevalently reported barrier types in the target population, which would inform the content/topics of the MI-based conversation tools to be applied in the pharmacist-patient encounters.

Phase two activities include recruitment efforts for study participants and baseline data collection. Recruitment activities include group recruitment events, invitation letters, flyers and phone calls by MI-

trained PharmD students. The primary outcome, medication adherence will be assessed using validated measures of patient self-report and medication refill records. Secondary outcomes include changes in clinical outcomes (glycemic control (hemoglobin A1C), blood pressure, and presence of depressive symptoms), humanistic outcomes (health-related quality of life and patient satisfaction with treatment), and economic/healthcare utilization outcomes (emergency department visits and hospital admissions).

Phase three activities will focus on intervention implementation, post-intervention and follow-up data collection activities. This report describes methods for the study, phase one results, and lessons learned in a real-world intervention setting.

Results: Of the 260 participants in the hospital-based worksite wellness program, 143 patients responded to the anonymous phase one needs assessment survey (n=143/260, 55% of the population). The results identified the six most frequently reported barriers to adherence in the target population. These patient-specified barriers were, forgetting, managing side effects, refilling prescriptions on time, taking medication during work/travels/weekends, depressive symptoms, and not understanding medication benefits. The communication tools were tailored for these topics. MI training outcomes for interventionists showed improvement in knowledge and confidence towards applying MI communication skills.

Conclusions: Findings from the needs assessment indicated barriers to medication adherence in the target population. These findings will be useful in designing the communication tools to address patient-specified reasons for medication nonadherence. Real-world patient care settings are fast-paced and provider-patient encounters are often brief and routine. Pharmacists trained in MI and using conversation aids to facilitate adherence problem-solving and goal-setting may impact diabetes outcomes. It is hoped that the results of the study will add to the growing literature on the effectiveness of MI in chronic disease management.

Introduction

Diabetes mellitus includes a range of metabolic diseases that lead to uncontrolled glycemic levels resulting from inadequate insulin secretion, insulin uptake, or both.[1] According to the Centers for Disease Control and Prevention (CDC), about 30 million of the US population are living with diabetes and 7.2 million with diabetes are undiagnosed.[2] Medication adherence plays a pivotal role in the long term control of diabetes-related complications[3], yet, the literature reports a 51% adherence rate with prescribed medications among T2D patients, and 21% of adolescents with T1D achieve the target glycemic goals set by the American Diabetes Association (ADA). [4-6]

The prevalence and burden of diabetes signal the need for interventions that promote positive changes in patient health behaviors in the self-management of Type 1 Diabetes (T1D) and Type 2 Diabetes (T2D). Behavioral interventions have been used for impacting the health behaviors important to managing T1D or T2D.[7] Health behavior change interventions are being offered to patients in various settings for chronic disease management. Workplace Wellness Programs (WWPs) offer a convenient setting to implement behavioral interventions. These programs are increasingly studied as a setting to implement behavioral interventions for chronic disease management among employee populations. In recent years, WWPs were reported in the literature as effective platforms to deliver behavior change interventions, improve employee health, boost productivity, and reduce health care costs.[8-11]

The CDC defined WWPs as "a coordinated and comprehensive set of health promotion and protection strategies implemented at the worksite that include programs, policies, benefits, environmental supports, and links to the surrounding community designed to encourage the health and safety of all employees".[12] Most WWPs are designed to promote healthy lifestyle, prevent disease, and/or provide support in the self-management of existing chronic health conditions.[13] Features of successful WWPs

have included evidence-based best practices, adequate resource allocation, and structured programs that support/fit organizational culture.[14]

In looking at strategies to address medication nonadherence and improve health outcomes, comprehensive patient counseling based on Motivational Interviewing (MI) is an approach with an evidence base for health behavior change.[15-18] The effectiveness and clinical utility of MI in promoting health behaviors is documented in addressing diverse health conditions, including diabetes management.[19] The impact of MI was first observed in treating addictions. The use of MI has now evolved as an intervention "tool-box" to help patients engage and sustain self-care behaviors needed for optimal chronic disease management.[20]

The application of MI encompasses patient-centered communication skills and a way of being referred to as the 'spirit of MI'. This "way of being" is characterized by relating with people in a purposeful, genuine, and person-centered way. There are four primary elements that reflect the 'Spirit of MI' and these include collaboration or partnership, acceptance, compassion, and evocation.[20] The primary communication principles of MI include expressing empathy, developing discrepancy, rolling with resistance/avoiding argumentation, and supporting self-efficacy. [20] Accurate empathy encompasses verbal and nonverbal communication that reflect compassion and genuine interest in the well-being of the patient, and is a purposeful way of communicating with patients with the primary aim of fostering a collaborative relationship which is needed for health behavior change conversations. The processes of MI require the interventionist to apply MI micro skills which include asking open-ended questions, supporting autonomy, affirmations (praise), reflections, and summaries.[21] These skills are applied with the sole aim of eliciting intrinsic motivation, sustaining and strengthening change talk, and consolidating specific action plans in partnership with the patient.

Findings from the literature support the need for investigations that assess the impact of MI-based interventions on medication nonadherence in diabetes.[8 15] One important project studying MI-trained pharmacists' intervention in diabetes self-management was the Discussions on Taking Medications for

Diabetes (DOTx.MED) pilot study conducted by the American Pharmacists Association (APhA) Foundation.[22] The primary objective of the study was to evaluate the effect of Structured Communication Interventions (SCIs) on diabetes medication adherence; results showed improvements in medication adherence after the intervention. A systematic search of the literature revealed a gap for future MI-based intervention research to further explore the target behavior of medication adherence in diabetes self-management.[8] This study serves to examine this gap within WWPs. The overarching objective of this study is to evaluate the effectiveness of a pharmacist-led MI-based counseling intervention on medication-taking behavior among adults with T1D and T2D in the unique setting of a WWP. The target population includes employees and employee dependents enrolled in a hospital-based WWP for diabetes management.

In this report, the study protocol is described, including methods and results for the needs assessment, training outcomes for the interventionists, and lessons learned in the first phase of the Motivational Interviewing for Diabetes Medication Adherence (MIDMA) study. The primary objective of the MIDMA study will be to assess the effectiveness of a semi-structured, pharmacist-led MI-based intervention in improving medication adherence among T1D and T2D patients in the hospital-based diabetes management WWP. This report will describe methods and implementation results for the first phase of the study as noted above. Implications for practice and dissemination-translational efforts of these methods in real-world patient care settings will also be discussed.

Methods

Study activities are divided into three phases including development, recruitment, and implementation of the intervention. The study duration is six months, divided into a three-month intervention phase and three-month follow-up time line. Data are collected at baseline, post-intervention, and three-month follow-up. Methods for all three phases will be described, with results presented only for the development phase (Phase One).

Study Design, Setting, and Participants

The study design is a single-site, prospective, pre- and post- intervention design with one group. The study is implemented in a convenience sample of hospital employees and their dependents with T1D or T2D currently enrolled in the hospital's diabetes WWP. The diabetes WWP currently has 260 participants enrolled in the program.

The setting of the study is the outpatient diabetes and nutrition center of a 350-bed regional hospital in a Southeastern state where diabetes is prevalent at a rate higher than the national average. The outpatient diabetes clinic offers comprehensive inpatient and outpatient diabetes education and management and is accredited by the American Diabetes Association (ADA). The healthcare team includes registered dietitians, nurses, pharmacists, certified diabetes educators, and an endocrinologist. The interventionists for this study were pharmacists and PharmD/PGY-1 residents who were present at the diabetes education center one day every week. This study was approved by the university and hospital Institutional Review Boards (IRB).

Sample

Participant eligibility criteria: Target participants were employees or employee dependents with T1D or T2D enrolled in the hospital's diabetes management WWP, aged 19 years or older, and who consented after being informed about the study. Current treatment at the time of recruitment was oral antihyperglycemic agents (AHAs), and/or injectables (e.g. insulin, and glucagon-like peptide-1 [GLP-1] analogues).

Exclusion criteria: Pregnant women, persons unable to complete the baseline assessments due to low English proficiency, and patients not filling their diabetes prescriptions at the hospital pharmacy were

excluded. The latter were excluded due to the proposed need for access to prescription refill data of study participants.

Sample size: An *a priori* power analysis approach was applied to determine the required sample size to power the analyses for the study. The sample size and effect size were based on recommendations by Cohen and colleagues, suggesting that sample sizes of 75 or greater are required for a medium effect size (0.20) in studies applying multiple regression for statistical analysis.[23] A literature search indicated effect sizes that ranged from 0.24 and 0.31 for studies similar to the MIDMA study, including the American Pharmacists Association Foundation's Dotx Med Project, which was a pilot study and served as a background for the MIDMA study. [24 25]

The required error margin of 5% (α =0.05) was determined to obtain the desired precision of 95% confidence interval. To account for an estimated potential attrition rate of 35%, efforts were made to recruit 120 participants. The G*Power software was utilized for sample size calculation.[26] All 170 eligible WWP employee participants were recruited for the study.

Rationale for Study Design

The prospective, pre-and-post study aims to evaluate intervention in a non-randomized sample, which is not uncommon in studies taking place in real-world practice settings and workflow. The overarching aim is to examine the potential for associations between an intervention and target variables. Control groups are often utilized, where feasible, to strengthen internal validity and claims for association or causation between target variables. However, a randomized controlled design was not feasible in the MIDMA study because of two reasons: 1) the study setting is a single site where one pharmacist (interventionist) and one PharmD resident are designated to provide medication therapy management services to patients enrolled in the WWP for diabetes management and therefore these are the available interventionists for this study and could potentially contaminate a control group, if one were used, by engaging their MI training with both groups[26], and 2) the organizational leadership for the study site

requested for the intervention to be offered to all WWP participants who would consent to join the study. For these reasons and time constraints preventing a cross-over design, a pre-and post-experimental design, where participating patients serve as their own control, was feasible in the MIDMA study.

Phase One: Development

Needs Assessment

A preliminary needs assessment was conducted among the target population to: 1) identify level of medication non-adherence within the target population, and 2) identify most prevalent medication adherence barrier topics to be included in development of the Structured Motivational Interviewing Tool (SMIT) conversation tools. This is an important first step within a population to ensure that the available barrier topic choices are salient or specific to the target participants while still being able to produce the tools before the encounters. To accomplish this, a brief, semi-structured survey was developed to ask about diabetes type and prescribed diabetes medications, how many days in the past week were any doses missed, and an open-ended section for the respondent to describe what prevents them from taking diabetes medications as prescribed when they do not. The survey was anonymous and voluntarily completed by patients in the waiting room of the diabetes clinic or online (Qualtrics) in response to an emailed request by the diabetes clinic director. Once data were gathered, a qualitative analysis was conducted by two researchers (GE and JK) to identify barrier topic themes and then quantify participant responses across the themes to reveal the six most prevalent to be included as topics for the semi-structured MI-based conversation tools.

Design of the Semi-Structured Motivational Interviewing Tools (SMITs)

The SMIT communication tools are based on MI principles, and are adapted in part from the DOTx.MED SCI structure. The SMITs are a set of paper-based tools intended to facilitate practitioner-patient communication in a brief, patient-centered interaction. The SMIT use autonomy support for the patient to select the most salient adherence barrier topic to discuss during the encounter. The SMIT design

includes a section to assess readiness or confidence (MI-based ruler) to start the conversation. The next section discusses possible solutions to barriers for each target reason for non-adherence and then goal setting for overcoming the barrier, and culminates in a signature area at the bottom for expression of commitment to the stated goal setting by the participant.

Once developed, the SMITs were pre-tested for face and content validity by obtaining inputs from three diabetes educators and other researchers experienced in survey design. The SMITs were then pilot tested for structure and delivery process with a group of approximately 15 participants and additional minor edits were then made based on inputs from the pharmacists who piloted them. The final version was produced with color graphics.

Motivational Interviewing Training for Pharmacists

MI is a complex skills set and way of being that relies on a series of applied practice and feedback processes to enhance skills uptake.[27] MI training for interventionists in this study included a two-day interactive overview and skills development training. This amount of training time has been described as adequate for base-level skills uptake and feasibility.[28]

The content for the evidence-based MI training model, developed by the experienced project collaborator and which had been applied in training approximately 3,000 practitioners across health professions, was applied. The training workshop began with exercises intended to create an interactive and supportive rapport among participants, and progressed through activities for cognitive development of MI concepts. This is a critical step leading to engaging participants in MI skills development exercises. The training was customized to fit the MIDMA project contexts relevant to diabetes and medication taking challenges. Cases for role-play were developed to incorporate the target contexts, patients, conditions/co-morbid conditions, and medication taking challenges.

The day-two exercises included two rounds of role play with MI expert facilitation and the feedback which MI originator William Miller asserts is a key strategy in effective MI training.[29] The small group role play ensures that everyone will get an optimal two turns to practice, get feedback, and reinforce MI skills development. Having the project pharmacists/residents participate in the training with a small group of other providers allowed for the implementation of the optimal group training model for the initial study personnel. With the subsequent departure of the primary pharmacist, and hiring of a new pharmacist, a second training was provided in brief format for the new pharmacist along with one other health care provider. Role play was conducted with these two trainees and the previously-trained resident.

A trainee pre- and post-knowledge assessment was administered, along with assessment of confidence. Competence was assessed at post training using the validated, Motivational Interviewing Skills in Health Care Encounters (MISHCE) instrument, which was validated for the specific MI training model applied among the study interventionists.[30] The MISHCE will also be used to assess intervention fidelity in the study implementation phase by using it to assess audio recordings of a random sample of actual patient encounters.

Phase Two: Recruitment and Incentives

Recruitment

Of the 260 patients in the diabetes WWP, 170 participants were identified as eligible using Electronic Health Records (EHR). Recruitment activities will include group enrollment events, phone calls, invitation letters mailed to eligible participants, and recruitment calls made by a team of MI-trained PharmD students. Potential participants could attend one of three group enrollment events to receive detailed information about the study, sign the consent form, and complete baseline data collection.

Retention Incentives

Potential participants are informed about the four random drawing events spread evenly across the study data collection points. Participants will be entered in raffle draws for a chance to win a $50 gift

card after completing data assessment at each data timeline (baseline, post-intervention and follow-up). The fourth raffle draw is meant to incentivize participants to complete all study activities since it will include persons who completed all three data collections.

Phase Three: Intervention Implementation and Data Collection

Pharmacist-Delivered MI Counseling for Medication Adherence

The intervention protocol includes a brief MI-based session focused on diabetes medication adherence and monthly scheduled meetings with the pharmacist for three months. Each session focuses on patient-specified reason(s) or challenges for non-adherence with diabetes medications. The pharmacist assesses medication adherence for each diabetes medication at the start of each meeting using the self-report measure, the Medometer.[31] The counseling session is audio taped for subsequent fidelity assessment. The process for each meeting is as follows:

1. The pharmacist or PharmD resident welcomes the patient and briefly summarizes the purpose of the meeting and informs/reminds the patient that the session will be audio-taped for research purposes.
2. The pharmacist/resident utilizes the autonomy-supporting MI micro skill known as "agenda setting" to ask the patient which of the SMIT medication taking barrier topics he/she would like to discuss. An organized folio with paper-based copies of all the target SMIT topics is available to the pharmacist to retrieve and use as a conversational tool at each meeting. In addition, medication adherence for each prescribed diabetes medication will be assessed at each meeting using the Medometer.[31]
3. Questions on the SMIT are used to elicit change talk; the goal-setting section is applied for collaborative goal-setting towards changing medication taking behavior by helping patients towards planning for resolving the chosen barrier topic. The MI-trained pharmacist/resident applies a patient-centered MI approach to guide the patient towards overcoming ambivalence to

behavior change (by supporting patient autonomy, eliciting patient-specified motivators or change talk, and collaborating on goal setting towards overcoming barriers for behavior change).

4. The pharmacist would make a copy of the completed SMIT for research data, and the patient would take the original with them. A refrigerator magnet with a clip on it was professionally produced as a reminder card to write upcoming intervention session appointments, and will be given to the participant to clip the completed SMIT to the home refrigerator as a reminder of the goal setting for overcoming the medication adherence barrier.

Data Collection and Outcome Measures

Major data collection points would occur at baseline, post-intervention, and follow-up (3 months after the post-intervention data collection). During the implementation phase, some variables would also be collected at each meeting (e.g., the completed SMIT document, and medication adherence self-report for each diabetes medication using the Medometer). Data sources would include EHR (A1C and blood pressure) and self-report using validated measures.

Primary Outcome Measures

The primary objective of the study iss to assess changes in medication adherence at each data collection. A multi-mode approach iss proposed to evaluate medication adherence based on an objective measure (calculated from participant prescription refill records) and a subjective measure (self-report of adherence). Including both objective and subjective measures is proposed to serve as a validation assessment for adherence.

Objective measure: The Proportion of Days Covered (PDC) is calculated from pharmacy refill records; the likelihood of achieving most of the potential clinical benefits from a diabetes medication is recognized at a threshold of at least 80%.[32] The PDC gives a conservative estimate of the adherence rate because it represents amount of time one actually possesses the medication and accounts for medication switching or multi-therapy.[32]

Subjective measure: Self-reported medication adherence will be measured with the Summary of Diabetes Self-care Activities - Medication Subscale (SDSCA) and also with the Medometer.[31]

The SDSCA-MS is a diabetes-specific validated measure used for assessing diabetes medication adherence and/or insulin use. The SDSCA as a whole is an instrument developed to evaluate self-care activities that impact diabetes management: general diet, specific diet, exercise, blood glucose monitoring, foot care, smoking, and medication adherence.[33] The SDSCA medication subscale is useful as a stand-alone measure of medication adherence and insulin use among patients with T1D and T2D.[34] Medication adherence is based on number of days in the last seven days that a medication was taken at the prescribed dose.[33] The overall score is calculated based on the average score across all the diabetes medication types taken by a participant (oral/injectable/insulin).[33]

The Medometer is a visual analog scale that was designed to resemble a speedometer.[31] Medication adherence is measured using a recall period of four weeks, with the adherence meter ranging from 0% (none of the doses taken) to 100% (all doses taken) and beyond to 120% (additional doses taken). The measure is particularly useful as a visual tool for assessing medication adherence during provider-patient encounters, particularly if there is concern about low literacy or health literacy in a patient population. In this study, the pharmacist will explain the scale to the participant and ask the participant to place a mark on the scale to indicate his/her level of medication adherence. The measure will be applied at each meeting to assess adherence for each prescribed diabetes medication.

Secondary Outcome Measures

Secondary outcomes include clinical, humanistic and economic outcomes. Target clinical variables are hemoglobin A1C, blood pressure (BP), and presence of depressive symptoms. The presence of depressive symptoms will be assessed using a validated self-report measure, the Patient Health Questionnaire (PHQ-9) which the study setting has already been using.[35] Humanistic outcomes collected in this study include quality of life and patient satisfaction. Quality of life will be collected using generic and disease-specific measures, the Medical Outcomes Study (MOS) Short-Form 12 (SF-12)[36] and the

Audit of Diabetes-Dependent Quality of Life (ADDQoL-19)[37], respectively. The validated Diabetes Treatment Satisfaction Questionnaire (DTSQ)[38] will be applied to collect patient satisfaction with treatment. Since cost data are not available, economic proxy indicators will be collected based on health care utilization variables. These will be collected in this study via self-report for number of emergency department (ED) visits and hospital admissions.

Intervention Fidelity Assessment

Intervention fidelity will be assessed to determine pharmacist adherence to the MI-basis for the intervention. Each pharmacist-patient encounter will be audio-taped and a random sample of audiotaped MI transcripts will be evaluated by one MI expert using the MISHCE, a validated measure of MI skills and is based on the MI training model used in this study as noted previously.[30]

Statistical Analyses

Prior to analysis, data is cleaned and inspected for missing data and normality. The Little's Missing Completely at Random (MCAR) test is used to determine whether missing data followed the MCAR pattern; a non-significant result would indicate that missing data could be treated as MCAR.[39] If the level of missing data is <5% and the MCAR's test is non-significant ($p<0.05$), missing data will be resolved using the imputation method, where missing data is replaced with the variable mean.

Data will be used to evaluate for deviation from normality using established normality statistics; recommendations suggested by Tabachnick and Fidell will be applied to resolve non-normal distributions.[40] Descriptive analysis will be used to evaluate target variables and trends in the application of the communication tools. All analyses will be performed using SPSS Windows, version 21 (IBM SPSS, Chicago IL, USA).

Results

Phase One Results

The results from the Phase One needs assessment, the development of the SMITs. and the training outcomes for the interventionists are reported in this section. In addition, intervention characteristics and implementation facilitators and barriers are reported as well.

Needs Assessment and Participants' Adherence Barriers

The needs assessment examined prevalence of nonadherence and prevalence of adherence barrier type in the target population to inform development of salient SMIT topics. Respondents **(**n=143/260, 55% of population) to the preliminary anonymous survey described previously reported their primary barriers to medication adherence. Table 1 summarizes the six most prevalent patient-specified adherence barrier themes identified in qualitative analysis of the open-ended survey responses were (1) remembering to take medications, (2) managing side effects, (3) understanding the benefits of diabetes medicines, (4) managing feelings of sadness or depression, (5) refilling a prescription, and (6) taking medications during work, on weekends, or during travels. The study developed and applied six SMIT communication tools tailored to these topics. Further, medication non-adherence was assessed as part of the needs assessment using the item, "indicate on a scale of 0-7 days, the number of days any dose was missed in the past week for diabetes medication/insulin". The patient was instructed to write down all prescribed diabetes medications and the number of days missed in a table that was included as part of the survey. The results indicated that 47.5% of the respondents reported being nonadherent to some degree.

Table 1. Medication Adherence Barriers Identified from the Needs Assessment (N=143)

Medication Adherence Barrier Topics	Frequency (%)
Remembering to take diabetes medications	43 (30.1)
Feeling down (depressive symptoms)	3 (2.1)
Managing side effects	4 (2.8)

Refilling a prescription	5 (3.4)
Understanding the benefits of diabetes medications	6 (4.2)
Taking medications during work, on weekends, or during travels	7 (4.9)

The intervention phase of the MIDMA pilot study (Phase 3) will involve the application of a patient-selected SMIT at each pharmacist-patient encounter. Each SMIT topic is tailored towards a conversation topic for medication nonadherence based on the themes in Table 1and participants will choose a currently salient topic for each prescribed diabetes medication/insulin at each meeting.

Motivational Interviewing Training for Interventionists

The knowledge pre-test administered before the training asked the interventionists their level of familiarity with MI (on a scale from 1-10, with 1 being least). Scores on overall familiarity with MI prior to the training among the pharmacists (two pharmacists over time) and PharmD resident ranged from 1-9, with the mean being 6.14. The resident had been previously exposed to the training model in her first year of pharmacy school. However, this exposure was four years prior to the study. The post-test scores for familiarity increased for each of the three interventionists, with scores ranging from 7-10 for overall MI familiarity after the training. The mean post-training familiarity score was 8.62, representing an increase in overall familiarity with MI of approximately 2.5 points from pre-training to post-training. Since the number of pharmacists was so small, tests for statistically significant differences were not applied.

The confidence question for both the pre- and post-tests asked the pharmacists to rate their confidence for using MI skills (on a scale from 1-10, with 1 being least). The mean pre-training confidence rating was 5.21. Post-training confidence for using the MI skills was rated at a mean 8.25, indicating a 3.04-point increase in confidence for using the skills after the training.

A previously established and validated internal MI test for conceptual and applications knowledge, based on the training model, was administered before and after the training. The test includes 17 multiple choice or true/false questions, including items asking for selection of the most MI-consistent response to a patient statement and within a pharmacist-patient dialog. The percentage of correct items for the pre-test knowledge assessment ranged from 67% to 81%. Post-test knowledge scores ranged from 78% to 91%**.**

It is the opinion of the MI expert role play facilitator that the three interventionists achieved a "proficient" level status, with two demonstrating higher than average skills acquisition when compared to others exposed to the training model over time.

Methods Implementation Challenges

As the time line for the intervention implementation approached, the MIDMA study required revisions to measurement and data collection plans due to unexpected EHR and organizational changes in the study setting. Due to a switch to new EHR system, some data, including prescription refills, were no longer readily available and the process for acquiring them from the prior system was complicated by the hospital's revelation of legal concerns since the patients were also employees of the hospital; in addition, the outpatient pharmacy was privatized during the course of the study, meaning the patient would have to engage another consent and four separate trips to the pharmacy or study setting office (separate building a half mile away) to acquire and provide their refill data since it was deemed that this could pose HIPAA and employer/employee privacy violations to conduct via email. These barriers influenced the decision to modify the data collection source for medication adherence to self-report only via the measures described previously.

Discussion

Diabetes management involves patient engagement and lifestyle modifications for positive health outcomes, and yet, health behavior change is difficult and overwhelming for most patients. Medication

adherence is a primary self-care behavior for optimal diabetes management, improved quality of life and reduction in risk of long-term complications.[3] Pharmacists offer various services, including medication therapy management, which provide unique opportunities for behavioral counseling interventions towards improving medication-taking behaviors. Further, the application of conversation aids that incorporate the patient's perspective is a promising approach to facilitate behavior change counseling in clinical settings.

Needs Assessment Discussion

The results of the needs assessment indicated that forgetfulness was the primary medication adherence barrier topic identified by most of the respondents. Medication nonadherence as a result of forgetfulness is a frequently reported, preventable barrier to medication adherence; several strategies are available to help patients remember to take their medications in a timely manner and reduce number of missed doses.[41] The literature reports effective strategies to improve adherence to prescribed medications. These strategies include phone-based reminders (text messages and smart phone applications), packaging/organizing options (e.g., blister pack and pill box), and others.[42 43] Electronic reminder options can prompt patients towards taking medications at the scheduled times [48], keep track of complex treatment regimens,[49] and improve overall medication adherence. It is important to note that the needs assessment results in this study are representative of the medication adherence barriers reported by this population. This step is a critical step in creating conversation topic tools that are salient within the target population.

MI Training Outcomes Discussion

In considering the training outcomes for the interventionists, overall knowledge of MI concepts and confidence in applying MI skills improved after training. The role-play and feedback process during the training was useful towards building confidence and enhancing skill uptake for the interventionists.[29] Further, previous research among student pharmacists briefly trained in MI indicated that higher levels of confidence after MI training was a significant predictor of a stronger intention to apply MI skills in future practice sites.[44] The case scenarios applied for the MI training sessions were designed to incorporate

medication adherence problems often experienced in T1D and T2D patient encounters. Training modules that are designed specifically for health care practitioners have been reported to enhance MI knowledge uptake and skills application.[45] Specific MI skills useful in face-to-face patient counseling include identifying and reinforcing change talk, expressing empathy, and rolling with resistance. Overall, the MI training structure and content in the current study was suited to the clinical context of the target patient population. Findings from this study will provide information on the effectiveness of a pharmacist-delivered MI intervention in improving diabetes medication adherence in a hospital-based WWP population and will hopefully inform methods that can be adapted for use in other potential health care settings and patient populations.

Limitations

Various strategies were integrated in the study methods to improve rigor; however, the study will be implemented in a real-world clinical setting and potential limitations in the study are acknowledged. First, selection bias is a potential limitation for studies that are non-randomized and participants are recruited from a small patient population. In addition, one of the study eligibility criteria is that participants need to refill their prescription at the hospital's pharmacy because the proposed study methods included prescription refill records as a data source to determine changes in medication adherence. This inclusion criteria could potentially introduce selection bias in the study.

Furthermore, it is important to ascertain the impact of unforeseen organizational changes on a research study prior to implementation. The collaborators at the practice site did not foresee the legal implications that the changes in employee data policy, privatization of the hospital's pharmacy department and changes in EHR platform would have on the study data collection process that was agreed upon ahead of time. These changes pose a limitation in accessing the proposed prescription refill records data for the study participants. Hence, the primary study outcome, changes in medication adherence will be based only on self-report data.

Next, the interventionists' limited schedule could pose a potential limitation for participants who may not be available to meet the pharmacist on the designated day that the pharmacists are scheduled to work in the diabetes clinic. The pharmacist and PharmD resident will be assigned to meet the patient for medication therapy management at the diabetes clinic once a week. The intervention phase of the study is structured to fit the interventionists' schedule and this restriction in scheduling could pose a constraint for some participants during the intervention phase.

Implications for Practice

The core elements of the SMIT were streamlined and modified based on identified barriers to medication adherence in the target population. Specifically, the SMIT was designed to be delivered in a tangible, paper-based format to enhance participants' engagement, and to enhance collaboration between pharmacist and patient. In addition, the intervention is structured to support participants' autonomy, where the SMIT topic to be discussed will be determined by the participant at the beginning of each meeting. In addition, the patient is given the autonomy to suggest other topics if all the SMITs topic do not apply to current barriers to medication adherence.

Finally, securing external funding would improve the compensation structure and potentially improve participation and retention. To encourage participation in the study, a raffle draw event will take place after each data collection phase to incentivize participation in the study. Four raffle draw events are scheduled across the study timeline for a chance to win a $50 visa card at each draw. However, winning the raffle draw is not guaranteed and this could pose a barrier to participation.

If the findings of the intervention phase of the study suggest support for impact of semi-structured encounters with an MI-trained pharmacist, this could help inform decision-making on ways to optimize provider-patient encounters towards improving patient engagement, self-care behaviors, and outcomes.

Implications for Research

The overarching objective of the MIDMA study is to improve health outcomes by impacting medication taking behavior. The innovative feature of the intervention is focused on the pharmacist-

delivered MI and SMITs components which may offer support to the pharmacist to strengthen self-efficacy for using MI skills in talking with patients and may strengthen patient self-efficacy towards striving for medication-taking goals. Potential contributions of the MIDMA study include examining the; (1) usefulness of MI counseling strategies for diabetes medication adherence and insulin use among adults with T1D and T2D, (2) clinical impact and economic benefits of engaging patients in brief, evidence-based health behavior change conversations aimed at impacting specific health behaviors, and (3) utility of the SMITs as conversation aids for eliciting change talk and gaining commitment to goal setting for a specific target behavior (medication adherence).

Conclusion

Medication adherence is one of the primary behavioral targets towards achieving optimal control in diabetes management. Pharmacists are in a unique position to offer patient-centered medication adherence interventions and provide support to overcome patient-specified reasons for medication non-adherence. Study findings serve to inform future research endeavors for interventions that could potentially impact medication-taking behavior where patient-specified barriers for medication nonadherence are addressed during provider-patient encounters and strategies to overcome adherence barriers are collaboratively explored during encounters. In summary, interventions designed to address both self-care knowledge and barriers to medication adherence could potentially impact medication-taking behavior and other self-care activities in diabetes management.

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CHAPTER 4

RESULTS

Manuscript 3

Title: Effects from a Pharmacist-led Intervention in a Workplace Wellness Program: The Motivational Interviewing for Diabetes Medication Adherence Study (MIDMA)

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Abstract

Objectives: Medication nonadherence is a major barrier towards attaining treatment goals in diabetes management. Workplace Wellness Programs (WWPs) provide a convenient setting for employers to implement programs that are focused on chronic disease prevention and management. Motivational Interviewing (MI) is a patient-centered counseling approach with proven effectiveness in helping patients adopt and sustain health behaviors for chronic disease management. Although studies have documented the impact of MI in diabetes management, the effectiveness of an integrated, pharmacist-delivered approach using MI-based communication prompt tools to help patients decide to modify medication-taking behavior remains unknown among diabetes patients enrolled in a WWP. This study assessed a brief pharmacist-delivered, MI-based intervention for diabetes medication taking behavior among patients with type 1 diabetes (T1D) and type 2 diabetes (T2D) in a hospital-based WWP.

Methods: A prospective, one-group, pre- and post-intervention study with three months follow-up was implemented. Pharmacists trained in MI delivered three face-to-face sessions of brief MI-based counseling using semi-structured conversation tools that support patient-specified reasons for medication nonadherence. The three sessions were delivered over a 12-week timeline in a diabetes clinic's outpatient education center. Study duration was six months and primary data were collected at baseline, post-intervention (3 months after baseline), and at follow-up (3 months after post-intervention) using self-report and Electronic Health Record (EHR). The primary outcome was change in self-reported medication adherence at each MI session (based on the Medometer measure) and at each primary data collection time point (based on the Summary of Diabetes Self-care Activities- Medication Subscale (SDSCA-MS)); the secondary outcomes were change in clinical outcomes (hemoglobin A1C, blood pressure, and depressive symptoms), humanistic outcomes (health-related quality of life and patient satisfaction with treatment), and economic indicators (health care utilization using emergency department visits and hospital admissions).

Results: Of the 170 eligible participants in the WWP, 53 consented to the study (31.2% of the target population); most of the participants were female 30(56.6%), average age was 54 years, and T2D was the predominant diagnosis 48(90.6%). Medication adherence based on the Medometer showed a statistically significant change from baseline to post-intervention, $t_{(35)} = -4.485$, $p < 0.00$; the SDSCA-MS results showed improvement in medication adherence, but it was not statistically significant. Among the clinical variables, diastolic blood pressure showed a statistically significant improvement, $F_{(2, 70)} = 3.57$, $p = 0.034$. Other clinical outcomes demonstrated changes, but they were not statistically significant. The Physical Component Summary (PCS) score and Mental Component Summary (MCS) score on the Short Form-12 (sf-12) measure for health-related quality of life increased significantly from baseline to follow-up; PCS, $F_{(2, 58)} = 7.53$, $p = 0.003$ and MCS, $F_{(2, 58)} = 3.92$, $p = 0.025$. Diabetes treatment satisfaction and economic indicators (emergency department visits and hospital admissions) did not show statistically significant improvement.

Conclusions: Findings from this pilot study support the clinical utility of an integrated semi-structured MI-based counseling encounters to improve medication nonadherence and health related quality of life in a WWP for patients living with T1D and T2D. Further investigation using a larger sample and control group is needed to fully explore MI impact towards modifying target behaviors for diabetes management.

Introduction

Health behavior change and adherence to prescribed medications are important targets for striving to achieve improved glycemic control and positive health outcomes in diabetes management. The Centers for Disease Control and Prevention (CDC) estimates that diabetes affects 30.3 million people in the United States and more than 1 in 4 patients are undiagnosed.[1] A 2017 report by the American Diabetes Association (ADA) indicated the economic burden of treating diagnosed diabetes in the United States was estimated at $327 billion.[2] The American Association of Diabetes Educators (AADE) identified seven target behaviors that are useful for diabetes management; these behaviors include medication adherence, healthy eating (diet), blood glucose monitoring, being active (increased physical activity (exercise)), healthy coping, problem solving, and reducing risks.[3] Medication nonadherence among patients living with diabetes has been linked to increased risk of complications, morbidity and mortality.[4] Since, medication nonadherence is an impactful and modifiable self-management behavior, this suggests a need for health care providers to engage strategies to help patients adopt and maintain this key health behavior.

Although various behavior change strategies are available to help patients adhere to treatment regimens, Motivational Interviewing (MI) is a patient-centered approach to facilitate behavior change conversations during provider-patient encounters.[5] The literature reports few published studies of MI-based medication adherence interventions for diabetes patients, although MI has been shown to be effective in modifying dietary behavior,[6] enhancing weight loss,[7] and improving glycemic control.[8] The fundamental objective of MI encounters is to elicit intrinsic motivation and overcome ambivalence towards changing a target behavior. The interventionist approaches the patient with the spirit of MI, which is a clinical "way of being" that is based on three primary elements: collaboration (between the interventionist and the patient), evocation (eliciting motivation for change), and emphasizing the autonomy of the patient.[5] In addition, MI principles should be incorporated in the conversation and these include expressing empathy, supporting self-efficacy towards behavior goals, rolling with resistance/avoiding argumentation, and developing discrepancy (between present circumstances and

patients' specified desires or goals). [5] Pharmacist-patient encounters offer a great opportunity to apply MI-based communication skills towards modifying medication taking behavior. Various settings offer the opportunity for providers to impact patients' health behaviors towards optimal disease management, and these includes inpatient settings, outpatient clinics, community pharmacy settings, and Workplace Wellness Programs (WWPs).

A WWP is defined as any workplace health promotion activity or organizational policy designed to support employee health behavior and chronic disease prevention and management, to improve health outcomes.[9] Witt and Ablah identified three goals that motivated employers to adopt WWPs.[10] These included 1) lowering heath care costs, 2) addressing human relations objectives, and 3) improving employee productivity. In recent years, WWPs are reported in the literature as effective platforms to deliver behavior change interventions, improve employee health, boost productivity, and reduce health care costs. [6 11-13] A well-designed WWP offers a convenient setting for providers to implement behavior change interventions focused on specific health behaviors for chronic disease management such as medication nonadherence, increased physical activity, dietary changes, and disease monitoring.

Studies that support the effectiveness of this approach include the landmark Asheville study[14] and the pilot study jointly developed and implemented by the American Pharmacist Association (APhA) and the APhA Foundation, known as the Discussions on Taking Medications (DOTx.MED) Diabetes pilot program.[15] In the Asheville study, pharmacists delivered diabetes disease management in a workplace wellness initiative for employees of the City of Asheville living with T1D and T2D. The results from the Asheville study showed a significant improvement in glycemic control and satisfaction with pharmacy services. Long-term outcomes (5 years) indicated a reduction in direct medical costs.[14] The DOTx.MED study evaluated the impact of pharmacist-delivered MI-based, Structured Communication Interventions (SCIs) among T2D patients. The SCIs were designed as quick conversation guides for pharmacists in a community pharmacy setting. The intervention goals centered around improving provider-patient communication, diabetes medication adherence, and patient satisfaction. The primary outcome of

medication adherence, based on the proportion of days covered, improved for the intervention group by 6.55% after 180 days, while the control group improved by 3.75%.

The positive results reported in the DOTx.MED study support the potential for MI in helping patients engage in medication-taking behavior, and indicate the need to explore the effectiveness of structured MI counseling for diabetes medication adherence among diabetes patients. The significance and potential contribution of the current study includes 1) identifying the usefulness of pharmacist-delivered MI-based counseling to improve medication adherence, 2) the utility of conversation tools based on patient-specified reasons for medication nonadherence in pharmacist-patient encounters, and 3) the compatibility of brief behavior change interventions in the clinical setting workflow.

The current study, the Motivational Interviewing for Diabetes Medication Adherence (MIDMA) study, was designed to evaluate the effectiveness of a pharmacist-delivered, MI-based counseling intervention using semi-structured communication aids (Structured Motivational Interviewing Tools (SMITs)) to modify medication-taking behavior in patients with T1D and T2D enrolled in a hospital-based diabetes management WWP. The primary objective of the study was to evaluate the effects of the intervention on diabetes medication adherence. The secondary objectives of the study were to assess changes in clinical outcomes (A1C, blood pressure and depressive symptoms), humanistic outcomes (health-related quality of life and patient satisfaction with treatment), and economic indicators (emergency department visits and hospital admissions).

Methods

Study Design and Setting

A summary of study methods is provided here since the detailed study methods are described elsewhere.[16] The study design was a single-site, prospective, pre and post design with one group. Study duration was six months occurring across a 3-month intervention and a 3-month follow-up. Data were collected at baseline, post-intervention, and at follow-up assessment. The study interventionists were

pharmacists and a PharmD resident who offered clinical services at the diabetes center on one fixed day each week.

The study setting was the outpatient diabetes clinic of a 350-bed regional hospital and participants were recruited from the diabetes management WWP offered by the hospital to employees and employee dependents. The diabetes outpatient clinic' education program is accredited by the ADA and offers comprehensive diabetes care and education. The interdisciplinary healthcare team includes nurses, pharmacists, certified diabetes educators, registered dieticians, and an endocrinologist. This study protocol was approved by the university and hospital Institutional Review Boards (IRB).

Participants

Eligibility criteria for participation included enrollment in the hospital-based WWP, aged 19 years or older, and with prescribed current treatment at the time of recruitment of oral hypoglycemic agents (AHAs), and/or injectables (e.g. insulin, and glucagon-like peptide-1 [GLP-1] analogues).

Sample size and power

A prospective or a priori power analysis approach was applied to determine the required sample size to power this study. The G*Power software was utilized for sample size calculation.[17] Recommendations by Cohen and colleagues was applied in determining the required sample size and effect size for the MIDMA study.[18] These recommendations indicate that sample sizes of 75 or greater are required for a medium effect size (0.20) in studies that utilized multiple regression for statistical analysis. Effect sizes that ranged from 0.24 to 0.31 was reported in the literature in studies similar to the MIDMA study, including the Dotx Med Project, which was a pilot study and served as a background for the MIDMA study.[14 19] The required error margin was 5% (α =0.05) with a 95% confidence interval. The study activities were divided across three phases and these are summarized in Figure 1.

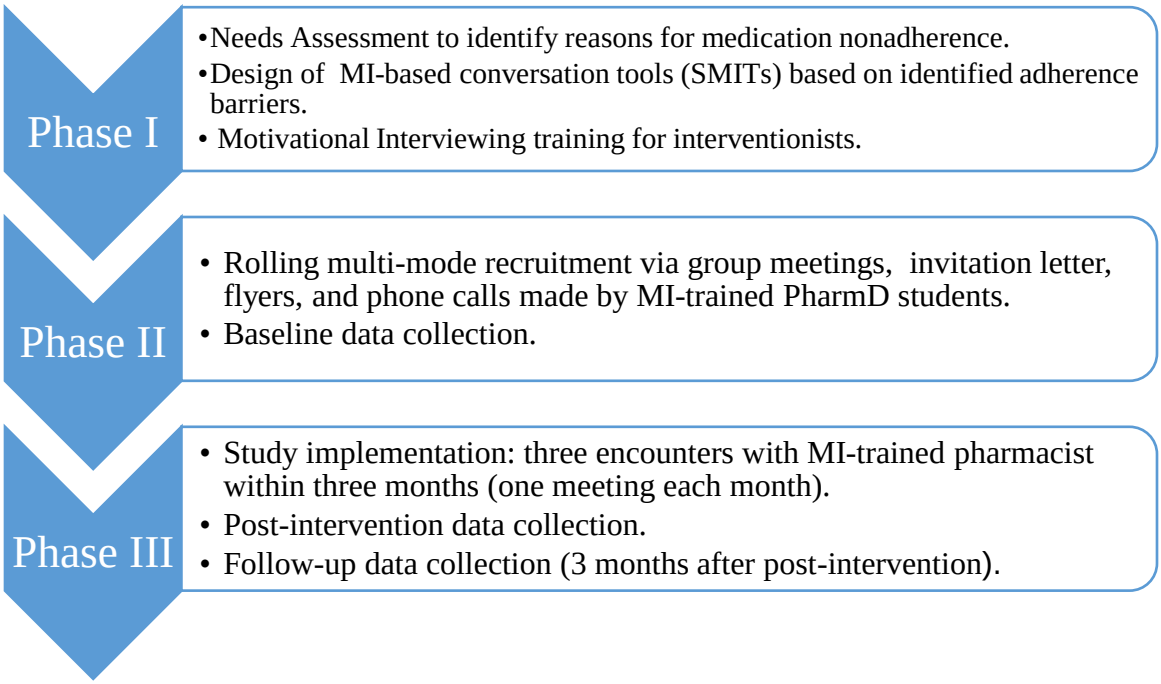

Figure 1: Flowchart of MIDMA Study Phases

Phase One Methods

Phase one included a needs assessment to determine prevalence of nonadherence and prevalence of salient barriers to adherence in the target population, development of the semi-structured MI conversation tools (SMITs), and MI training for the interventionists.

Needs Assessment and Development of the SMITs

Details for the methods used in the needs assessment and SMIT development are reported elsewhere.[16] In summary, after qualitative analysis was conducted by two researchers (GE and JK) to identify most salient themes, the responses to the open-ended questions in the anonymous survey of the target population asking for report of reasons for nonadherence (barriers) were quantified across themes to determine the six most prevalent. The six paper-based SMIT options were formed using these topics

and incorporated relevant MI skills and micro skills (eliciting change talk, autonomy support, self-efficacy support, goal setting, and commitment signature for reinforcement of the commitment).

Motivational Interviewing Training for Interventionists

Details on training and intervention structure are described elsewhere.[16] Briefly, MI training was based on a two-day workshop for a group of eight practitioners that included the interventionists, two clinical pharmacists and a PharmD resident. The training model is described elsewhere and included role-play and feedback exercises for MI skills application relevant to medication adherence among patients with T1D and T2D.[16] Trainee knowledge and confidence was assessed before and after the training. Interventionists' competence and intervention fidelity were assessed using the Motivational Interviewing Skills in Health Care Encounters (MISHCE) instrument; a validated measure for MI skills and fidelity assessment and is based on the specific MI training model applied among the study interventionists.[20]

Phase Two Methods

Recruitment, Incentives, and Baseline Data Collection

Eligible patients were identified using the Electronic Health Records (EHR); recruitment efforts included group enrollment events, mailed letters, and study flyers. In addition, study recruitment phone calls were made by MI-trained PharmD students to eligible WWP participants. Participation was incentivized by offering four random raffle draw events for a chance to win a $50 gift card for those participants completing data assessment at each data timeline (baseline, post-intervention and follow-up). The fourth raffle draw was to incentivize participants to complete all study activities. Baseline data collection took place just after a researcher conducted the informed consent and before interacting with the pharmacist.

Phase Three Methods

Intervention Process

The intervention was based on one-on-one brief MI-based counseling; three sessions were offered across the 3-month intervention time line. In brief, at the start of each meeting, the pharmacist assessed the patient's medication adherence for each diabetes medication using the Medometer,[21] a self-report measure that resembles a speedometer. To support patient autonomy, the patient was asked to choose one of the six SMIT topics, based on their perception of their current primary barrier to medication adherence. The SMIT was used to guide the conversation, with sections that included a ruler of confidence, frequency, or importance for the target barrier/behavior, MI-based inquiry to elicit change talk/motivations, patient ideas for how to overcome the barrier, and specific goal-setting for overcoming the barrier. At the end the meeting, the completed SMIT document was signed and dated by the patient. The pharmacist gave the original of the document to the patient and encouraged him/her to keep the document in a visible place (e.g. refrigerator door) as a reminder of patient-specified goals for medication adherence.

Intermediate Variables and Self-Report Psychosocial Variables

Medical history variables were collected based on self-report and included diabetes type, treatment type, duration of disease, duration of participation in the WWP, and comorbid conditions. In addition, diabetes self-management knowledge was measured using an 8-item knowledge questionnaire which evaluates diabetes general self-management knowledge using multiple-choice questions. The measure was developed by the health care team at the study setting, based on the content for ADA-accredited diabetes education classes. Higher scores on the survey imply higher knowledge of diabetes self-management behaviors. In addition, the short form version of the Marlowe-Crowne Social Desirability Scale (MC-SDS) questionnaire was collected to evaluate the potential presence of social desirability bias in self-reported data.[22] Scores on the MC-SDS were correlated with target variables to

determine the potential presence of social desirability bias in the self-report of behavioral and psycho/social variables.

Psychosocial variables were collected to assess relationships with medication adherence and glycemic control. Two psychosocial variables were collected, diabetes self-efficacy for medication adherence and diabetes distress. The Diabetes Medication Self-Efficacy Survey (DMSES) was used to assess self-efficacy for diabetes medication taking behavior.[23] The measure is a 9-item Likert-type scale that evaluates confidence for medication taking behavior in various uncomfortable or tempting situations. The scale is anchored to reflect level of confidence in taking diabetes medication as prescribed (1=definitely not confident, to 5 = definitely confident). Possible scores range from nine to 45, with higher scores signifying higher levels of confidence in ability to engage in diabetes medication adherence.

Emotional and/or psychological distress have been reported to interfere with optimal adherence to diabetes self-management behaviors. Diabetes distress was measured using the Problem Areas in Diabetes (PAID-5) survey.[24] Possible scores range from 0 to 20 with higher scores suggesting greater emotional distress related to diabetes self-management.

Data Collection and Outcome Measures

Medication adherence measures

The primary objective of the study was to assess changes in medication adherence at post-intervention and follow-up assessment. Self-reported medication adherence was measured with the Summary of Diabetes Self-care Activities - Medication Subscale (SDSCA-MS) [25] and also with the Medometer.[21] The SDSCA-MS is a diabetes-specific validated measure used for assessing diabetes medication adherence and/or insulin use. The SDSCA as a whole is an instrument developed to evaluate self-management activities that impact diabetes management: general diet, exercise, blood glucose monitoring, foot care, smoking and medication adherence.[25] The SDSCA medication subscale is useful as a stand-alone measure of medication adherence and insulin use among patients with T1D and T2D. [25 26]

Medication adherence is based on number of days in the last seven days that medication was taken at the prescribed dose.[25] The overall score is calculated based on the average score across all the diabetes medication types taken by a participant (oral/injectable/insulin).[25]

The Medometer is a visual analog scale that was designed to resemble a speedometer.[21] Medication adherence is measured using a recall period of four weeks, with the adherence meter ranging from 0% (none of the doses taken), to 100% (all doses taken), and beyond to 120% (additional doses taken). The measure is particularly useful as a visual tool for assessing medication adherence during provider-patient encounters, particularly if there is concern about low literacy or health literacy in a patient population. In this study, the pharmacist explained the scale to the participant and asked the participant to place a mark on the scale to indicate the level of medication adherence. The measure was applied at each meeting to assess adherence for each prescribed diabetes medication.

Clinical outcomes measures

Clinical variables were A1C, blood pressure (BP), and presence of depressive symptoms. The hemoglobin A1C is a valuable indicator of average glycemic control over the past three months and is therefore collected at 3-month intervals for patients enrolled in the diabetes management WWP at the study setting. The A1C values used for data analysis were from the most recent test result recorded in the EHR (~ 1-3 months prior) for each data collection point (baseline, post-intervention, and follow-up). In addition, to examine potential validity threats from variability in timing of A1C collection in the pre-intervention phase, participants' A1C were analyzed from the previous 12 months before baseline assessment. The average was compared with baseline A1C to assess significant differences in previous 12-month average A1C and most recent A1C.

Blood pressure was assessed by clinical staff at each data collection and saved in the EHR. Both A1C and blood pressure values were collected from the EHR for study purposes. The presence of depressive symptoms was assessed using a validated self-report measure, the Patient Health

Questionnaire (PHQ-9).[27] The PHQ-9 was developed as a routine screening tool in outpatient settings and also includes one item that screens for suicide ideation in major depressive disorders (MDD).[27] Since, the PHQ-9 is routinely administered at this study setting and a protocol is in place for treatment of depression or suicidality is identified, the PHQ-9 protocol at the study setting was added to the MIDMA study protocol as well. The cut-off values for the clinical indicators were based on recommendations by the American Diabetes Association (ADA) Standards of Medical Care in Diabetes[28] and the PHQ-9 interpretation guide[27]: A1C <7%, systolic blood pressure (SBP) <130 mmHg, diastolic blood pressure (DBP) <80 mmHg, and PHQ-9 scores of 0-4, 5-9, 10-14, 15-19 and 20-27 indicating categories of depressive symptom severity at 'none,' 'mild,' 'moderate,' 'moderately severe' and 'severe depression,' respectively.

Health related quality of life (HRQoL) measure

Generic and disease-specific measures are applied in this study to collect self-report of health related quality of life; the Medical Outcomes Study (MOS) Short-Form 12 (SF-12)[29] was the generic measure and the Audit of Diabetes-Dependent Quality of Life (ADDQoL-19) was the diabetes-specific measure.[30]

The SF-12 is a valid and reliable generic instrument derived from the short-form 36 questionnaire.[29 31] Assessment of HRQoL was based on two summary scores, the physical component summary (PCS) score and the mental component summary (MCS) score. Items on the PCS include report for level of physical limitation or impact in performing moderate activities; the MCS includes items on emotional and psychological wellbeing. The PCS and MCS scores ranges from 0 (worse) to 100 (best), with higher scores implying better HRQoL.

The ADDQoL-19 assesses the importance and impact of diabetes on perceived QoL based on three primary scores, "Present QoL score", "Diabetes-dependent QoL score", and "Average weighted impact score". [32] The "Present QoL score" evaluates the current QoL status of the patient using a scale

(+3 = excellent to -3 = extremely bad). The "Diabetes-dependent QoL score" evaluates patients' quality of life in the absence of diabetes (+3 = very much better to -1 = worse). Each of the 19 items assesses how diabetes impacts a specific life domain and the importance of that life domain to the patient. Five domains are given the option of "Not Applicable" and these items evaluate work life, intimate relationships, vacation, the presence of family/relatives, and sexual life. The "impact score" is multiplied by the "importance score" to obtain the weighted impact score. The "Average weighted impact score" is obtained by averaging the weighted impact score obtained from the 19 diabetes-specific domain items. A final, open-ended question further measures a patient's global perception of the impact of diabetes on HRQoL.

Patient satisfaction with treatment measure

Patient satisfaction was measured using the Diabetes Treatment Satisfaction Questionnaire (DTSQ).[33] The DTSQ status ($DTSQ_s$) was collected at baseline, and DTSQ change ($DTSQ_c$) at post intervention and follow-up. The DTSQs is different from the DTSQc scale in that the DTSQs scale is anchored as 0 = very dissatisfied to 6=very satisfied, and possible scores range from 0 to 36. A middle zero point in the DTSQc scale indicates a lack of change after the intervention (3 = much more satisfied now to -3 = much less satisfied now) and possible scores range from -18 to +18. However, perceived frequency of hyperglycemia and hypoglycemia (items 2 and 3) were evaluated independently based on the questions, "how often have you felt that your blood sugars have been unacceptably high recently?" and "how often have you felt that your blood sugars have been unacceptably low recently?". Responses to these two items was based on the same scale, but with a different anchor wording (3 = much more of the time now to -3 = much less of the time now). The scale was interpreted in reverse where a lower score indicates less feelings of hyperglycemia, hypoglycemia, or fewer events taking place. Participants were instructed to respond to the DTSQ based on changes in their experience with current treatment before and after the MI-based counseling intervention for medication adherence.

Healthcare utilization variables and measures

Health care utilization variables were collected to represent economic outcomes in a proxy variable manner. These were collected in this study via self-report for number of emergency department (ED) visits and hospital admissions. A 6-month recall period was used to collect these variables at baseline and a 3-month recall period was used at post-intervention and follow-up assessments.

Statistical Analyses

Prior to analyses, data were cleaned and inspected for missing data and normality. The Little's Missing Completely at Random (MCAR) test was used to determine whether missing data followed the MCAR pattern; a non-significant result would indicate that missing data could be treated as MCAR.[34] Since, the level of missing data was <5% and the MCAR's test was non-significant ($p<0.05$), the problem of missing data was resolved using the imputation method, where missing data were replaced with the variable mean at baseline and post-intervention.

The last-observation-carried-forward (LOCF) method was applied at follow-up to improve sample size for statistical analyses. The LOCF method involved inputting post intervention assessment data for participants who dropped out of the study at the follow-up assessment. As noted previously, the threshold values for clinical outcome variables were based on recommendations by the American Diabetes Association (ADA) Standards of Medical Care in Diabetes[28] and the PHQ-9 interpretation guide.[27]

Table 1 summarizes the data analyses plan. Data were evaluated for deviation from normality using established normality statistics; recommendations suggested by Tabachnick and Fidell were applied.[35] However, none of the study variables required transformation for data analyses. Descriptive analyses were used to evaluate demographic and medical history variables and target variables. A parametric or non-parametric statistical method was used based on data deviation from normality. To identify variables that significantly correlated with medication adherence or glycemic control, the correlation coefficient (Pearson Product Moment or Spearman's rho) was applied. Statistical tests from

the data analysis plan were applied (t-test, repeated measures ANOVA, Mann-Whitney U test, or the Kruskal-Wallis test) to determine significant changes among target variables. An a priori significance level of $p < 0.05$ was used for all statistical tests. All analyses were performed using SPSS Windows, version 21 (IBM SPSS, Chicago IL, USA).

Table 1. Target Outcomes, Measures and Data Analyses

Outcome variables	Measures	Statistical Analysis
Part 1: Change in diabetes medication adherence.	Self-report:	Analysis 1: To determine significant changes in medication adherence:
	Summary of Diabetes Self-care Activities (SDSCA) medication subscale	Wilcoxon signed rank test
	Medometer	Paired sample t-test
Part 2: Factors that significantly relate with medication adherence	SDSCA-MS	Analysis 2: To determine variables with significant correlation to medication adherence at post-intervention:
		Pearson Product Moment or Spearman's rho
Part 1: Change in clinical indicators	EHR: Hemoglobin A1C and blood pressure Self-report: Presence of depressive	Analysis 1: To determine changes in clinical indicators post intervention and at follow-up:
		Repeated measures ANOVA

	symptoms (Patient Health Questionnaire (PHQ-9))	
Part 2: Factors that significantly relate with glycemic control	Hemoglobin A1C	Analysis 2: To determine variables with significant correlation to glycemic control at post-intervention:
		Bivariate correlation: Pearson Product Moment or Spearman's rho
Part 1: Changes in health care utilization	Emergency department visits and hospital admissions	Analysis 1: Descriptive statistics to evaluate changes in healthcare utilization variables from baseline to follow-up: Frequencies and percentage
Part 2: Changes in humanistic outcomes	Quality of life (QoL); Short Form-12 (SF-12) and Audit of Diabetes -Dependent Quality of Life (ADDQoL-19)	Analysis 2: To determine changes in HRQoL and patient satisfaction with treatment from baseline to follow-up
		Repeated measures ANOVA
	Patient satisfaction; Diabetes Treatment Satisfaction Questionnaire (DTSQ)	Paired sample t-test

Results

Participation and Sample Characteristics

At baseline, 53 of the 170 eligible WWP members enrolled, resulting in a participation rate of 31.2%. Baseline characteristics included a higher percentage of female participants 30(56.6%), an average

age of 54 years, average diabetes disease duration of 10 years, and average duration of enrollment in WWP of 6.4 years. Most of the participants were married 35(71.4%), completed high school 21(42%) or college 17(34%) and the predominant diagnosis was T2D, 48(90.6%). In addition, bivariate correlation statistics was applied to compare participants' self-report data with the MC-SDS questionnaire as part of the effort to identify the potential presence of social desirability bias. The results indicated a nonsignificant relationship between the MC-SDS and participants self-report data.

At post-intervention, 36 participants had completed all pharmacist-patient encounters and data collections, resulting in 32% attrition. At the end of the study, after the three-month follow-up period, 28 participants completed the follow-up data assessment giving an overall attrition rate from baseline of 47%. The flow diagram for enrollment and retention from baseline to follow-up is shown in Figure 2 and participants' characteristics at baseline are described in Table 2.

Table 2. Baseline participant characteristics (n=53)

Variables*	**n (%)**
Gender	
Male	23 (43.4)
Female	30 (56.6)
Race	
Caucasian	25 (47.2)
African American	26 (49.1)
Hispanic	2 (3.8)
Education Level Completed	
Junior high	1 (2.0)
High school	21 (42.0)
College	17 (34.0)

Trade school	7 (14.0)
Post graduate	4 (8.0)
Marital Status	
Single	5 (10.2)
Married or with partner	35 (71.4)
Divorced	5 (10.2)
Widowed	4 (8.2)
Diabetes type	
Type 1 diabetes	5(9.4)
Type 2 diabetes	48(90.6)
Diabetes medication Group	
Oral	32(60.4)
Non-insulin injectables	1 (1.9)
Insulin	5 (9.4)
Combination	15 (28.3)
	Mean (SD)
Age (years)	54.0 (8.7)
Duration of diabetes disease (years)	10.0 (6.9)
Participation in WWP (years)	6.4 (3.9)
Marlowe-Crowne Social Desirability Scale	10 (2.1)

*= Not all participants reported their demographic variables. WWP= Worksite Wellness Program

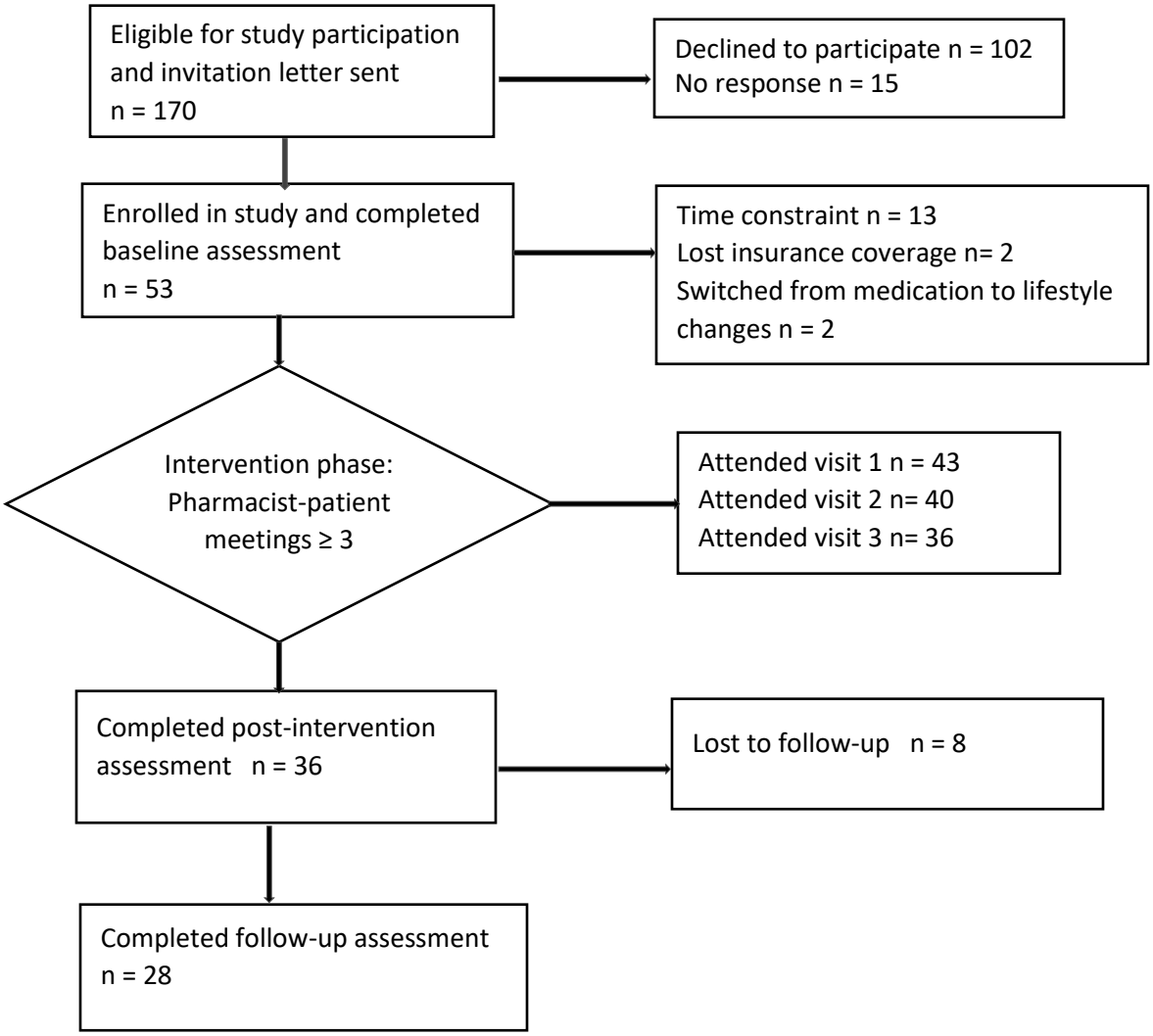

Figure 2: Participation flow chart and data collection sequence

Completers and Non-completers

Participants who completed all study activities (n=28) did not differ from those who did not complete the study (n=25), by type of diabetes diagnosis ($t_{(51)} = -1.51$, $p = 0.136$), diabetes medication category ($t_{(51)} = -0.59$, $p = 0.55$), ethnicity ($t_{(51)} = -0.072$, $p = 0.943$), age ($t_{(50)} = -1.048$, $p = 0.299$), gender ($t_{(51)} = -0.629$, $p = 0.532$), level of glycemic control ($t_{(51)} = -0.286$, $p = 0.776$), knowledge of diabetes self-management ($t_{(51)} = 0.363$, $p = 0.718$), presence of comorbid conditions ($t_{(51)} = 0.07$, $p = 0.942$), and satisfaction with perceived levels of hyperglycemia ($t_{(51)} = -2.032$, $p = 0.047$). However, statistically significant differences were observed between participants who completed the study compared to participants who did not complete on their level of education, $X^2 (4, N=50) = 4.31$, $p = 0.038$, and duration of participation in the WWP ($t_{(51)} = -3.043$, $p = 0.004$). Most of the participants who completed the study had a college degree and average duration of participation in the WWP was 8 .0 years (SD =3.56). Among those who did not complete, most had completed high school and average participation in the WWP was 4.5 years (SD = 3.60). Overall, a higher level of education and a longer duration of participation in the WWP was reported among participants that completed the study compared to participants who did not complete. Furthermore, many of the participants who dropped out of the study at the intervention phase had indicated a lack of time to accommodate study activities (n=13). A few participants (n=2) indicated that they had lost their insurance coverage, which implies cost as a barrier

Implementation Outcomes for the Structured Communication Tools (SMIT)

Patient SMIT Selections

The intervention phase of the MIDMA pilot study involved the application of the SMIT at each pharmacist-patient encounter. In looking at frequency of SMIT topic use, the most common patient-specified reason for medication non-adherence at the *first* of the three meetings was “remembering to take diabetes medications” 13(30%). Other SMIT topics selected in the first session as medication adherence barriers for current discussion by patients included managing side effects 9(21%), not understanding the benefits of their diabetes medication 9(21%) and taking medication during off-schedule times 9(21%). The SMIT topic that addressed feeling down as a primary reason for medication nonadherence at the first

pharmacist-patient encounter was the least selected topic 3(7%). The results on the implementation of the SMIT across all three pharmacist-patient encounters are summarized in Table 3.

Table 3. Implementation of SMIT and Frequency of Delivery

SMIT	Frequency of SMIT delivery n (%)		
	Visit 1 (N=43)	**Visit 2 (N=40)**	**Visit 3 (N=36)**
Feeling down (depressive symptoms)	3 (7.0)	7 (17.5)	6 (16.7)
Managing side effects	9 (21.0)	7 (17.5)	4 (11.1)
Refilling a prescription	0	6 (15.0)	6 (16.7)
Understanding the benefits of diabetes medications	9 (21.0)	9 (22.5)	8 (22.2)
Taking medications during work, on weekends, or during travels	9 (21.0)	9 (22.5)	9 (25.0)
Remembering to take diabetes medications	13 (30)	2 (5.0)	3 (8.3)

SMIT = Structured Motivational Interviewing Tools

Pharmacist-reported Perceptions of Using the SMIT

Semi-structured interviews with the study pharmacists regarding their perceptions and confidence in using the SMITs to facilitate patient behavior and goal setting conversations were conducted and suggest that the SMITs were perceived as useful. The interventionists (pharmacists) reported that they liked using them; they expressed that the conversation tools increased their confidence in using the MI approach in the encounter and felt that their skills were reinforced by the reminder and the practice. One pharmacist also said the process of letting the patient decide which topic to discuss was a positive experience for the patient in the autonomy support but also for the pharmacist in knowing where to go in the conversation and knowing that it was positive that the patient chose that topic. She expressed a perception that this supported the collaborative relationship and connection with the patient.

Primary Outcome: Medication Adherence

The Medometer Results

The primary outcome of medication adherence was measured at each visit using the Medometer (self-report measure that recalls medication adherence in the last four weeks). A total of three meetings was scheduled for each participant over the 12-week (3 months) intervention. A total of 43 participants attended the first one-on-one meeting with the pharmacist and 36 participants completed the intervention phase. A paired samples t-test was conducted to compare the medication adherence score on the first visit with the score at the third visit. There was a statistically significant difference in medication adherence between the visit one score (M= 90.0, SD = 11.62) and the visit three score (M=93.0, SD= 14.32); $t_{(35)} = -4.485$, $p < 0.00$. The results for changes in medication adherence in the intervention phase are reported in Table 4.

Table 4. Self-reported Changes in Mean (SD) Medication Adherence Based on the Medometer

	Visit 1 (N = 43)	**Visit 2 (N = 40)**	**Visit 3 (N= 36)**	**p**
Overall	90.0 (11.62)	94.0 (11.92)	93.0 (14.32)	0.00
Change from visit 1		4	3	
Percent Change		4.4	3.33	

$p < 0.05$

The SDSCA Medication Subscale Results

The SDSCA medication subscale was also applied; data analyses utilized the overall SDSCA score at the three data collection points. In addition, factors that significantly correlated with medication adherence were identified at post-intervention. For the correlation analysis, findings were reported for the overall SDSCA score and summary scores on the SDSCA for each diabetes medication category (oral

AHA, non-insulin injectable, and insulin). The medication adherence data were extremely skewed towards high adherence and acceptable levels of normality were not attained after data transformation techniques were applied. The Wilcoxon signed rank test was then applied to determine changes in medication adherence after the intervention and at the three-month follow-up assessment.

The average score on the SDSCA increased from baseline (M = 6.4, SD = 1.20) to post-intervention (M = 6.8, SD = 0.60) and reduced slightly at follow-up assessment (M =6.7, SD = 0.69). However, change in medication adherence based on the Wilcoxon signed ranks test was not statistically significant in comparing baseline to post-intervention (z = -1.457, p = 0.145), post-intervention to follow-up (z = -0.154, p = 0.877), and baseline to follow-up (z = -1.497, p = 0.134). Figure 3 shows changes in medication adherence based on the SDSCA overall score.

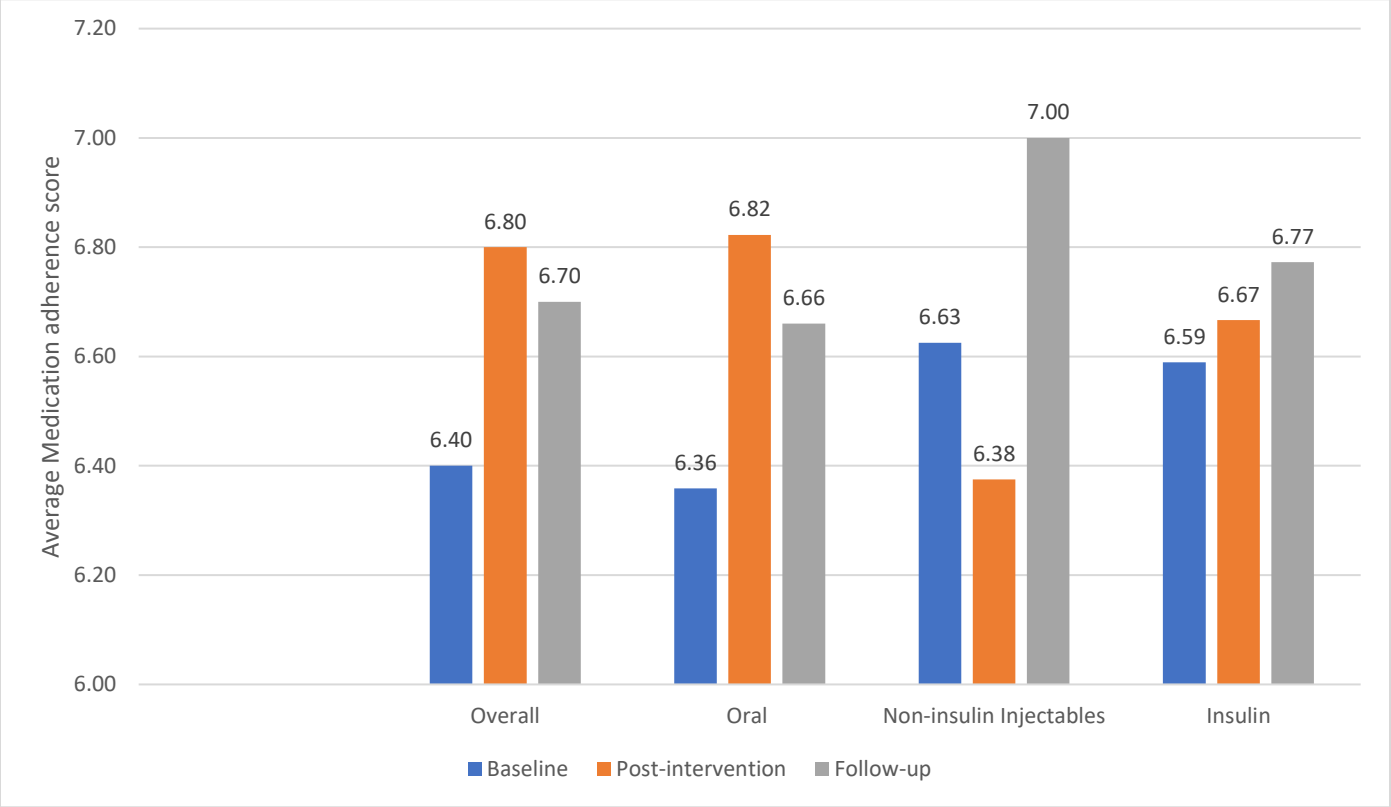

Figure 3. Changes in SDSCA Medication Adherence from Baseline to Follow-up Assessment

Comparison Between the Adherent and Non-Adherent Groups

The SDSCA overall score was dichotomized as <7 days for the non-adherent group and 7 days for the adherent group.[36] Percentage change from baseline to post intervention increased for the non-adherent group, there was a 52.5% improvement in medication nonadherence from baseline to post-intervention. Overall improvement from baseline to follow-up in the nonadherent group was 25%. Wilcoxon signed ranks test for the nonadherent group was not statistically significantly different from baseline to post-intervention (Z = -0.67, p =0.50), or follow-up (z= -0.45, p = 0.66). Findings for the comparison between the adherent and non-adherent group are summarized in Figure 4.

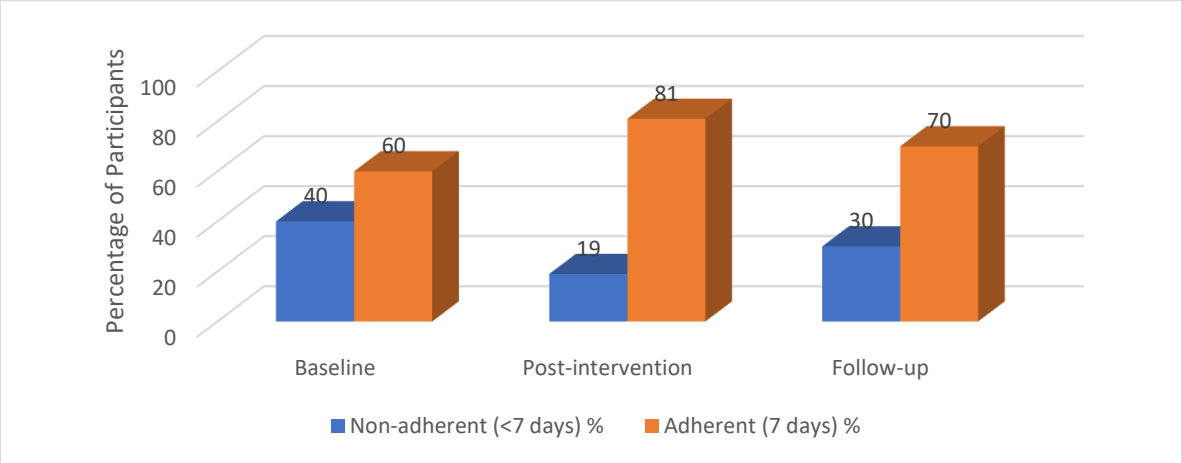

Figure 4. Comparison between Adherent and Nonadherent Groups by SDSCA Score

Correlation Analysis for Medication Adherence

The target variables having statistically significant correlation with medication adherence, based on the overall score on the SDSCA and scores for each medication category at post-intervention are summarized in Table 5. Target variables that showed significant correlation with medication adherence after the intervention were relationship status, r = -0.51, p= 0.002, knowledge for diabetes self-management (post-intervention assessment), r = -0.41, p = 0.016, HRQoL at baseline (ADDQoL present

QoL score), r = 0.48, p = 0.003, A1C at baseline, r = -0.36, p = 0.03, and A1C at post-intervention, r = -0.49, p = 0.003. A one-way ANOVA was performed to identify the relationship group that significantly contributes to the correlation with medication adherence. The result indicated there was a significant effect of relationship status on medication adherence, ($F_{(3,30)} = 5.62$, p = 0.004). The Bonferroni post hoc test indicated that the mean medication adherence score for the "widowed" group (M = 5.58, SD= 1.50) was significantly different (lower) than all the other groups, "single" (M = 7.0, SD= 0.00), "married/with partner" (M = 6.8, SD= 0.37), and "divorced" (M = 7.0, SD= 0.00).

Table 5. Medication Adherence and Target Variables: Statistically Significant Correlations at Post-Intervention Data Collection (n=36)

Overall Score: Summary of Diabetes Self-Management Activities – Medication Subscale (SDSCA)		
Factors	**Correlation**	**p**
Relationship status	-0.51	0.002
A1C		
Baseline	-0.36	0.03
Post-intervention	-0.49	0.003
Quality of life - Present ADDQoL score (baseline)	0.48	0.003
Knowledge (post-intervention)	0.41	0.016
Oral AHAs Group: SDSCA		
Knowledge (post-intervention)	0.50	0.006
A1c (post-intervention)	-0.47	0.008
Present ADDQoL score (baseline)	0.57	0.001
Non-insulin injectable Group: SDSCA		

Gender	-0.72	0.04
Insulin Group: SDSCA		
A1c (post-intervention)	0.61	0.036
Satisfaction - perceived hyperglycemia (post-intervention)	-0.68	0.014
Diabetes distress (baseline)	-0.60	0.038
Present ADDQoL score (baseline)	0.70	0.016

Correlation = Pearson product moment (continuous variables) or Spearman rho (categorical variables), $p < 0.05$, DBP = Diastolic blood pressure, ADDQoL = Audit of Diabetes Dependent Quality of Life, MCS = Mental Summary Score, AHAs= Antihyperglycemic Agents

Secondary Outcomes

Clinical outcomes results

A one-way within-subject repeated measures ANOVA (RM ANOVA) was used to determine significant changes in target clinical variables (hemoglobin A1C, blood pressure and presence of depressive symptoms) among study participants across the three data time points, baseline, post-intervention and three-month follow-up. Bivariate correlation analysis was applied to identify variables that significantly relate with glycemic control at post-intervention. First, a paired samples t-test was conducted to compare the average A1C in the one-year pre-intervention period and A1C at baseline. There was a nonsignificant difference in scores for pre-intervention A1C (M= 7.2, SD = 1.15) and baseline A1C (M=7.2, SD= 1.25); $t(52) = 0.025$, $p = 0.980$.

Prior to the RM ANOVA analysis, data were analyzed to ensure that assumptions were satisfied for the RM ANOVA test. Results of the one-way within-subjects RM ANOVA showed a statistically significant change in diastolic blood pressure (DBP), ($F_{(2, 70)} = 3.57$, $p = 0.034$, $\eta^{2} = 0.09$). Results indicated that within-subject difference accounted for 9% of the variance in DBP. Post hoc analysis using

the Bonferroni test showed a statistically significant difference decrease the baseline DBP (M= 83, SD= 7.9) and the post-intervention DBP (M= 80, SD= 8.2) p = 0.02. All other clinical variables did not show a statistically significant improvement; A1C ($F_{(2, 70)} = 2.47$, p = 0.09, $\eta^{2} = 0.07$), systolic blood pressure (SBP) ($F_{(2, 70)} = 1.71$, p = 0.188, $\eta^{2} = 0.05$), and depressive symptom ($F_{(1, 39)} = 1.35$, p = 0.262, $\eta^{2} = 0.04$). The results for the RM ANOVA are summarized in Table 6.

Table 6. Change in Clinical Outcomes at Baseline, Post-intervention, and 3-month Follow-up

	Baseline, N=53 **Mean (SD)**	**3 months, N= 36** **Mean (SD)**	**6 months, N= 28*** **Mean (SD)**	p **value**
Hemoglobin A1C (%)	7.2 (1.12)	7.1 (1.13)	7.1 (0.79)	0.092
SBP (mmHg)	133 (15.24)	130 (14.05)	132 (14.61)	0.188
DBP (mmHg)	83 (7.9)	80 (8.2)	82 (6.1)	0.034
Depressive symptoms (PHQ-9 score)	4.4 (5.43)	3.6 (3.35)	3.0(3.79)	0.267

p < 0.05, DBP = Diastolic blood pressure, SBP = Systolic blood pressure, PHQ-9 = Patient Health Questionnaire, *= Follow-up sample based on 36 participants using the last-observation-carried-forward

In addition, it was important to examine the proportion of the baseline sample with clinical values within the recommended ranges. Results indicated the following for the proportion of the study sample with adequate control for clinical indicators at baseline: glycemic control 25(47%), systolic blood pressure 22(42%) and diastolic blood pressure 18(33%). The PHQ-9 score at baseline indicated that most participants did not have depressive symptoms 36(67.4%). Further, depressive symptoms reported for the PHQ-9 score categories were mild 9(18.4%), moderate 3(6.1%), moderately severe 3(6.1%), and severe 1(2%) depressive symptoms.

Correlation analysis results for glycemic control

The target variables having statistically significant relationships with glycemic control at post intervention are summarized in Table 7. The variables with significant relationships with glycemic control at post-intervention were A1C at baseline, $r = 0.857$, $p < 0.000$, and overall adherence score (SDSCA) at baseline, $r = -0.461$, $p = 0.005$ and post-intervention, $r = -0.488$, $p = 0.003$. The results showed that lower A1C at post intervention was significantly correlated with higher scores on the SDSCA, indicating increased medication adherence.

Table 7. Glycemic Control at Post-intervention: Target Variables with Significant Correlations

Factors	**Correlation**	**p**
Baseline A1C	0.857	0.000
Baseline medication adherence (SDSCA)	-0.461	0.005
Post-intervention medication adherence (SDSCA)	-0.488	0.003

$p < 0.05$, Correlation = Pearson product moment (continuous variables) or Spearman rho (categorical variables), SDSCA = Summary of Diabetes Self-care Activities – Medication Subscale

Humanistic outcomes results

Changes in self-reported health-related quality of life, patient satisfaction and economic indicators (emergency department visits and hospital admissions) were assessed for statistically significant differences across the time points of baseline, post-intervention, and follow-up among study participants.

Health related quality of life was measured using a generic measure (SF-12) and a diabetes-specific measure (ADDQoL-19). A one-way within-subjects RM ANOVA was conducted to evaluate changes in quality of life scores. Data were evaluated prior to analyses to confirm that assumptions for the RM ANOVA test were satisfied. Table 8 reports the results for each of the quality of life measures.

Generic measure for HRQoL: the SF-12

In assessing the PCS score of the SF-12, a statistically significant change was observed for the PCS score, ($F_{(2, 58)} = 7.53$, $p = 0.003$, $\eta^{2} = 0.206$). Post hoc analyses based on the Bonferroni pairwise comparison test showed that all three measures of the PCS score were significantly different from each other. The PCS score at baseline was significant lower than the PCS score at post intervention ($p = 0.016$) and lower than the PCS score at follow-up ($p = 0.023$). The within-subjects difference contributed 20.6% of the variance in the PCS score.

Also, a statistically significant change was observed for the MCS score, $F_{(2, 58)} = 3.92$, $p = 0.025$, $\eta^{2} = 0.119$). Results indicate that approximately 12% of the variance in the MCS score was attributed to the within-subjects difference. Post hoc analyses based on the Bonferroni test revealed a statistically significant difference between the baseline MCS score and the post-intervention MCS score ($p = 0.041$).

Diabetes-specific measure for HRQoL: the ADDQoL-19

The RM ANOVA results for the ADDQoL-19 scores; the AWI, "Present QoL score", and "Diabetes-dependent QoL score" were not statistically significantly different from baseline to follow-up assessment (AWI ($F_{(2, 68)} = 1.53$, $p = 0.225$), "Present QoL score" ($F_{(2, 68)} = 1.97$, $p = 0.148$), and "Diabetes-dependent QoL score" ($F_{(2, 64)} = 1.17$, $p = 0.316$)). Results for quality of life assessments using the SF-12 and ADDQoL-19 are reported in Table 8.

Descriptive analysis for the ADDQoL-19 showed an increase from baseline to follow-up but these changes were not statistically significant. The Average Weighted Impact (AWI) score increased from baseline (mean= -1.66, SD=1.89), to post intervention (mean= -1.65, SD=1.88), and follow-up

assessment (mean= -1.61, SD=1.66). Similarly, a positive change was observed in the "diabetes-dependent QoL score" from baseline (mean= -1.20, SD=1.02), to post intervention (mean= -1.0, SD=1.02), and to follow-up assessment (mean= -0.9, SD=0.97). The "present QoL score" increased from baseline (mean=1.27, SD = 1.05) to post intervention (mean=1.53, SD = 0.77). However, a decrease was observed at follow-up assessment (mean = 1.40, SD=0.74).

Table 8. Change in Mean Health-related Quality of Life Scores

	Baseline, N=53 Mean (SD)	**Post-intervention, N= 36 Mean (SD)**	**Follow-up, N= 28*** **Mean (SD)**	**p value**
SF-12				
PCS	42.5 (5.83)	47.0 (9.04)	47.3 (8.76)	0.003
MCS	47.2 (7.25)	51.1 (5.57)	50.6 (7.43)	0.025
ADDQoL-19				
Present QoL score	1.27 (1.05)	1.53 (0.77)	1.40 (0.74)	0.148
Diabetes-dependent QoL score	-1.20 (1.02)	-1 (1.02)	-0.9 (0.97)	0.316
Average Weighted Impact score	-1.66 (1.89)	-1.65 (1.88)	-1.61 (1.66)	0.225

$p < 0.05$, SF-12 = Short Form - 12, PCS = Physical Component Summary, MCS = Mental Component Summary, ADDQoL-19 = Audit of Diabetes Dependent Quality of Life -19, *= Follow-up sample based on 36 participants using the last-observation-carried-forward method

Diabetes treatment satisfaction

At baseline, the average overall satisfaction score on the DTSQs was 31.21 (SD = 4.81), "perceived hyperglycemia" score (M = 2.52, SD = 1.69), and the "perceived hypoglycemia" score (M = 1.13, SD = 1.43).

The results for changes in diabetes treatment satisfaction are summarized in Table 9. Patient satisfaction at post-intervention was analyzed in two formats using the summary scores and all the item scores on the DTSQc. Next, a paired sample t-test was conducted to compare the DTSQc at post-intervention with the follow-up assessment. The overall satisfaction score on the DTSQc was not significantly different between post-intervention (M= 11.77, SD = 6.27) and follow-up assessment, (M=10.7, SD= 6.67), t (52) = 1.015, p= 0.318. Also, there was a statistically nonsignificant change for the domain score for "perceived hyperglycemia" from post-intervention (M= 0.54, SD= 1.60) to follow-up (M= 0.11, SD= 1.82), t (27) = 0.842, p= 0.408, and the domain score for "perceived hypoglycemia" from post-intervention (M= -0.20, SD= 1.57) to follow-up (M= -0.07, SD= 1.82), t (27) = -0.47, p= 0.642.

Table 9. Change in Mean DTSQc Domain Scores from Post-intervention to Follow-up

	Post-intervention, N= 36 **Mean (SD)**	**Follow-up, N= 28*** **Mean (SD)**	**Change**	**p value**
Current treatment	2.03 (1.15)	1.93 (1.27)	0.10	0.615
Convenience	1.51 (1.58)	1.30 (1.44)	0.21	0.251
Flexibility	1.49 (1.62)	1.30 (1.38)	0.19	0.398
Understanding	2.17 (1.15	1.81 (1.39)	0.36	0.095
Recommend	2.23 (1.13)	2.30 (1.07)	-0.07	0.819
Continue	2.34 (1.19)	2.07 (1.21)	0.27	0.484
Perceived hyperglycemia	0.54 (1.60)	0.11 (1.83)	0.43	0.408
Perceived hypoglycemia	-0.20 (1.57)	-0.07 (1.82)	0.13	0.642
Overall score	11.77 (6.27)	10.7 (6.67)	1.07	0.318

*= Follow-up sample based on 36 participants using the last-observation-carried-forward method

Healthcare utilization results

In assessing healthcare utilization, the target variables were self-report of frequency of emergency department (ED) visits and hospital admissions. At baseline, the reported frequency of emergency department visits was 2(6.2%) and frequency of hospital admissions was 2(6.2%). None of the participants reported emergency department visits or hospital admissions at post-intervention and follow-up assessment. Findings for healthcare utilization are reported in Table 10.

Table 10. Change in emergency department visits and hospital admissions

	Baseline, N=53 **Frequency (%)**	**3 months, N= 36** **Frequency (%)**	**6 months, N= 28** **Frequency (%)**
Emergency room visits	2 (6.2)	0	0
Hospital admissions	2 (6.2)	0	0

*= Follow-up sample based on 36 participants using the last-observation-carried-forward method

Motivational Interviewing Intervention Fidelity Assessments

Each pharmacist-patient encounter for the study was audio-recorded using a digital voice recorder. A random sample of 12-15 recordings per pharmacist over time was analyzed by an MI expert (JK) for MI-consistent approach and skills/language. A validated measure, the MISHCE (Motivational Interviewing Skills in HealthCare Encounters)[20] was used to determine a score of MI consistency across these encounters. Pharmacist 1 encounters (n = 12) achieved an average score of 88.0%, ranging from 84.5% to 91.5%; Pharmacist 2 encounters (n = 15) achieved 91.5% as the average score, ranging from 87% to 94%.

Discussion

The overall purpose of this study was to evaluate the effectiveness of a brief pharmacist-led motivational interviewing intervention to improve adherence to prescribed diabetes medications. Also,

this study assessed changes in clinical indicators, health related quality of life, patient satisfaction with treatment and healthcare utilization (ED visits and hospital admission) as proxy variables for economic indicators. Of the 170 eligible employees enrolled in the WWP, 53 agreed to participate in the study and 28 participants completed all study activities and data collection. A comparison analysis between participants who completed the study and those who dropped out revealed two factors that was significantly different between the two groups. Participants who completed the study reported having a higher level of education based on a college degree and a longer duration of enrollment in the WWP.

Use of the Communication Tools: The SMIT

The results of the implementation phase support the usefulness of the conversation tools towards addressing medication adherence barriers in an autonomy-supporting way. The SMIT tools apply evidence-based communication strategies to optimize the probability of adherence and improve health outcomes in diabetes management. In looking at the application of the communication tools, the SMIT showed an interesting pattern for patient-specified reasons for medication nonadherence across the three pharmacist-patient visits.

At the first visit, the primary reason for medication nonadherence with the highest frequency was forgetfulness 13(30%) based on the SMIT topic "remembering to take diabetes medications". The pharmacist guided the participants in goal-setting strategies for overcoming forgetfulness and improving medication adherence. Such strategies included smart phone applications. As a result, this barrier topic choice declined to the lowest percentage 3(8.3%) at the third visit. This finding is consistent with the literature which reports effective strategies to help patients remember to take prescribed medications at the specified time, and these include phone-based reminders (text messages and smart phone applications) and packaging options (blister pack and pill box).[37 38] Electronic reminders are also reported to prompt patients towards taking medications at the scheduled time, [48] and keep track of complex treatment regimens.[49]

In considering patient-specified reasons for non-adherence on the third visit, the SMIT topic with the highest frequency was "taking medications during work, on weekends, or during travels". This barrier indicates the difficulty that patients experience in balancing medication regimen and a busy schedule at work, or relaxation during weekends. The frequency of this topic was sustained across the three visits. This finding signals a need for interventions that address prioritization and balancing of responsibilities to accommodate diabetes self-management activities which include medication taking, being active, healthy eating, and blood glucose monitoring.

Although, the intervention process indicated that the participant should choose a topic from the SMITs, some participants indicated barrier topics that were not covered by the communication tools (e.g. diet and weight management). The flexibility to choose other barrier topics was included because one of the key elements of MI is to support the patients' autonomy. In addition, adherence to treatment regimen is influenced by the components of patient-centered care, such as respect for patient autonomy, preferences, and patient-provider relationship.[39]

Furthermore, pharmacists' feedback on the usefulness of the SMIT to their facilitating the encounters and helping build a collaboration with the patient was positive and increased their own confidence in using and adhering to MI communication strategies. The overall findings on the application of the SMIT highlight adherence barriers that need further investigation towards improving medication adherence and health outcomes, while also showing promise as a tool useful to both the patient and practitioner.

Primary Outcomes Discussion: Medication Adherence

Medometer

Adherence to prescribed diabetes medications is an important factor towards attaining recommended treatment goals in diabetes management. Findings based on the Medometer indicated a significant increase in overall medication adherence from the first meeting to the third meeting, $t_{(35)} = -$

4.485, p< 0.00. The results of this pilot study showed that semi structured pharmacist-patient interactions could have modest effect towards helping patients improve medication adherence; a larger sample size and longer study duration may have revealed stronger effects. The literature reports improvement in medication adherence in similar studies where the effectiveness of a pharmacist-delivered intervention was investigated.[15 40 41] Further, face-to-face pharmacist-patient counseling encounters in a community pharmacy setting have been reported to be more effective than mail-order pharmacy phone calls.[40]

It is important to examine the clinical significance of the study findings and ascertain the relevance of the significant outcomes to clinicians, policymakers, and patients. The clinical significance of the study findings needs to be interpreted with caution because of the small sample size and characteristics of the specific target population (employees and employee dependents in a hospital-based WWP); the increase in medication adherence observed in this pilot study provides evidence that a brief face-to-face MI-based counseling intervention can improve medication taking behavior in patients living with diabetes. The improvement in patients' medication-taking behavior after the targeted MI-based counseling intervention demonstrates the benefits clinicians can derive by collecting information on reasons for nonadherence to help efficiently target provider-patient communication on adherence to health behaviors.

The SDSCA medication subscale

For the SDSCA measure, an increase in medication adherence was observed in the overall score at post intervention, but this change was not statistically significant. In assessing adherence by diabetes medication categories, a marked improvement in adherence for oral AHAs and insulin was observed after the intervention. For the non-insulin injectable category, improvement was observed at the follow-up assessment. However, these findings were not statistically significant as well. The comparison analyses between patients that reported less than 7 days medication adherence on the SDSCA versus 7 days adherence indicated a 52% improvement in overall medication adherence for the non-adherent group after the MI-based intervention, but this change was non-significant.

In comparing our findings with the literature, a systematic review by Sapkota and colleagues examined the impact of various interventions for diabetes medication nonadherence in T2D patients.[42] The review assessed a total of 52 studies to determine the effectiveness of the target interventions on diabetes medication nonadherence. The review showed that 22 studies reported increased medication adherence, and nine studies reported positive changes in both medication adherence and glycemic control.[42] The sample size for these studies varied from 5 participants in a case-series study to 5,123 participants in a cohort pre-post study, and study duration ranged from 10 weeks to 4 years. The strategies applied for the interventions ranged from educational programs to mobile health interventions. However, a single strategy that guaranteed improvement consistently could not be identified.[42] Similarly, the findings in the MIDMA pilot study indicated increased medication adherence after the intervention based on the Medometer, but the longitudinal assessment using the SDSCA did not show significant improvement.

In considering medication adherence for each medication category, the findings for the oral AHA group were like that of the overall SDSCA score, where the post intervention improvement in adherence was not sustained at follow-up assessment. This similarity in findings between the overall SDSCA score and the oral AHA group could be attributed to the fact that the latter group contributed over 60% of the overall participants' population. The insulin category was the only group where a steady improvement was observed after the intervention and at follow-up assessment. A systematic review which evaluated factors that positively impacted adherence to insulin therapy among T1D and T2D indicated two strategies to enhance adherence to insulin.[43] These strategies included using a device (e.g. insulin pen or insulin pump) to administer insulin and enrollment in insurance programs that offer low financial burden to the patient. These two factors were applicable in our study population where participants in the hospital-based WWP receive optimal care for diabetes management, and co-pays for diabetes medications and supplies are waived as incentive to attract and retain participants in the WWP.

Although, the small sample size for completers placed limitations on performing inferential statistics, the data analyses plan was modified to reflect results for correlation analysis between overall score on the SDSCA with study variables after the intervention. In addition, each medication category (oral, non-insulin injectable, and insulin) was evaluated to identify significant correlation with target variables. The variables that demonstrated significant correlation with the overall SDSCA medication adherence score were relationship status, glycemic control (baseline and post-intervention A1c), HRQoL (ADDQoL "present" score), and diabetes self-management knowledge at post intervention. Furthermore, the "widowed" group under the relationship status reported significantly lower scores for medication adherence. This could possibly be attributed to a lack of spousal support in chronic disease management. Studies have reported that patients with spousal support are more likely to adhere to their medication regimen.[44] [45] A mixed-methods study by Mayberry and colleagues showed that perceived lack of support from family members was associated with less adherence to diabetes medications, and lower levels of adherence was associated with inadequate glycemic control.[46]

Target variables that significantly correlated with medication adherence in the oral AHAs group included participants' diabetes self-management knowledge, glycemic control, and HRQoL (present QoL score). In the non-insulin injectable group, gender was significantly correlated with medication adherence, while for the insulin group, glycemic control, satisfaction with perceived level of hyperglycemia, diabetes distress and HRQoL were significantly correlation with medication adherence.

The "present QoL score" is based on the question in the ADDQoL-19, "in general, my present quality of life is?" which measures the global impact of diabetes on the patient's quality of life. Perceptions of a favorable quality of life in a general sense was positively correlated with improved medication adherence across all AHA categories. Similar findings were reported in a study that evaluated the relationship between medication adherence and HRQoL among T2D patients.[47] Medication adherence was significantly related with four domains of HRQoL; physical, psychological, social relationships, and environmental.[47]

Medication adherence based on the overall SDSCA score and oral AHAs score at post-intervention was significantly correlated with diabetes self-management knowledge. This finding is consistent with the literature, where patients who are knowledgeable about diabetes self-management were more adherent to AHA regimens and, had A1C values in the recommended range for optimal diabetes control.[48] [49] A possible explanation for the relationship between diabetes knowledge and medication adherence in the study population could be attributed to the integrated approach used for the intervention. In this approach self-management knowledge was provided based on patients' specified reasons for nonadherence and accountability structures were applied for goal-setting in the context of MI principles which includes eliciting change-talk and supporting patients' autonomy.

Secondary Outcomes Discussion

Clinical outcomes

A large percentage of participants at baseline were within ADA recommended range for glycemic control 25(47%) and systolic blood pressure 22(42%), but a few participants had a diastolic blood pressure within the recommended range 18(33%). This could possibly explain the significant finding for changes in diastolic blood pressure, but a nonsignificant finding for glycemic control and systolic blood pressure. In addition, the PHQ-9 score at baseline indicated that a high percentage of participants reported a lack of depressive symptoms 36(67.4%). A few participants reported a PHQ-9 score within the categories for mild 9(18.4%), moderate 3(6.1%), moderately severe 3(6.1%), and severe 1(2%) depression. Also, nonsignificant finding was observed for the PHQ-9 score. It is important to acknowledge that improvement in clinical outcomes could be a useful indicator towards reducing risks associated with long term diabetes-related complications.[14] Studies in the literature have reported findings for clinical outcomes that contrast with the MIDMA study findings. Impact of a pharmacist-led intervention have been linked to adequate control of clinical indicators in diabetes management; these included A1C[50] and blood pressure.[50]

Target variables that indicated a significant correlation with glycemic control at post-intervention were baseline A1C and medication adherence (baseline and post-intervention) using the overall score on the SDSCA medication subscale. The landmark Asheville study, a pharmacist-led WWP intervention for diabetes management reported similar findings; glycemic control (A1C) at baseline was a significant predictor of optimal glycemic control over time as measured at follow-up assessments.[14] In the MIDMA study, it was observed that medication adherence was significantly correlated with glycemic control at post-intervention, and other studies in the literature have reported similar findings; a systematic review by Capoccia and colleagues reported that higher adherence to AHAs was associated with improved glycemic control, reduced medical cost, fewer ED visits and hospital admissions.[51]

Health-related quality of life

In examining HRQoL outcomes, the MCS and PCS score on the SF-12 showed a statistically significant improvement from baseline to follow-up assessment. The observed significant improvement in MCS suggests improved mental empowerment towards diabetes management.[52] A cohort study that involved 380 T2D patients from four community clinics explored the association between quality of life and glycemic control and reported a significant association between glycemic control and the MCS score. The study findings indicated that a 5% reduction in A1C was associated with a 1% increase in MCS score.[52] The PCS reflects limitation in physical functioning such as moving a table, bowling or climbing several stairs, and interference of pain in daily activities. The patient can assess the effects of diabetes on his/her physical functioning (e.g. climbing several flights of stairs) and mental wellbeing, and readily provide feedback on the SF-12.[47] However, for the ADDQoL-19, quality of life is assessed based on 19 domains relevant to diabetes management. Although, five of the 19 domains have the "Not Applicable" option, some domains in the ADDQoL-19 may not have been impacted by diabetes within the short intervention time line. For example, the domain that assesses activities such as going on vacation or long-distance travel. Activities that require extensive traveling may likely not take place among several participants in our target population (employees and employee dependents in a busy regional hospital

worksite) during the brief intervention period. Another example is the domain that evaluates the impact of diabetes on the patient's finances. Participants in the study were less likely to be impacted by the financial burden of diabetes medication because one of the benefits of participating in the hospital-based WWP included waived copays on diabetes medication refills and free provision of diabetes supplies.

Nevertheless, the ADDQoL-19 is a useful measure to assess HRQoL in diabetes management and the open-ended question at the end of the measure was useful towards identifying additional factors that negatively impacted medication adherence. The open-ended item asked the question, "are there any other ways in which diabetes, its management and complications affect your quality of life?". Comments given by participants suggested difficulty with; taking diabetes medications, blood glucose monitoring during travel, and food portion control. Overall, the open-ended question on the ADDQoL-19 provided additional information on the impact of diabetes management on the patients' quality of life.

Patient satisfaction with diabetes treatment

In evaluating outcomes for patient satisfaction with treatment, high treatment satisfaction was reported at post intervention for the overall DTSQc score (M = 11.7, SD= 6.27), and the average "perceived hypoglycemia score" (M= -0.20, SD= 1.57) indicated less occurrence of hypoglycemia events. Treatment satisfaction have been shown to improve for patients who switch from oral diabetes medications to insulin despite the discomfort of daily insulin injections.[53] Further, patients with adequate glycemic control (A1c 7%) tend to report high treatment satisfaction, since glycemic control have been shown to relate with adequate diabetes management.[53]

The item by item analysis on the DTSQc indicated the highest level of satisfaction was reported for "how satisfied will you be to continue with your present form of treatment?" (M= 2.34, SD= 1.19). This seems congruent with the sample characteristics that suggest these participants were mostly well-controlled, suggesting that they may be satisfied with treatment results. The lowest satisfaction score was reported for perceived hyperglycemia (M=0.54, SD=1.60). Several factors impact adherence and

willingness to continue with current diabetes treatment regimen, these includes treatment flexibility, cost, difficulty with administering medication, patient motivation and education.[54] Pharmacist-patient encounters provide the opportunity to assess treatment satisfaction and patients' willingness to continue with current treatment. Effective provider-patient communication in diabetes management have been shown to associate with higher treatment satisfaction, improved medication adherence, portion size reduction and adequate glycemic control.[55] Although, causation cannot be implied in the current pilot study due to the absence of a comparator group and non-randomized design, findings suggest further investigations to better understand the relationship between patient satisfaction with treatment and MI-based counseling interventions.

Economic indicators

Participants reported two incidents at baseline for diabetes-related ED visits 2(6.2%) and hospital admissions 2(6.2%). At post-intervention and follow-up assessment, none of the retained participants reported diabetes-related ED visits or hospital admissions. Low rates of ED visits and hospital admissions is a positive indicator of good diabetes control.[56] Poor medication adherence has been linked to a higher rate of ED visits, hospital admissions and medical costs among diabetes patients.[51] Lau and Nau reported that T2D patients with <80% adherence to oral hypoglycemic medications in the past one year had a higher risk of hospitalization in the next year.[57] Medication nonadherence leads to a higher economic burden for the payer where healthcare costs increase for inpatient costs and reduce for medications and supplies.[58]

Limitations

While measures were taken to strive for collection of valid and reliable data in this study, it is important to highlight limitations of the study. First, randomization or inclusion of designated comparator group would have been useful in this pilot study. However, a randomized controlled design was not applied due to 1) limited time, funding and resources for the study, and 2) the potential risk of

contamination bias because the study site had one pharmacist and PharmD to provide medication therapy management to all the patients. The MI-trained pharmacist could inadvertently deliver MI-based communication to patients in the control group during routine care. Second, selection bias was a limitation, where patients that are already within recommended rage for optimal diabetes control tend to enroll and complete study activities. The initial design of the study was to exclude patients who are within the recommended range for medication adherence (PDC $\geq$ 80% and A1c $\leq$ 7%). The decision of the organizational leadership at the study site was that the intervention be offered to all patients who consent to join. This decision can potentially introduce selection bias where participants are already adherent and study results will show little improvement from baseline. In addition, the short study duration and small sample size in the MIDMA study are possible barriers towards observing a meaningful change in target outcomes such as the A1C for glycemic control. Since, the A1C requires approximately 3 months to reflect changes in glycemic control.[59]

Another limitation was the ceiling effect observed at baseline for the medication adherence self-report measure, SDSCA. The ceiling effect is a phenomenon where most of the participants report the highest possible score on a measure, leaving little room for post-intervention assessment to reflect a significant change. Additional limitations include, limited external generalizability, potential recall bias and social desirability bias. Additional steps were implemented to reduce social desirability bias and the Marlow Crown Social Desirability Scale (MC-SDS) was applied in the study.[22] There was a non-significant relationship between the MC-SDS and target variables. Further, the LOCF method was applied to increase sample size at follow-up for data analyses. The LOCF method could produce conservative results in studies where participants in the intervention group tend to drop-out frequently. This could potentially impact the analysis of the effects of the intervention since it is unknown whether dropout rates would have continued in the same pattern as at post-intervention. However, treatment effects that are established based on a conservation method support evidence of the intervention effects from a regulatory perspective.[60] In addition, the baseline comparison of those who stayed in the study and those who

dropped out suggests that those who left were less controlled and less adherent than those who stayed which suggests that interpretation of results assuming a continuum should be approached with caution.

Implications

Pharmacists play a major role in facilitating medication-based and lifestyle modification interventions because they are often available and accessible in different health care settings including community, out-patient clinics, and hospital settings. Additionally, pharmacists are uniquely positioned to identify medication nonadherence and provide or recommend appropriate interventions to positively impact health outcomes. The current study applied an integrated approach (MI-based counseling with communication tools) to modify medication nonadherence for diabetes self-management. An integrated approach to diabetes management, using a structured approach of education and patient-centered counseling, and goal-setting is a promising approach to help patients attain treatment goals.

The findings from the MIDMA intervention indicate that various aspects of the study could be adapted and applied towards managing other types of chronic conditions and health behaviors. The communication tools were designed as a patient-centered approach to tailor each encounter towards the barriers indicated by the patient as salient in that moment. The findings in this study showed improvement in medication adherence after the intervention, supporting claims for the effectiveness of the intervention approach applied in the MIDMA study. The strategy of first identifying patient-specified barriers to behavior change, and then focusing the provider-patient encounter towards possible solutions to overcome these barriers, could be applied towards improving other health behaviors including healthy eating, physical activity, and self-monitoring of chronic conditions (e.g. blood pressure and blood glucose in patients living with high blood pressure and diabetes respectively), among others.

Another aspect of this study with implementation and dissemination implications was that the intervention process was adapted to fit the existing workflow and personnel structure at the diabetes out-patient care and education clinic. The pharmacist-patient meetings and data collection procedures were tailored to reduce process burden for the participants, interventionists, and staff at the study site. The intervention encounters were scheduled to occur on Tuesdays, the only day of the week that the pharmacist meets patients at the diabetes clinic. Since the organizational need at the study setting was to implement a program which could improve health outcomes for employees and employee dependents enrolled in the WWP for diabetes management, the MIDMA study was aimed to be useful towards meeting the organizational need as well.

Furthermore, findings from the comparison analysis between participants who completed the study and those who did not complete suggests that future research efforts for recruitment and retention of participants in similar intervention research endeavors could benefit from strategies that support the retention of participants who report a lower level of education and are newly enrolled in disease management programs (e.g. a WWP).

Conclusions

The improvement in medication adherence in the intervention phase and positive changes in HRQoL observed in the MIDMA pilot study supports the clinical utility of a brief pharmacist-led MI counseling intervention for medication nonadherence in diabetes patients. In addition, the frequency of application of the SMIT across the three visits helped to reveal barrier domains for medication nonadherence that persisted even after three encounters with the pharmacist. Future research efforts can explore interventions to help overcome these barriers and improve health outcomes in diabetes management.

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CHAPTER 5

DISCUSSION AND CONCLUSIONS

Study Sample Characteristics

Various strategies were applied in the recruitment phase, but the target sample size needed for the proposed statistical analyses was not achieved. The small final sample size informed the decision to modify the proposed data analyses plan. Hence, appropriate statistical tests were applied to accommodate the final sample size at the end of the study.

The baseline characteristics of the participants were comparable to population characteristics reported in the 2015 Alabama data from the Behavior Risk Factor Surveillance System (BRFSS).[101] The BRFSS report indicated that the prevalence of diabetes in Alabama was higher among females and African Americans. Further, participants' characteristics on prevalence for T2D and category of prescribed diabetes medication was consistent with US population statistics, which report that T2D affects over 90% of the population of patients living with diabetes in the US, [102] and the first-line treatment for T2D is oral antihyperglycemic agents (AHAs).[103]

It is also important to evaluate the patient sample and identify factors that are significantly different between participants who completed the study and those who did not complete the study. The results indicated that participants who completed the study reported a longer duration of participation in the WWP, and a higher level of education based on a college degree or more advanced degree. Reasons for non-completion of Diabetes Self-Management Education (DSME) have been explored in previous research at the study setting for the MIDMA study. A cross-sectional study that was implemented by Hunt and colleagues to identify reason for non-completion of DSME classes reported cost, logistical issues and patients' obligations as some of the more prevalent barriers to non-completion of DSME classes.[104]

Implementation of the Communication Tools: The SMITs

The development of the SMITs was informed by the needs assessment in the target population; the initial phase one assessment was conducted to identify the most prevalent self-reported barriers to medication adherence in this target population. The six topics selected for SMIT composition were based on the most frequent barriers identified by respondents to the needs assessment anonymous survey; this was done to strive for relevance and content and face validity to the SMITs in the target population. This step was important for this study but limits generalizability of these SMITs to other populations whose members may have different prevalent barriers to medication adherence. However, the most frequently reported barrier in this study dealt with forgetting, which is frequently reported as the most prevalent reason for nonadherence in other studies as described next.

The application of the SMITs served as a pharmacist-patient conversation tool during the MI-based counseling sessions. In addition, the SMITs were useful for identifying a patient's primary barrier to medication adherence in the target population. At the first visit, the topic with the highest frequency was "remembering to take diabetes medications". Other studies in the literature that explored barriers to medication nonadherence have reported that forgetfulness was a primary factor for missed doses and poor medication adherence.[105 106] A review by Datye and colleagues indicated that the most common reason for medication nonadherence in diabetes self-management was forgetting.[92] The literature reports effective strategies to help patients remember to take prescribed medications at the specified time, and these include phone-based reminders (text messages and smart phone applications) and packaging options (blister pack and pill box).[107 108] Electronic reminder options and mobile applications prompt patients towards taking medications at the scheduled time,[109] keep track of complex treatment regimens,[110] and improve overall medication adherence and some of these were discussed with MIDMA participants by study pharmacists. It was encouraging to observe that forgetfulness was the least selected barrier on the third visit, which suggests that the participants had perhaps gained helpful strategies to address forgetfulness towards taking their medications as prescribed in the first or second visit.

The most frequently selected SMIT topic (barrier to medication adherence) on the third visit was "taking medications during work, on weekends, or during travels," which refers to difficulty with balancing medication adherence with a busy work schedule or events that were out of the participant's routine. The percentage of participants indicating that this topic was a primary barrier to medication adherence did not decrease across the three visits. Adherence to prescribed AHAs, including insulin, can be difficult for patients/employees in a busy work setting. This finding suggests that there may be a need for employers to explore possible work setting options that will support medication taking in the workplace; these could include examples like incorporating the employee's medication taking schedule into the daily workflow or allowing flexible work schedules to support complex medication regimens like insulin use.

Although the intervention process directed the participant to choose a topic from the SMITs, some participants indicated barrier topics that were not part of the SMITs (e.g. diet or healthy eating). The flexibility to choose other barrier topics was supported in the spirit of being patient-centered and including the key MI element of supporting patient autonomy. In addition, adherence to a treatment regimen has been shown to be influenced by exposure to practitioners exhibiting components of patient-centered care, such as respect for patient autonomy, preferences, and patient-provider relationship.[111]

Medication Adherence

Medication adherence was assessed using two self-report measures, the SDSCA-MS [23] and the Medometer.[24] These two measures evaluate medication nonadherence directly using a specified recall period. Voils and colleagues reviewed self-report measures of medication adherence and offered recommendations for improving the measurement of medication nonadherence. [112] Their recommendations indicated that direct measurement of medication nonadherence fails to provide information on reasons for nonadherence, an important factor for designing interventions.[112] In addition, a longitudinal data collection method was recommended, to help decipher whether nonadherence is chronic or episodic. [112] These recommendations were somewhat applied in the MIDMA study over the three-month study period and subsequent follow-up three months later. Reasons for medication non-adherence

were explored in tandem with the MI-based counseling intervention and data were collected longitudinally.

Primary Outcome: Medication Adherence

Change in Medication Adherence as Reported on the Medometer

The Medometer is a useful instrument for assessing medication nonadherence in primary care settings.[24] In the MIDMA study, the Medometer was applied at each one-on-one pharmacist-patient meeting to assess medication nonadherence. A recall time of the prior four weeks was requested in the Medometer instructions. This recall period was suitable for the study because each pharmacist-patient visit was to take place in four-week sequences. A significant increase in medication adherence was observed between the first meeting and the third meeting, $t_{(35)} = -4.485$, $p < 0.00$ based on the overall score on the Medometer. Pharmacist-led interventions have been shown to be effective towards improving medication nonadherence.[10 61 113] Further, face-to-face pharmacist-patient counseling in a community pharmacy setting has been reported to be more effective than mail-order pharmacy phone calls.[113] The increase in medication adherence observed in this pilot study provides evidence suggesting that a brief face-to-face MI-based counseling intervention can improve medication taking behavior in patients living with diabetes. The improvement observed in patients' medication adherence behavior after the targeted MI-based counseling intervention demonstrates the benefits researchers can derive by collecting information about reasons for nonadherence to help improve adherence interventions.

Change in Medication Adherence based on the SDSCA Medication Subscale

The SDSCA is a validated instrument for self-report of medication nonadherence.[23] The recall time requested in the SDSCA instructions is "the past 7 days". In the MIDMA study, medication nonadherence based on the SDSCA did not show a significant improvement from baseline to follow-up assessment in the overall score or medication category scores (oral, noninsulin injectable, and insulin).

This is consistent with findings reported in the literature for studies that assessed medication nonadherence in diabetes management.[114]-[115]

A systematic review by Sapkota and colleagues examined the impact of various interventions on diabetes medication nonadherence in T2D patients.[115] The review assessed a total of 52 studies to determine the effectiveness of the target interventions on diabetes medication nonadherence. The review indicated that 22 studies reported increased medication adherence, and nine studies reported positive changes in both medication adherence and glycemic control.[115] The sample size for these studies varied from five (5) participants in a case-series study to 5,123 participants in a cohort pre-post study, and study duration ranged from ten weeks to four years. The strategies applied for the interventions ranged from educational programs to mobile health interventions. However, a single strategy that generated improvement consistently could not be identified.[115] Similarly, the Medometer-based findings in the MIDMA pilot study indicated increased medication adherence during the intervention phase but the SDSCA-MS measure did not show statistical significant improvement for the longitudinal assessment of medication adherence. The results should be interpreted with caution since the study sample size was small, and considerably smaller than the a priori power analysis conducted to meet parameters for the more rigorous analyses that were proposed but couldn't be used within the small sample size.

Medication adherence in each treatment type showed significant correlation with target study variables. For adherence to oral AHAs, the variables glycemic control (r= -0.468), diabetes self-management knowledge (r= 0.497), and quality of life (r= 0.574) were significantly correlated. Adherence to injectable non-insulin was only significantly related with participant's gender (r= -0.729); however, the small sample size for the non-insulin group hindered inferential analysis towards identifying the specific gender affected. Also, adherence to insulin was significantly related with the variables glycemic control (r= - 0.609), satisfaction with perceived level of hyperglycemia (r= -0.684), diabetes distress (r= -0.602), and quality of life (r= 0.70). Poor adherence to insulin use among T1D patients is often unintentional and life-threatening because the body depends completely on external insulin in T1D diabetes management. [89]

However, medication nonadherence in T2D patients, including insulin nonadherence, could be influenced by several factors. [91 92]

A systematic review that identified barriers and facilitators to initiate insulin in T2D patients reported three barrier domains; patient-related factors, provider factors, and system factors.[116] Most of these factors were identified as barriers among T1D patients as well.[89] Patient-related factors included fear of pain and injection, impact of insulin side effects, perception that insulin indicated severe disease or end-stage of diabetes, and inconvenience/difficulty with administering insulin. Provider factors included physician inertia and communication barriers. The primary system factor identified was a lack of practitioner time regarding insulin regimen instruction or problem-solving. The reported facilitators to insulin adherence included understanding the benefits of insulin, self-efficacy towards administering insulin, and patient having received education and training.[89 116]

Overall, factors that impact adherence to diabetes medications have been grouped into the following areas; (1) psychosocial factors (peer influence, perceptions of social support, forgetfulness, and others), (2) clinical factors (anxiety, depression, eating disorders, fear of hypoglycemia), and (3) external factors (treatment cost, patient-provider communication, interference from activities which could lead to forgetting).[91 92] Psychosocial factors such as diabetes distress have also been shown to impact medication adherence in diabetes self-management.[117] The positive impact of adequate adherence to prescribed diabetes medication and favorable glycemic control has been documented by previous studies.[115 118] A cohort study that examined the longitudinal effect of medication adherence on glycemic control was conducted among 11,272 veterans.[118] Medication nonadherence in that study was assessed using the medication possession ratio (MPR), and poor glycemic control at baseline was defined as A1C >8%. Average duration of follow-up in that study was 5.4 years. Findings indicated that each percentage increase in MPR was associated with a 48% lower likelihood of poor glycemic control in the sample patients.[118]

Secondary Outcomes

Change in Clinical Outcomes

All the target clinical outcomes assessed in the MIDMA study showed improvement after the intervention, but only diastolic blood pressure showed a significant change from baseline. A high percentage of the participants had clinical values close to the guidelines-defined target values at baseline, suggesting that participants who chose to participate were already well-controlled, leaving little room to show significant improvement. Research has shown that any improvement in clinical outcomes for diabetes management is beneficial towards reducing risks and long term complications of diabetes, hence, the improvements in clinical outcomes observed were considered important for potential risk reduction even though the small statistically significant differences might be considered clinically insigificant.[20 119] A few factors in the MIDMA pilot study could have impacted study findings, leading to statistical non-significance in most changes in the clinical indicators.

Some of these factors could be: 1) The brief intervention duration (3 months) could potentially reduce the chances of observing changes in glycemic control because glycemic control, as measured by the A1C, reflects changes in blood glucose in approximately three months. 2) At baseline, a high number of participants had already attained the ADA recommended range for glycemic control based on the A1C (n = 25(47%)) and SBP (n = 22(42.0%)). Similarly, most participants (n = 36(67.4%)) did not report symptoms of depression based on the PHQ-9 score. However, fewer (n =18(33%)) participants' DBP values were within the recommended range, thereby leaving more room for improvement in DBP than other clinical variables examined within the MIDMA study. 3) The small sample size for data analysis likely compromised the ability to obtain statistical significance in some analyses. Future applications of the MIDMA methods and SMITs should aim for longer duration with more encounters and incentives to attract and retain more patients in general, and more poorly controlled patients specifically. With adequate time and resources, these three changes could be applied to give a more thorough examination of potential for demonstrating statistically and clinically significant improvements after the MI-based intervention.

In looking at factors that showed significant correlation with glycemic control after the intervention, these factors included A1C at baseline (r=0.857), medication adherence (baseline (r= -0.461), and medication adherence (post-intervention (r= -0.488)). Similar findings were observed in the Asheville study for glycemic control.[9] In that study, pharmacists offered medication therapy services in a worksite initiative for patients with diabetes. A five-year follow-up analysis to identify significant predictors of glycemic control revealed that baseline glycemic control using the A1C was a significant predictor of adequate glycemic control at follow-up assessments.

Health-related Quality of Life (HRQoL)

Optimal work productivity in diabetes patients is closely linked to quality of life domains, which includes physical and mental components. Fluctuations in glucose levels which could lead to hypoglycemia during a typical work day have been shown to impact work productivity and HRQoL.[120] The generic measure applied in this pilot study to assess HRQoL, the SF-12, showed significant improvement from baseline to follow-up on the Physical Component Summary (PCS) score and Mental Component Summary (MCS) score. In addition, the diabetes-specific measure, the Audit of Diabetes Dependent Quality of Life (ADDQoL-19) showed positive improvement across study data collection points, but the changes were not statistically significant.

A possible factor that influenced the observed differences in findings between the SF-12 and the ADDQoL-19 is the quality of life domains captured by the SF-12 which reflect physical and mental well-being, two fundamental factors impacted by diabetes management. The patient can assess his/her perceptions of the effects of diabetes on his/her physical functioning (e.g. climbing several flights of stairs) and mental wellbeing, and respond accordingly on the SF-12. However, for the ADDQoL-19, quality of life is assessed based on 19 domains relevant to diabetes management. Although, five of the 19 domains have a "Not Applicable" option, some domains in the ADDQoL-19 may not have been impacted

by diabetes within the short intervention time line of the MIDMA study. For example, this might include the domain that assesses activities such as going on vacation or long-distance travel; activities that require extensive traveling may not have taken place for participants in this sample (employees and employee dependents in a busy regional hospital worksite) during the brief intervention period. Another example is the domain that evaluates the impact of diabetes on the patient's finances. Participants in the study were less likely to be impacted by the financial burden of diabetes medication because one of the benefits of participating in the hospital-based WWP included waived copays on diabetes medication refills and free provision of diabetes supplies.

Nevertheless, the ADDQoL-19 is a useful measure to assess HRQoL in diabetes management and the open-ended question at the end of the measure was useful towards identifying additional factors that negatively impacted medication adherence. The open-ended item asked the question, "Are there any other ways in which diabetes, its management and complications affect your quality of life?" Comments given by participants suggested difficulty with taking diabetes medications, blood glucose monitoring during travel, and food portion control. Overall, the open-ended question on the ADDQoL-19 provided additional information on the impact of diabetes management on participants' quality of life.

Patient Satisfaction with Diabetes Treatment

Assessing patient satisfaction with diabetes treatment is an important quality indicator in a hospital setting and is useful for examining outcomes of pharmacotherapies in diabetes management. In the current study, the average patient satisfaction with treatment on the DTSQc overall satisfaction score (M=11.7, SD= 6.27) was high at post intervention. However, the follow-up DTSQc score reduced from post intervention assessment (M=10.7, SD = 6.67) but the change was not significant. In the follow-up phase, the average overall satisfaction with treatment reduced by 1.07 point among the study participants. A similar trend was observed in six of the eight satisfaction items where post-intervention level of satisfaction was not sustained but was reduced at the follow-up time point. The item that assessed the

likelihood to recommend current treatment increased by 0.1 point, and the item that assessed perceived level of hyperglycemia improved by 0.43 point from post intervention to follow-up.

Another important finding was that lower average scores were reported after the intervention for the items that evaluated "perceived treatment convenience" (M= 1.51, SD = 1.58) and "perceived treatment flexibility" (M=1.49, SD= 1.62); suggesting that providers should assess patients' perception on treatment convenience and flexibility to ascertain the need for additional education or pharmacotherapy adjustments. Further, patient satisfaction with treatment convenience and flexibility could be impacted when insulin is initiated.[121] Significant improvement in treatment satisfaction and glycemic control have been reported when mobile technology was used for insulin initiation and titration.[121 122] The mobile technology was based on a cloud-based diabetes management program delivered via patients' self-tracking, shared decision-making interfaces, secure text messages, and virtual clinic visits.[121] Overall, health care providers could explore the potential to apply effective strategies like these to reduce diabetes treatment burden and improve overall health outcomes.

Economic Indicators

Participants reported two incidents at baseline for diabetes-related ED visits (n = 2(6.2%)) and hospital admissions (n = 2(6.2%)). At post-intervention and follow-up assessment, none of the retained participants reported diabetes-related ED visits or overnight hospital admission. Low rates of ED visits and hospital admissions are a positive indicator of good diabetes control.[123] This makes sense within these results since most participants were already mostly well-controlled upon entry into the study.

Poor medication adherence has been linked to higher rates of ED visits, hospital admissions, and medical costs among diabetes patients.[124] Lau and Nau (2004) reported that T2D patients with <80% adherence to oral hypoglycemic medications within a one year prior timeline had a higher risk of hospital admission in the next year.[125] The negative outcomes of medication nonadherence have been reported to

result in a higher economic burden for the payer where healthcare costs increase for inpatient fees and reduce for medications and supplies.[126]

Intervention Fidelity Assessment

The interventionists' competence and fidelity assessments in the MIDMA study were assessed using the Motivational Interviewing Skills in Health Care Encounters (MISHCE) measure, a validated tool for MI skills and fidelity assessment which is based on the training model that was applied in the study.[127] In this study, the MISHCE was used by an MI expert to evaluate a random sample of audio-taped recordings that were collected at each pharmacist-patient meeting during the intervention phase. The interventionists' average MISHCE score for MI consistency across the pharmacist-patient encounters ranged from 88% to 94%. Fidelity assessment of MI-based interventions is highly encouraged to support claims for validity of study findings regarding impact of the intervention.[128] Results of the fidelity assessment indicate that the interventionists in this study were mostly exhibiting MI-consistent encounters with study participants.

A systematic review and meta-analysis that assessed the impact of MI-based interventions on medication adherence across several conditions/diseases, as well as the effectiveness of the intervention delivery method, reported positive changes in target outcomes.[128] Factors assessed in the review were intervention fidelity, fidelity-based feedback to the MI interventionists, MI exposure time, and the educational background of the interventionists. Disease conditions included were rheumatoid arthritis, HIV, osteoporosis, depression, multiple sclerosis, and hypertension. The impact of MI on medication adherence was significant for studies that reported medication adherence as a continuous variable or as a categorical variable. Studies that employed a fidelity assessment tool and provided fidelity-based feedback recorded superior results for MI. Interventionists demonstrating favorable patient outcomes primarily included nurses and MI-trained research assistants.[128]

Limitations

Methods were implemented that intended to collect valid and reliable data; yet, limitations exist and should be noted. First, utilizing a randomized controlled design or having a comparator group would have been optimal in this pilot study for supporting definitive claims for MI impact. However, a randomized controlled design was not possible due to 1) limited time and resources for the study, and 2) the potential risk of contamination bias because the MI-trained interventionists at the study site had to provide medication therapy management to all the participants in the WWP. The MI-trained pharmacist could inadvertently offer the intervention to patients in the control group during routine care. Second, self-selection bias was another limitation. Patients already mostly within recommended range for optimal diabetes control enrolled and completed study activities. The initial design of the study intended to only recruit persons *not* within the recommended ranges for medication adherence and glycemic control of PDC $\geq$ 80% and A1c < 7%, respectively. However, WWP leadership wanted the intervention to be offered to all patients who consented to join the study. This policy could potentially introduce bias where participants are already adherent and study results would show little improvement from baseline. In addition, since there were only 170 persons in the WWP population who qualified for the primary inclusion criteria, there would also have been further risk of inadequate sample size for study analyses if the consenting participants were divided into further smaller groups when randomized to intervention and control groups. Furthermore, a ceiling effect was observed at baseline for some of the self-report measures (e.g. the SDSCA and PHQ-9). The ceiling effect occurs when participants report values that are close to the most positive or controlled score for a scale, and this limits the opportunity to observe possible changes in the longitudinal assessments.

Additional limiting factors to consider include limited external generalizability, potential recall bias, and potential social desirability bias. External generalizability is also limited for the SMITs topics because the topics were based on an initial needs assessment that was conducted among the target population to identify most prevalent self-reported adherence barriers in this population. This may vary for other populations and a needs assessment to identify salient barriers for a target population should be

conducted before composing future SMITs to help contribute content and face validity of the tool for a study's sample.

In addition, the threat of social desirability in self-report seemed eminent in this study of patients who were also employees of the hospital whose WWP they belonged to. Steps were implemented to examine the potential for social desirability bias among self-reported measures for medication adherence and psycho/social variables; the Marlowe Crowne Social Desirability (MCSD-13) questionnaire was applied in the study.[29] There were non-significant relationships between the MCSD-13 and target variables, suggesting a low potential for the presence of social desirability bias; however, given the small sample size, this cannot be ruled out as a source of impactful bias.

Further, the last-observation-carried-forward (LOCF) method of handling missing data was applied to increase the sample size at follow-up for data analyses. This could potentially impact the observed results in the study since the baseline analysis of differences between those participants who ended up leaving the study versus those who stayed showed statistically significant differences in several key study variables. This is a concern in the study and should be noted for future research. Future studies could benefit from robust strategies to purposefully recruit and retain patients with poor adherence and with clinical indicators below recommended ranges.

Another limitation was the interventionists' schedule at the study setting. The interventionist pharmacists had other duties at the hospital and were assigned to the diabetes clinic only one day a week (Tuesdays). The intervention phase of the study was structured to fit the interventionists' schedule and this restriction in scheduling posed as a constraint for some participants during the intervention phase in scheduling their study visits; this may have contributed to attrition for some.

Finally, it is important to future researchers conducting a study within a real world setting to fully explore, where possible, pending organizational changes for potential impact on the study protocol prior to implementation. The collaborators at the diabetes clinic implementation site did not foresee or understand the legal implications or organizational changes that were pending or that emerged unexpectedly. In the MIDMA study, a few unexpected challenges emerged, forcing changes in proposed

study methods and analyses; there was a change in employee data policy, the hospital's outpatient pharmacy became privatized making collection of participants' medication refill claims data impossible to retrieve based on proposed methods, and a major change in EHR platform occurred that prevented access to proposed claims data. These changes posed limitations in accessing the proposed prescription refill records data for the study participants that would have provided the objective data comparison with the subjective self-report measures for the medication adherence focus of this study. Hence, the primary study outcome, change in medication adherence, was based only on self-report data, which may present bias limitations as noted above.

Implications for Practice

The primary objective of this study was to test the effectiveness of an MI-based intervention to improve medication adherence for patients living with T1D and T2D. The intervention was based on three semi-structured, pharmacist-delivered, MI-based counseling visits using communication aids (the SMITs) to identify salient barriers to medication adherence and facilitate the patient in goal setting for overcoming these. The intervention model utilized in the MIDMA pilot study has several strategies that have been shown to be useful in clinical settings. The patient-centered approach applied in the MIDMA study incorporated the patient's perspective in disease management. This approach supports the patient's autonomy in decision-making towards goal-setting for modifying the target behavior. In addition, the intervention was semi-structured and brief to accommodate a busy clinical setting. Moreover, the SMITS were useful for 1) identifying patients' barriers for medication adherence in an autonomy-supporting manner and, 2) supporting pharmacist facilitation of the visit and confidence in using the MI skills. Findings in this study support claims for potential effectiveness of the intervention towards reducing medication nonadherence as observed in the results for the self-report measure used.

Further, it is important to note that the intervention was structured to support a key MI premise and that is supporting patient autonomy; the SMIT topic to be discussed was selected by the participant at the beginning of each meeting, not by the pharmacist. In addition, the patient was given autonomy to

suggest other topics salient to him/her if none of the six SMIT topics were currently relevant as a barrier for medication adherence. Since, improved medication adherence has been shown to associate with better glycemic control,[118] fewer ED visits, [124] lower rate of hospital admission, [125] and lower medical costs,[126] then, it is advantageous to adopt and sustain interventions like the MIDMA in routine patient encounters for diabetes management. In addition, since the study pharmacists indicated that the tools were useful in building patient relationship and for increasing their own confidence in using the MI skills. The SMITs also helped facilitate a brief encounter in that most of the MIDMA-based portions of the pharmacist visits in this study took ten minutes or less to complete; this seems practical to consider for implementing in various busy pharmacy settings. The SMIT aspect of the study may have implications for practice application that warrant additional future research.

Implications for Research

The innovative features of the intervention were focused on the pharmacist-delivered MI-based interactions and the SMITs components which offer support structures towards attaining medication-taking goals for the patient and towards increasing confidence in MI skills use for the pharmacist. Potential contributions of the MIDMA study findings towards the existing literature includes: 1) the brief face-to-face MI-based counseling was effective in improving medication taking behavior among adults with T1D and T2D in a WWP, and 2) the application of the SMITs was useful as a conversation aid to identify barriers to adherence in an autonomy-supporting way, and to gain commitment to goal setting for a specific target behavior (medication adherence). These findings could help inform decision-making on optimizing provider-patient encounters towards improving patient engagement, self-management behaviors, and health outcomes.

The findings in the MIDMA pilot study provide preliminary background for future research efforts. Factors to consider in future research activities include 1) a longer implementation phase to accommodate possible changes that could occur in clinical variables, 2) extending the study to additional

practice sites to increase the sample size and generalizability, 3) using a randomized controlled study design, perhaps with a crossover design to be sure all participants receive the intervention, and 4) participation eligibility that would recruit patients with clinical indicators that are in the uncontrolled range (e.g., A1C > 8.0%). Also, future research directions can consider a SMIT approach to help patients set goals for modifying schedule during work or travel to accommodate medication taking and other self-management activities.

Finally, future research activities could benefit from additional funding to support research efforts, and improve incentive structure, which could potentially improve participation and retention. This study included four raffle draw events for a chance to win a $50 visa card; this amount and chance was not sufficient to attract a larger sample at baseline and retain the uncontrolled participants throughout the study.

Conclusions

Findings from the MIDMA pilot study suggest that there is support for the effectiveness of a brief, pharmacist-delivered MI-based counseling intervention to improve medication adherence among T1D and T2D patients in a hospital-based WWP. There was a significant improvement in medication adherence and HRQoL after the intervention. The positive changes observed in medication taking behavior, as well as the significant improvement in the mental and physical wellbeing of the participants, gives evidence to the clinical utility of the MI-based counseling intervention in the study population. In addition, the application of the communication tools (the SMITs) was useful towards streamlining the intervention to address the patients' barrier to medication adherence at each pharmacist-patient encounter. The frequency of specific barrier topics identified across the three visits helped to reveal salient patient barrier domains for medication nonadherence. Future research efforts can explore interventions to help overcome these barriers and improve health outcomes in diabetes management. Further investigation

using a larger sample and comparator group is needed to fully explore the impact MI-based interventions in modifying target behaviors for diabetes management.

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Appendix A – Needs Assessment

Diabetes Medication Taking

Please, provide responses for your diabetes medication only. If you are not taking any diabetes medication/insulin, then respond to question 1 only.

1. Which of the following applies to you for how your diabetes is treated?
    a. I am not taking any medication or insulin for my diabetes
    b. I am taking oral medication only
    c. I am taking/using insulin only
    d. I am taking other injectable, non-insulin medication only
    e. I am taking oral AND injectable, non-insulin medication
    f. I am taking/using insulin AND taking oral and/or non-insulin injectable medications
    g. Other (please specify) _____

2. In the table below, please list all prescribed **diabetes** medications/insulin in column 1, then, indicate on a scale of 0-7 days, the number of days ***any dose was missed in the past week*** for that diabetes medication/insulin
    Example: Metformin | 5 days

1. List of your oral , non-insulin injectables, and/or insulin	2. Days any dose, injection or unit was missed

3. If you missed any doses in the past week or previously, please circle your top 1-3 reasons.
    a. I NEVER miss any doses
    b. Benefits are questionable
    c. Feelings of sadness got in the way
    d. Did not understand how the diabetes medication/insulin works
    e. Keeping track of medication/insulin doses/units
    f. Medication/insulin adverse effects
    g. Timely refill of prescription medication/insulin
    h. Forgot to take my medication/insulin
    i. Feelings of lack of support
    j. Did not want people to see my medication/insulin
    k. Other (Please specify in the space below)

Remembering to Take Medicine (Diabetes Medication:_____)

How <u>CONFIDENT</u> are you that you will remember to take your diabetes medicine as prescribed *most* of the time (at least 6 of every 7 days)?

Mark how confident you are on the scale below. Circle the number that shows your rating:

(1 = not at all confident and 10 = very confident)

1	2	3	4	5	6	7	8	9	10

Not at all confident Very confident

What are the top 1-3 reasons you chose the number you marked and not a '1'?

_____

_____

_____

What will have to happen for the number you marked to be one or two numbers higher?

_____

_____

A few things (~1-3) I can do to remember to take my medicine as prescribed:

_____

_____

_____

Here are some ideas that have worked for other people with diabetes:

- Choosing a time/times and taking medicine at that same time every day.
- Keeping medicine near a coffee pot or toothbrush – something used every day at the same time.
- Taping a reminder note to the bathroom mirror, or a place that works for you.
- Using a reminder system like a pill box that is filled for the week ahead, or setting an alarm on a clock or cell phone.

MY GOAL FOR WHAT I WILL DO TO HELP REMEMBER:

_____

_____

Date:_____Patient:_____Time (mins):_____Pharmacist Initials:____
Next Appointment : _____

You are in control of taking care of your diabetes

Your pharmacist is an important partner who can help you by answering questions about your medicines and by helping you make your own plan for taking them.

1. Ask your pharmacist to help you make a complete, up-to-date list of all your medicines, including any nonprescription medicines, vitamins, and herbal products.
2. Get all your prescriptions filled from just one pharmacy. That way, the pharmacist can get to know you and can identify any problems or risks when you are prescribed new medicines.

Here are some important things to keep in mind about taking diabetes medicines.

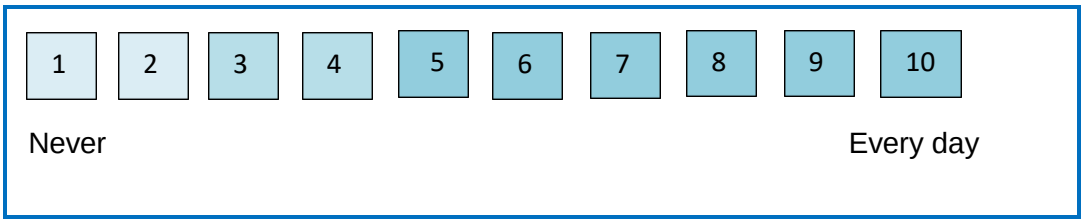
- Persons with diabetes benefit from healthy eating, being active, and taking medicines as directed.
- Medicines work in combination with healthy eating and being active to help prevent diabetes complications that could limit your life.
- Taking all your medicine as directed is one of the most important things you can do to take control of your own health and future.
- For diabetes medicines to work, they need to be taken as prescribed; this means taking them at the right time, and with the right dose, or number of pills/units.
- It is very important that you do not stop taking your diabetes medicines or take them less often without first talking with your pharmacist or doctor.
- Talk to your pharmacist or doctor if you have any questions about how your medicines work, what the benefits are, or if you are bothered by side effects.

- Try to always have enough medicine on hand so you don't run out. Your pharmacist may be able to help by planning with you for the refill schedule.
- Please don't be afraid to let your pharmacist know when you need help.

Diabetes Medicine Side Effects (Type of Medication:_____)

How OFTEN do side effects get in the way of taking your diabetes medicines as prescribed?

Mark how often side effects get in the way on the scale below. Circle the number that shows your rating between 1 and 10, where 1 = never and 10 = every day.



What side effects have you experienced that got in the way of taking your medicine as prescribed?

_____

_____

_____

A few things (1-3) I can think of to do to manage possible side effects of my diabetes medicine:

_____

_____

_____

Let your pharmacist or health care provider know about any problems you are having with side effects. **It is very important that you do not stop taking your medicines, reduce the prescribed dose, or take them less often on your own.**

MY GOAL FOR WHAT I WILL DO WHEN I FEEL LIKE SIDE EFFECTS WILL KEEP ME FROM TAKING MY MEDICINE:

_____

_____

Date:_____Name:_____Approx. Time (minutes):_____

Pharmacist initials:_____Next Appointment: _____

You are in control of taking care of your diabetes.

Your pharmacist is an important partner who can help you by answering questions about your medicines and by helping you make your own plan for taking them.

1. Ask your pharmacist to help you make a complete, up-to-date list of all your medicines, including any nonprescription medicines, vitamins, and herbal products.
2. Get all your prescriptions filled from just one pharmacy. That way, the pharmacist can get to know you and can identify any problems or risks when you are prescribed new medicines.

Here are some important things to keep in mind about taking diabetes medicines.

- Persons with diabetes benefit from healthy eating, being active, and taking medicines as directed.
- Medicines work in combination with healthy eating and being active to help prevent diabetes complications that could limit your life.
- Taking all your medicine as directed is one of the most important things you can do to take control of your own health and future.
- For diabetes medicines to work, they need to be taken as prescribed; this means taking them at the right time, and with the right dose, or number of pills/units.
- It is very important that you do not stop taking your diabetes medicines or take them less often without first talking with your pharmacist or doctor.
- Talk to your pharmacist or doctor if you have any questions about how your medicines work, what the benefits are, or if you are bothered by side effects.

- Try to always have enough medicine on hand so you don't run out. Your pharmacist may be able to help by planning with you for the refill schedule.
- Please don't be afraid to let your pharmacist know when you need help.

Benefits of Diabetes Medicines (Type of Diabetes Medication:_____)

How <u>IMPORTANT</u> is your diabetes medicines towards controlling your blood sugar and preventing health problems?

Mark how important it is on the scale below. Circle the number that shows your rating:

(1 = not at all important and 10 = very important).

1	2	3	4	5	6	7	8	9	10

Not at all Important Very Important

What do you **already know** about the benefits of taking diabetes medicines?

_____

_____

_____

What is the **biggest** question you have about the benefits of taking your diabetes medicines?

_____

_____

_____

Here are some important things to keep in mind about diabetes medicines:

- Diabetes medicines help to make your blood glucose levels go down.
- If your blood glucose level stays too high for too long, you could develop serious health problems. These problems include heart attack, stroke, kidney damage, blindness, and nerve damage.
- Taking diabetes medicine every day helps to make you feel better and prevent serious health problems over time.

Benefits of diabetes medicines that are important to me:

_____

_____

_____

Date:_____Patient:_____Approx. Time (minutes):_____
Pharmacist initials:_____Next Appointment:_____

Your pharmacist is an important partner who can help you by answering questions about your medicines and by helping you make your own plan for taking them.

1. Ask your pharmacist to help you make a complete, up-to-date list of all your medicines, including any nonprescription medicines, vitamins, and herbal products.
2. Get all your prescriptions filled from just one pharmacy. That way, the pharmacist can get to know you and can identify any problems or risks when you are prescribed new medicines.

Here are some important things to keep in mind about taking diabetes medicines.

- Persons with diabetes benefit from healthy eating, being active, and taking medicines as directed.

- Medicines work in combination with healthy eating and being active to help prevent diabetes complications that could limit your life.

- Taking all your medicine as directed is one of the most important things you can do to take control of your own health and future.

- For diabetes medicines to work, they need to be taken as prescribed; this means taking them at the right time, and with the right dose, or number of pills/units.

- It is very important that you do not stop taking your diabetes medicines or take them less often without first talking with your pharmacist or doctor.

- Talk to your pharmacist or doctor if you have any questions about how your medicines work, what the benefits are, or if you are bothered by side effects.

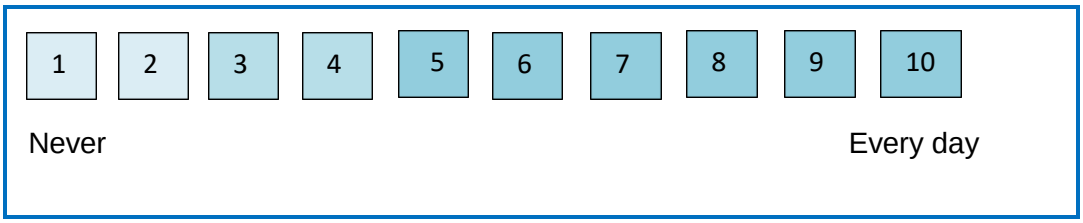
- Try to always have enough medicine on hand so you don't run out. Your pharmacist may be able to help by planning with you for the refill schedule.

- Please don't be afraid to let your pharmacist know when you need help.

Diabetes and Feeling Down or Sad

How OFTEN do feelings of being sad or down get in the way of taking your diabetes medicines as prescribed?

Mark how often these feelings get in the way on the scale below. Circle the number that shows your rating between 1 and 10, where 1 = never, and 10 = every day.



Feeling sad or down is very common in persons with diabetes - about 1 in every 5 people with diabetes regularly have these feelings. Many are not aware that these feelings get in the way of taking medications as prescribed. The good news is that effective treatments for depression are available. Depression is not a character flaw or a sign of weakness. It is a medical disorder, just like diabetes. Some of the signs are:

- Ongoing sad, anxious, or empty feelings
- Feeling guilty, worthless, or helpless
- Loss of interest in activities or hobbies usually enjoyed
- Loss of energy or feeling tired all the time
- Having problem concentrating, remembering details, or making decisions
- Having problem falling or staying asleep, or sleeping all the time
- Overeating or loss of appetite
- Having thoughts of suicide or death
- Ongoing aches and pains, headaches, cramps, or digestive problems that do not go away

A few things I can think of to do when I know my feelings of sadness or being down are getting in the way of taking my medicine as prescribed:

_____

_____

MY GOAL FOR WHAT I WILL DO WHEN MY SAD/DOWN FEELINGS KEEP ME FROM TAKING MY MEDICINE:

_____

_____

Date:_____Patient:_____Approx. Time (mins):____Rx initials:_____
Next Appointment: _____

You are in control of taking care of your diabetes.

Your pharmacist is an important partner who can help you by answering questions about your medicines and by helping you make your own plan for taking them.

1. Ask your pharmacist to help you make a complete, up-to-date list of all your medicines, including any nonprescription medicines, vitamins, and herbal products.
2. Get all your prescriptions filled from just one pharmacy. That way, the pharmacist can get to know you and can identify any problems or risks when you are prescribed new medicines.

Here are some important things to keep in mind about taking diabetes medicines.

- Persons with diabetes benefit from healthy eating, being active, and taking medicines as directed.
- Medicines work in combination with healthy eating and being active to help prevent diabetes complications that could limit your life.
- Taking all your medicine as directed is one of the most important things you can do to take control of your own health and future.
- For diabetes medicines to work, they need to be taken as prescribed; this means taking them at the right time, and with the right dose, or number of pills/units.
- It is very important that you do not stop taking your diabetes medicines or take them less often without first talking with your pharmacist or doctor.
- Talk to your pharmacist or doctor if you have any questions about how your medicines work, what the benefits are, or if you are bothered by side effects.

- Try to always have enough medicine on hand so you don't run out. Your pharmacist may be able to help by planning with you for the refill schedule.
- Please don't be afraid to let your pharmacist know when you need help.

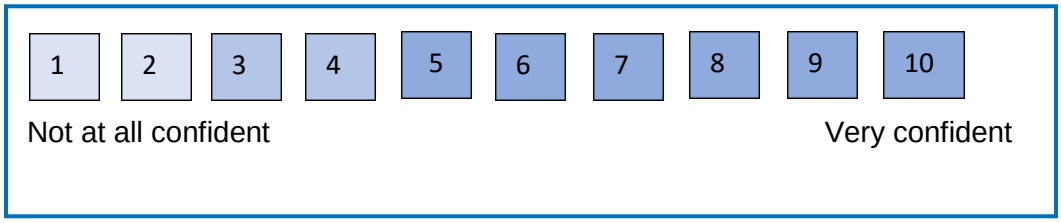
Taking Medicines and a Busy Schedule (Work, Travel, or Weekends)

(Type of Diabetes Medication:_____)

How <u>CONFIDENT</u> are you that you will remember to take your diabetes medicine as prescribed when on a busy schedule?

Mark how confident you are on the scale below. Circle the number that shows your rating:

(1 = not at all confident and 10 = very confident)



What are the top 1-3 reasons you chose the number you marked and not a '1'?

_____

_____

_____

What will have to happen for the number you marked to be one or two numbers higher?

_____

_____

A few strategies (~1-3) that can work for me towards managing a busy schedule and taking my medicine as prescribed:

_____

_____

_____

Tell your pharmacist or health care provider about how your schedule during work, vacation, or weekends could change your medication taking routine. Your pharmacist is ready to work with you on strategies that fit your busy schedule.

It is very important that you do not stop taking your medicines, reduce the prescribed dose, or take them less often on your own.

MY GOAL FOR WHAT I WILL DO TO HELP TAKE MY DIABETES MEDICINE WHEN BUSY:

_____

_____

_____

Date:_____Name:_____Time (mins):____Pharmacist:_____

Next Appointment_____

You are in control of taking care of your diabetes

Your pharmacist is an important partner who can help you by answering questions about your medicines and by helping you make your own plan for taking them.

1. Ask your pharmacist to help you make a complete, up-to-date list of all your medicines, including any nonprescription medicines, vitamins, and herbal products.
2. Get all your prescriptions filled from just one pharmacy. That way, the pharmacist can get to know you and can identify any problems or risks when you are prescribed new medicines.

Here are some important things to keep in mind about taking diabetes medicines.

- Persons with diabetes benefit from healthy eating, being active, and taking medicines as directed.

- Medicines work in combination with healthy eating and being active to help prevent diabetes complications that could limit your life.

- Taking all your medicine as directed is one of the most important things you can do to take control of your own health and future.

- For diabetes medicines to work, they need to be taken as prescribed; this means taking them at the right time, and with the right dose, or number of pills/units.

- It is very important that you do not stop taking your diabetes medicines or take them less often without first talking with your pharmacist or doctor.

- Talk to your pharmacist or doctor if you have any questions about how your medicines work, what the benefits are, or if you are bothered by side effects.

- Try to always have enough medicine on hand so you don't run out. Your pharmacist may be able to help by planning with you for the refill schedule.

- Please don't be afraid to let your pharmacist know when you need help.

Refilling Diabetes Medicines as Scheduled (Type of Medication:_____)

How IMPORTANT is it to refill your prescription medicines on time?

Mark how important it is on the scale below. Circle the number that shows your rating:

(1 = not at all important and 10 = very important).

1	2	3	4	5	6	7	8	9	10

Not at all Important Very Important

What are the top 1-3 reasons you chose the number you marked and not a '1'?

_____

_____

_____

What will have to happen for the number you marked to be one or two numbers higher?

_____

_____

When the refilled prescription isn't picked up on time, what is the biggest challenge causing this?

_____

A few things I can think of that could work for me to help in refilling my medicines on time?

_____

_____

Here are some ideas that have worked for other people:

- Make a "Refill Prescription" note on the calendar you use most often. Choose a refill date of about 1 week prior to the actual refill date to avoid running out of medication.
- Ask your pharmacist about prescription refill services and delivery services.
- Ask your pharmacist to send you refill reminders. Reminders usually can be sent by your preferred mode of communication with the pharmacy (mail, telephone, e-mail, or text message)

MY GOAL for what I will do to help me get my medicines refilled on time:

_____

_____

Date:_____Patient:_____Time (minutes):____Pharmacist:_____

Next Appointment:_____

You are in control of taking care of your diabetes

Your pharmacist is an important partner who can help you by answering questions about your medicines and by helping you make your own plan for taking them.

1. Ask your pharmacist to help you make a complete, up-to-date list of all your medicines, including any nonprescription medicines, vitamins, and herbal products.
2. Get all your prescriptions filled from just one pharmacy. That way, the pharmacist can get to know you and can identify any problems or risks when you are prescribed new medicines.

Here are some important things to keep in mind about taking diabetes medicines.

- Persons with diabetes benefit from healthy eating, being active, and taking medicines as directed.

- Medicines work in combination with healthy eating and being active to help prevent diabetes complications that could limit your life.

- Taking all your medicine as directed is one of the most important things you can do to take control of your own health and future.

- For diabetes medicines to work, they need to be taken as prescribed; this means taking them at the right time, and with the right dose, or number of pills/units.

- It is very important that you do not stop taking your diabetes medicines or take them less often without first talking with your pharmacist or doctor.

- Talk to your pharmacist or doctor if you have any questions about how your medicines work, what the benefits are, or if you are bothered by side effects.

- Try to always have enough medicine on hand so you don't run out. Your pharmacist may be able to help by planning with you for the refill schedule.

- Please don't be afraid to let your pharmacist know when you need help.

Appendix C - Survey Booklet at Baseline

Name:_____ **Today's Date:** _____

Please respond to all of the questions that apply to you. Skip sections that do not apply (for example, skip questions on insulin taking if you are not taking insulin for your diabetes).
There is no right or wrong answer to the questions; your responses will help us understand how people with diabetes feel about their treatment and how they feel about living with diabetes.

SECTION A

Race/Ethnicity:_____**Gender**:_____**Age:** _____

Highest Education Level Completed

- ☐ Grade school
- ☐ Middle school/junior high
- ☐ High school
- ☐ College
- ☐ Trade school
- ☐ Post graduate
- ☐ Doctorate

Marital Status:

- ☐ Single
- ☐ Married or with partner
- ☐ Divorced
- ☐ Widowed

How long have you had diabetes?_____Years_____Months

How long have you joined the EAMC Diabetes Disease Management?_____Years _____Months

In the **past 6 months,** how many times have you had to go to the Emergency Department (ER) because of problems related to your diabetes? _____

In the **past 6 months,** how many times have you had to stay overnight at the hospital because of problems related to your diabetes? _____

Have you been told by a doctor that you have any of the following? (Check all that apply)

- ☐ Diabetes
- ☐ High Blood Pressure
- ☐ High Cholesterol
- ☐ Liver problems
- ☐ Asthma/COPD
- ☐ GERD
- ☐ Dementia/Memory Loss
- ☐ Heart Disease
- ☐ Fibromyalgia
- ☐ Kidney Problems
- ☐ Gout
- ☐ Depression
- ☐ Circulation/numbness problems
- ☐ Mental Illnesses
- ☐ Other (Please specify) _____

SECTION B

Diabetes Medicine Taking (Oral medicines only on this form)

Please respond by checking either 'yes' or 'no' for each of the items in the box below. Respond here for only one of your oral diabetes medicines (you will write that medicine name in the space below). You will have a chance to respond for each of your other oral diabetes medicines (if any) on separate forms.

Name of this oral diabetes medicine: _____

Questions	**Yes**	**No**
Do you sometimes forget to take this oral diabetes medicine (pills)?		
People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past two weeks, where there any days when you did not take this oral diabetes medicine?		
Have you ever cut back or stopped taking your oral diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along this medicine?		
Did you take this medicine as prescribed yesterday?		
When you feel that your symptoms are under control, do you sometimes stop taking this oral medicine?		
Taking medicines every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan for this medicine?		

How often do you have difficulties sticking to your treatment plan for this medicine?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time

On how many of the **last SEVEN DAYS**, <u>was the entire prescribed daily amount</u> of this oral diabetes medicine taken?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

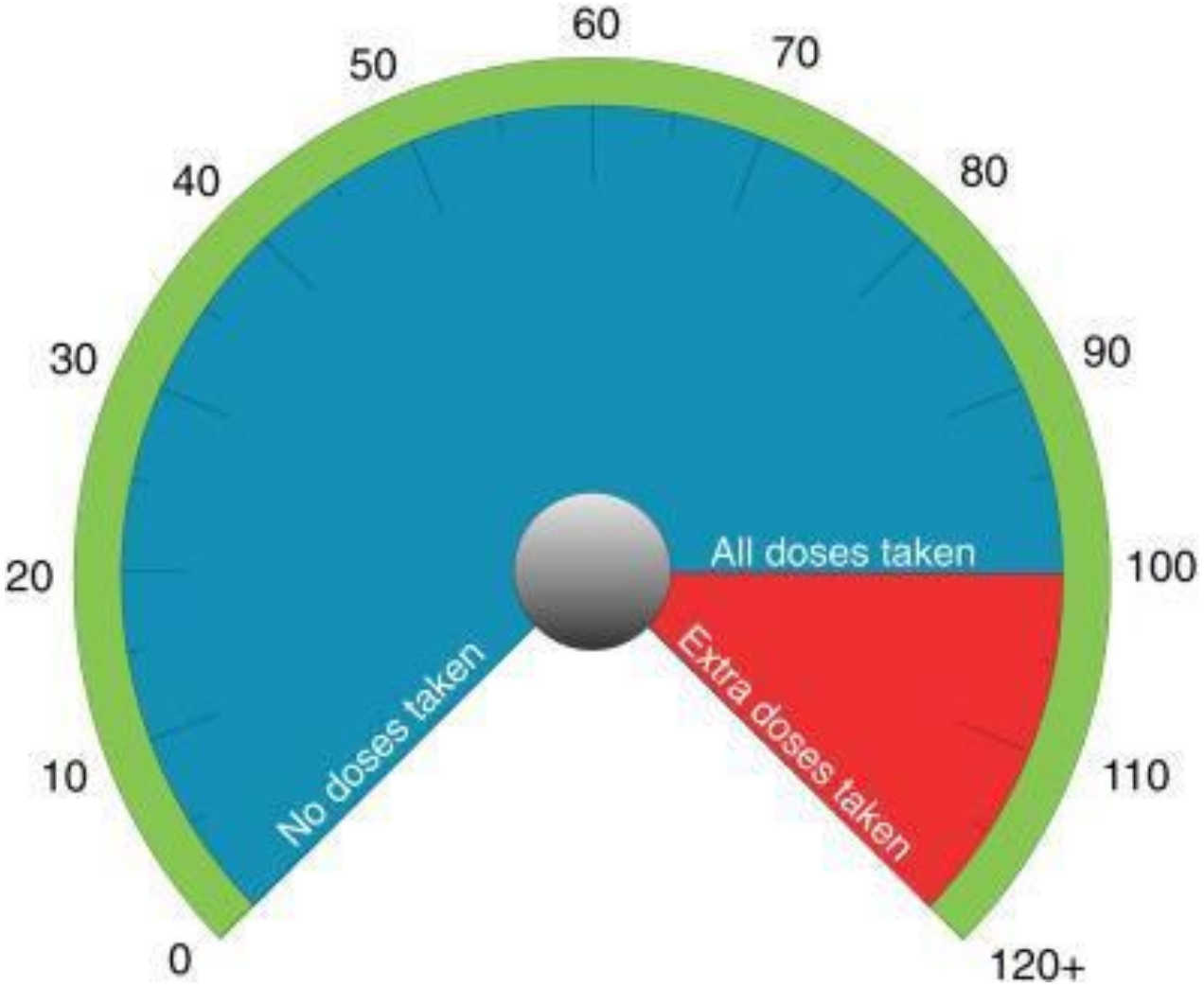
On how many of the **last SEVEN DAYS** <u>were the recommended number of pills per dose</u> taken for this oral diabetes medicine?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Please indicate on the scale below the number of days ***any dose was missed*** ***in the past week*** for this oral diabetes medicine.

☐ 0 Day ☐ 1 Day ☐ 2 Days ☐ 3 days ☐ 4 Days ☐ 5 Days ☐ 6 Days ☐ 7 Days

Think about the (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.



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Diabetes Medicine Taking (non-insulin injectable medicines)

Please respond by checking either 'yes' or 'no' for each of the items in the box below. Respond here for only one of your non-insulin injectable diabetes medicines (you will write that medicine name in the space below). You will have a chance to respond for each of your other non-insulin injectable diabetes medicines (if any) on separate forms.

Name of this injectable non-insulin diabetes medicine: _____

Does your treatment plan for this medicine require you to inject it daily or once a week?
___Daily
___Once a week
___Other (please specify) _____

Questions	Yes	No
Do you sometimes forget to take this non-insulin injectable diabetes medicine?		
People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past two weeks, where there any injections/doses you did not take when scheduled for this non-insulin injectable diabetes medicine?		
Have you ever cut back or stopped taking this non-insulin injectable diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along this injectable non-insulin diabetes medicine?		
Did you take all this non-insulin injectable diabetes medicines yesterday?		
When you feel that your symptoms are under control, do you sometimes stop taking this non-insulin injectable medicine?		
Taking non-insulin injectable diabetes medicines is a real inconvenience for some people. Do you ever feel hassled about sticking to the treatment plan for this medicine?		

How often do you have difficulties sticking to this treatment plan?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time

If your injection schedule is daily, respond to section A; if you injection schedule is weekly, respond to section B.

A. If your treatment plan requires you to inject this medicine every day, on how many of the last SEVEN DAYS, **did you inject** this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day **1 Day** **2 Days** **3 days** **4 Days** **5 Days** **6 Days** **7 Days**

If your treatment plan requires you to inject this medicine every day, on how many of the last SEVEN DAYS, **did you inject the complete dose** of this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day 1 Day 2 Days 3 days 4 Days 5 Days 6 Days 7 Days

Please indicate on the scale below the number of days ***any injection was missed in the past week*** for this non-insulin injectable diabetes medicine.

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day 1 Day 2 Days 3 days 4 Days 5 Days 6 Days 7 Days

OR

B. If your treatment plan requires you to inject this medicine once a week, on how many of the last FOUR WEEKS, **did you inject** this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐

0 Weeks 1 Week 2 Weeks 3 Weeks 4 Weeks

On how many of the last FOUR WEEKS, **was the complete dose injected** for this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐

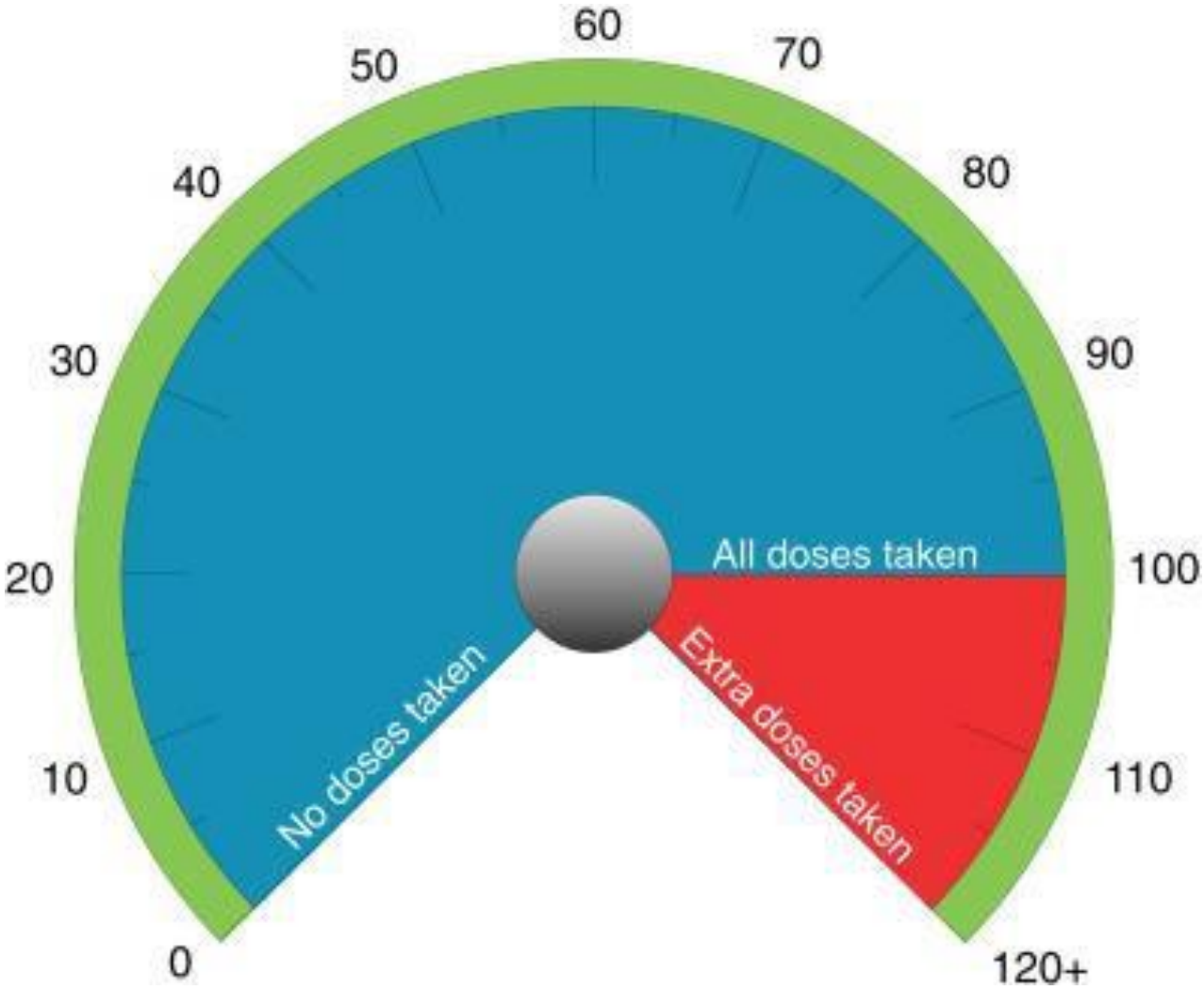
0 Weeks 1 Week 2 Weeks 3 Weeks 4 Weeks

Please indicate on the scale below the number of weeks ***any injection was missed in the past four weeks*** for this non-insulin injectable diabetes medicine.

☐ ☐ ☐ ☐ ☐

0 Weeks 1 Week 2 Weeks 3 Weeks 4 Weeks

Think about the non-insulin injectable (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.



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Diabetes Medicine Taking (Insulin only)

Please respond by checking either 'yes' or 'no' for each of the items in the box below. Respond here for only your insulin injectable (you will write that insulin name or just say "insulin" in the space below). You will have a chance to respond for each of your other insulin injectables (if any) on separate forms.

Name of injectable insulin: _____

Questions	Yes	No
Do you sometimes forget to inject your insulin?		
People sometimes miss injecting their insulin for reasons other than forgetting. Thinking over the past two weeks, where there any days when you did not inject your insulin diabetes medicine?		
Have you ever cut back or stopped injecting your insulin diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along your insulin?		
Did you inject all your insulin yesterday?		
When you feel that your symptoms are under control, do you sometimes stop injecting your insulin?		
Injecting insulin for your diabetes every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?		

How often do you have difficulties sticking to your treatment plan?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time.

On how many of the last SEVEN DAYS, **did you inject** your insulin as prescribed?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

On how many of the last SEVEN DAYS, **was your recommended insulin units injected as** prescribed?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Please indicate on the scale below the number of days ***any injection was missed in the past week*** for your insulin.

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Think about the insulin (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.

SECTION B

Diabetes Medicine Taking (Oral medicines only on this form)

Please respond by checking either 'yes' or 'no' for each of the items in the box below. Respond here for only one of your oral diabetes medicines (you will write that medicine name in the space below). You will have a chance to respond for each of your other oral diabetes medicines (if any) on separate forms.

Name of this oral diabetes medicine: _____

Questions	**Yes**	**No**
Do you sometimes forget to take this oral diabetes medicine (pills)?		
People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past two weeks, where there any days when you did not take this oral diabetes medicine?		
Have you ever cut back or stopped taking your oral diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along this medicine?		
Did you take this medicine as prescribed yesterday?		
When you feel that your symptoms are under control, do you sometimes stop taking this oral medicine?		
Taking medicines every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan for this medicine?		

How often do you have difficulties sticking to your treatment plan for this medicine?

A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time

On how many of the **last SEVEN DAYS**, <u>was the entire prescribed daily amount</u> of this oral diabetes medicine taken?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

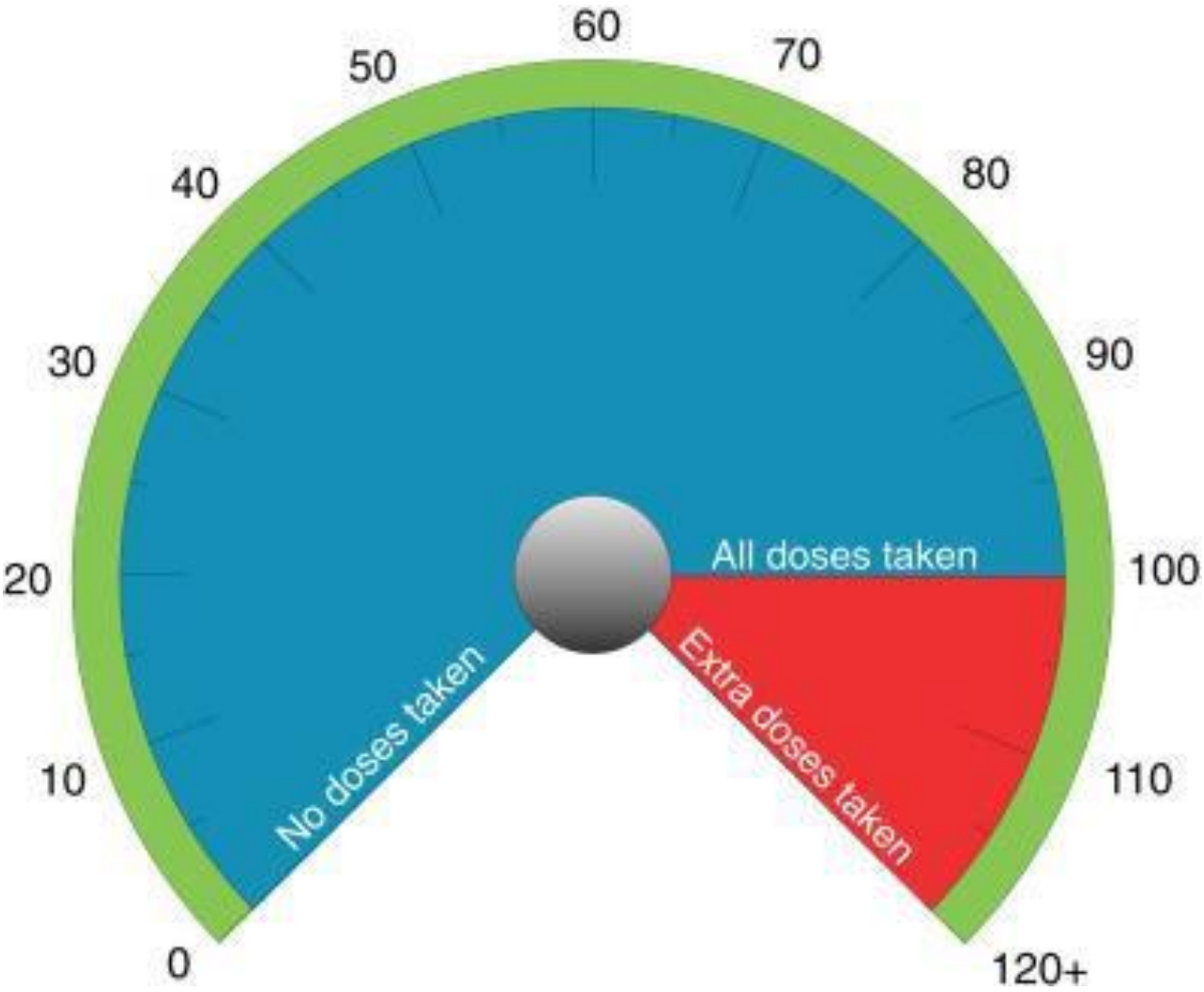
On how many of the **last SEVEN DAYS** <u>were the recommended number of pills per dose</u> taken for this oral diabetes medicine?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Please indicate on the scale below the number of days ***<u>any dose was missed</u> in the past week*** for this oral diabetes medicine.

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Think about the (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.



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Are you taking another oral diabetes medication? Yes ☐ No ☐

If Yes, please complete the next set of questions.
Name of other oral diabetes medicine: _____

Questions	**Yes**	**No**
Do you sometimes forget to take this oral diabetes medicine (pills)?		

People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past two weeks, where there any days when you did not take this oral diabetes medicine?		
Have you ever cut back or stopped taking your oral diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along this medicine?		
Did you take this medicine as prescribed yesterday?		
When you feel that your symptoms are under control, do you sometimes stop taking this oral medicine?		
Taking medicines every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan for this medicine?		

How often do you have difficulties sticking to your treatment plan for this medicine?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time

On how many of the **last SEVEN DAYS**, <u>was the entire prescribed daily amount</u> of this oral diabetes medicine taken?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day 1 Day 2 Days 3 days 4 Days 5 Days 6 Days 7 Days

On how many of the **last SEVEN DAYS** <u>were the recommended number of pills per dose</u> taken for this oral diabetes medicine?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

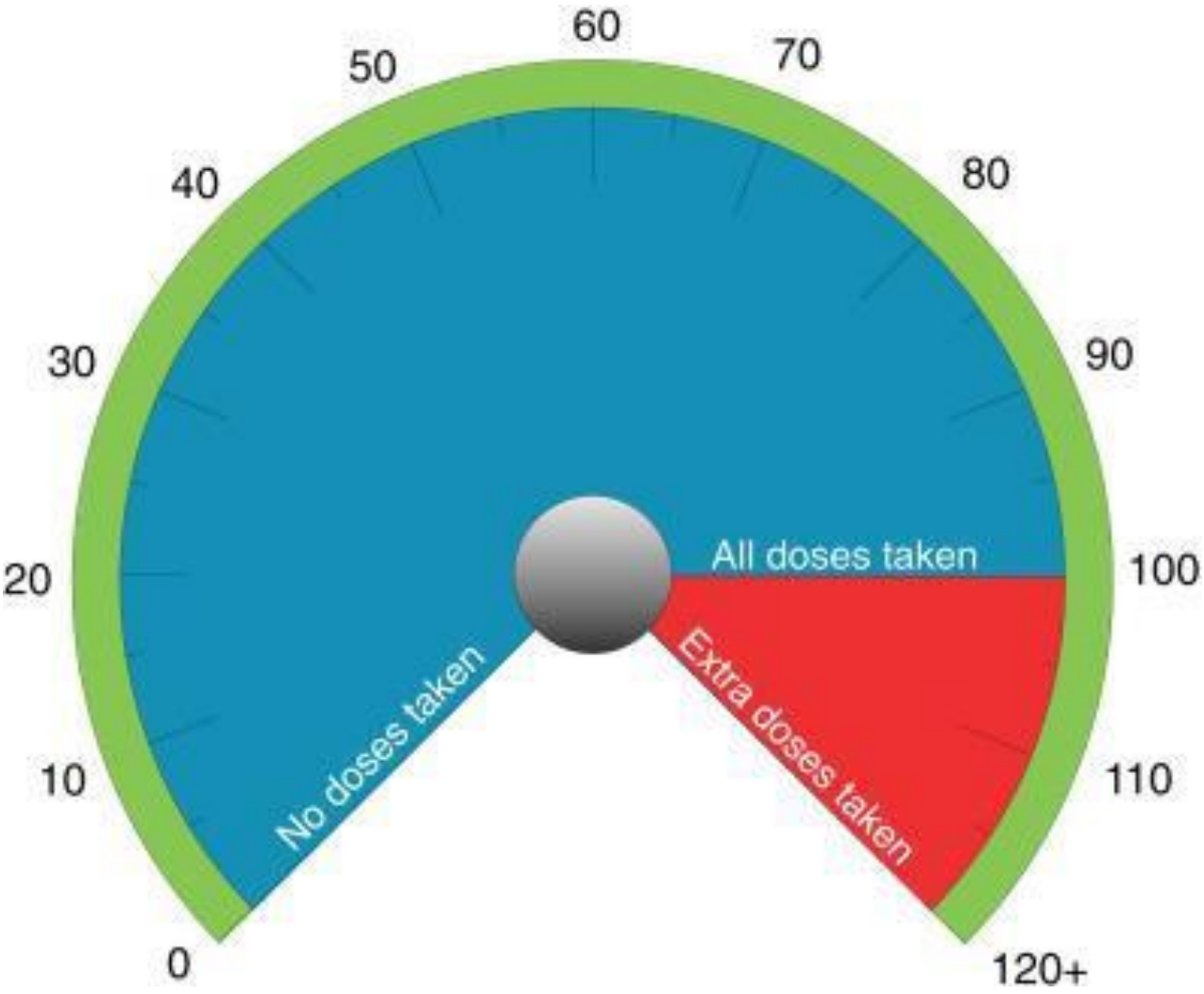
0 Day 1 Day 2 Days 3 days 4 Days 5 Days 6 Days 7 Days

Please indicate on the scale below the number of days ***<u>any dose was missed</u> in the past week*** for this oral diabetes medicine.

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day 1 Day 2 Days 3 days 4 Days 5 Days 6 Days 7 Days

Think about the (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.



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Diabetes Medicine Taking (non-insulin injectable medicines)

Please respond by checking either 'yes' or 'no' for each of the items in the box below. Respond here for only one of your non-insulin injectable diabetes medicines (you will write that medicine name in the space below). You will have a chance to respond for each of your other non-insulin injectable diabetes medicines (if any) on separate forms.

Name of this injectable non-insulin diabetes medicine: _____

Does your treatment plan for this medicine require you to inject it daily or once a week?
___Daily
___Once a week
___Other (please specify) _____

Questions	Yes	No
Do you sometimes forget to take this non-insulin injectable diabetes medicine?		
People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past two weeks, where there any injections/doses you did not take when scheduled for this non-insulin injectable diabetes medicine?		
Have you ever cut back or stopped taking this non-insulin injectable diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along this injectable non-insulin diabetes medicine?		
Did you take all this non-insulin injectable diabetes medicines yesterday?		
When you feel that your symptoms are under control, do you sometimes stop taking this non-insulin injectable medicine?		
Taking non-insulin injectable diabetes medicines is a real inconvenience for some people. Do you ever feel hassled about sticking to the treatment plan for this medicine?		

How often do you have difficulties sticking to this treatment plan?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time

If your injection schedule is daily, respond to section A; if you injection schedule is weekly, respond to section B.

C. If your treatment plan requires you to inject this medicine every day, on how many of the last SEVEN DAYS, **did you inject** this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 Day 1 Day 2 Days 3 days 4 Days 5 Days 6 Days 7 Days

If your treatment plan requires you to inject this medicine every day, on how many of the last SEVEN DAYS, **did you inject the complete dose** of this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day 1 Day 2 Days 3 days 4 Days 5 Days 6 Days 7 Days

Please indicate on the scale below the number of days ***any injection was missed in the past week*** for this non-insulin injectable diabetes medicine.

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day **1 Day** **2 Days** **3 days** **4 Days** **5 Days** **6 Days** **7 Days**

OR

D. If your treatment plan requires you to inject this medicine once a week, on how many of the last FOUR WEEKS, **did you inject** this non-insulin injectable diabetes medicine as prescribed?

☐ **0 Weeks** ☐ **1 Week** ☐ **2 Weeks** ☐ **3 Weeks** ☐ **4 Weeks**

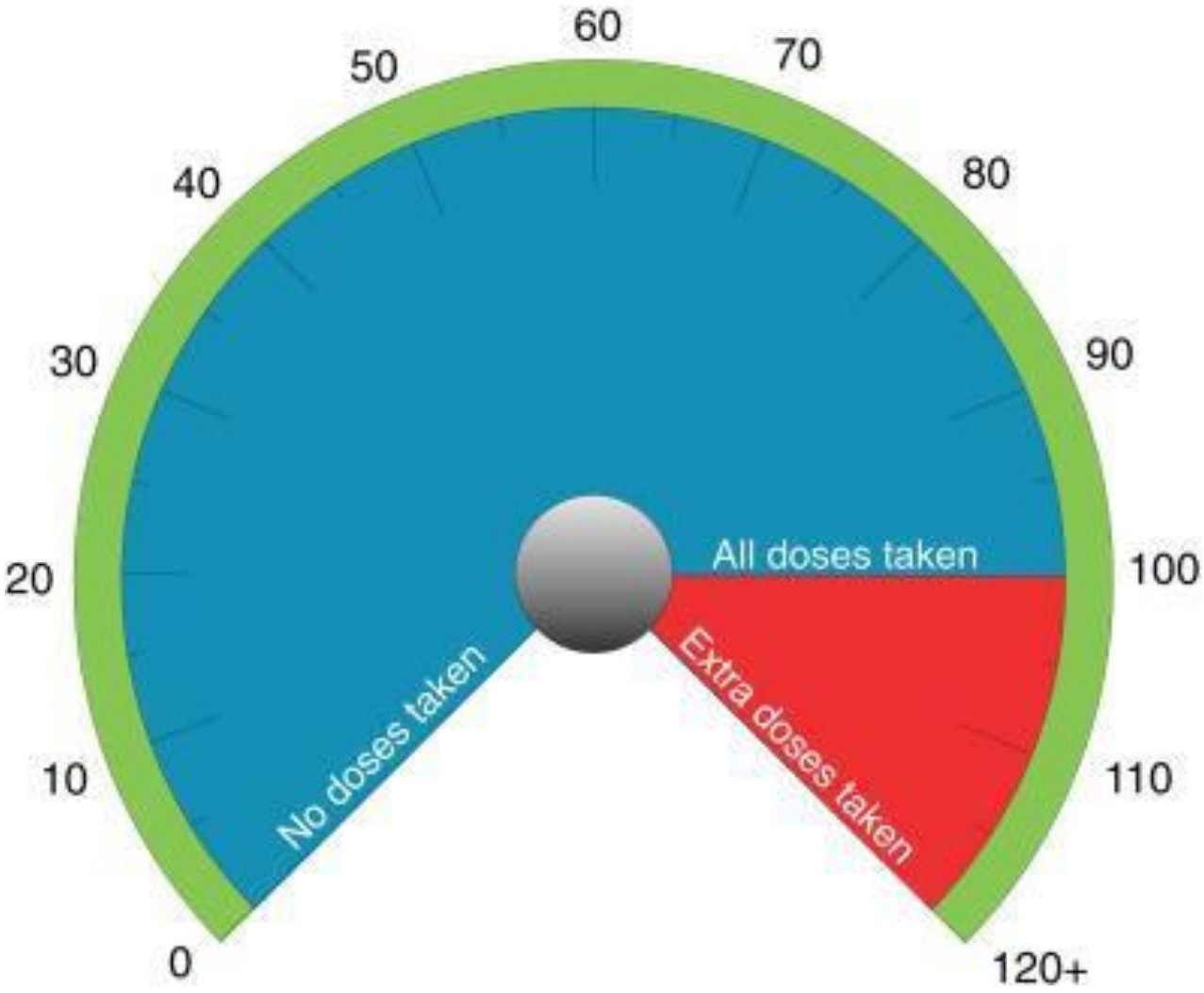
On how many of the last FOUR WEEKS, **was the complete dose injected** for this non-insulin injectable diabetes medicine as prescribed?

☐ **0 Weeks** ☐ **1 Week** ☐ **2 Weeks** ☐ **3 Weeks** ☐ **4 Weeks**

Please indicate on the scale below the number of weeks ***any injection was missed in the past four weeks*** for this non-insulin injectable diabetes medicine.

☐ **0 Weeks** ☐ **1 Week** ☐ **2 Weeks** ☐ **3 Weeks** ☐ **4 Weeks**

Think about the non-insulin injectable (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.



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Are you taking another injectable non-insulin diabetes medication? Yes ☐ No ☐

If Yes, please complete the next set of questions.

Name of this injectable non-insulin diabetes medicine: _____

Does your treatment plan for this medicine require you to inject it daily or once a week?
___Daily
___Once a week
___Other (please specify) _____

Questions	Yes	No
Do you sometimes forget to take this non-insulin injectable diabetes medicine?		
People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past two weeks, where there any injections/doses you did not take when scheduled for this non-insulin injectable diabetes medicine?		
Have you ever cut back or stopped taking this non-insulin injectable diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along this injectable non-insulin diabetes medicine?		
Did you take all this non-insulin injectable diabetes medicines yesterday?		
When you feel that your symptoms are under control, do you sometimes stop taking this non-insulin injectable medicine?		
Taking non-insulin injectable diabetes medicines is a real inconvenience for some people. Do you ever feel hassled about sticking to the treatment plan for this medicine?		

How often do you have difficulties sticking to this treatment plan?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time

If your injection schedule is daily, respond to section A; if you injection schedule is weekly, respond to section B.

E. If your treatment plan requires you to inject this medicine every day, on how many of the last SEVEN DAYS, **did you inject** this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

2 Day 1 Day 2 Days 3 days 4 Days 5 Days 6 Days 7 Days

If your treatment plan requires you to inject this medicine every day, on how many of the last SEVEN DAYS, **did you inject the complete dose** of this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day 1 Day 2 Days 3 days 4 Days 5 Days 6 Days 7 Days

Please indicate on the scale below the number of days ***any injection was missed in the past week*** for this non-insulin injectable diabetes medicine.

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day **1 Day** **2 Days** **3 days** **4 Days** **5 Days** **6 Days** **7 Days**

OR

F. **If your treatment plan requires you to inject this medicine once a week**, on how many of the last FOUR WEEKS, **did you inject** this non-insulin injectable diabetes medicine as prescribed?

☐ **0 Weeks** ☐ **1 Week** ☐ **2 Weeks** ☐ **3 Weeks** ☐ **4 Weeks**

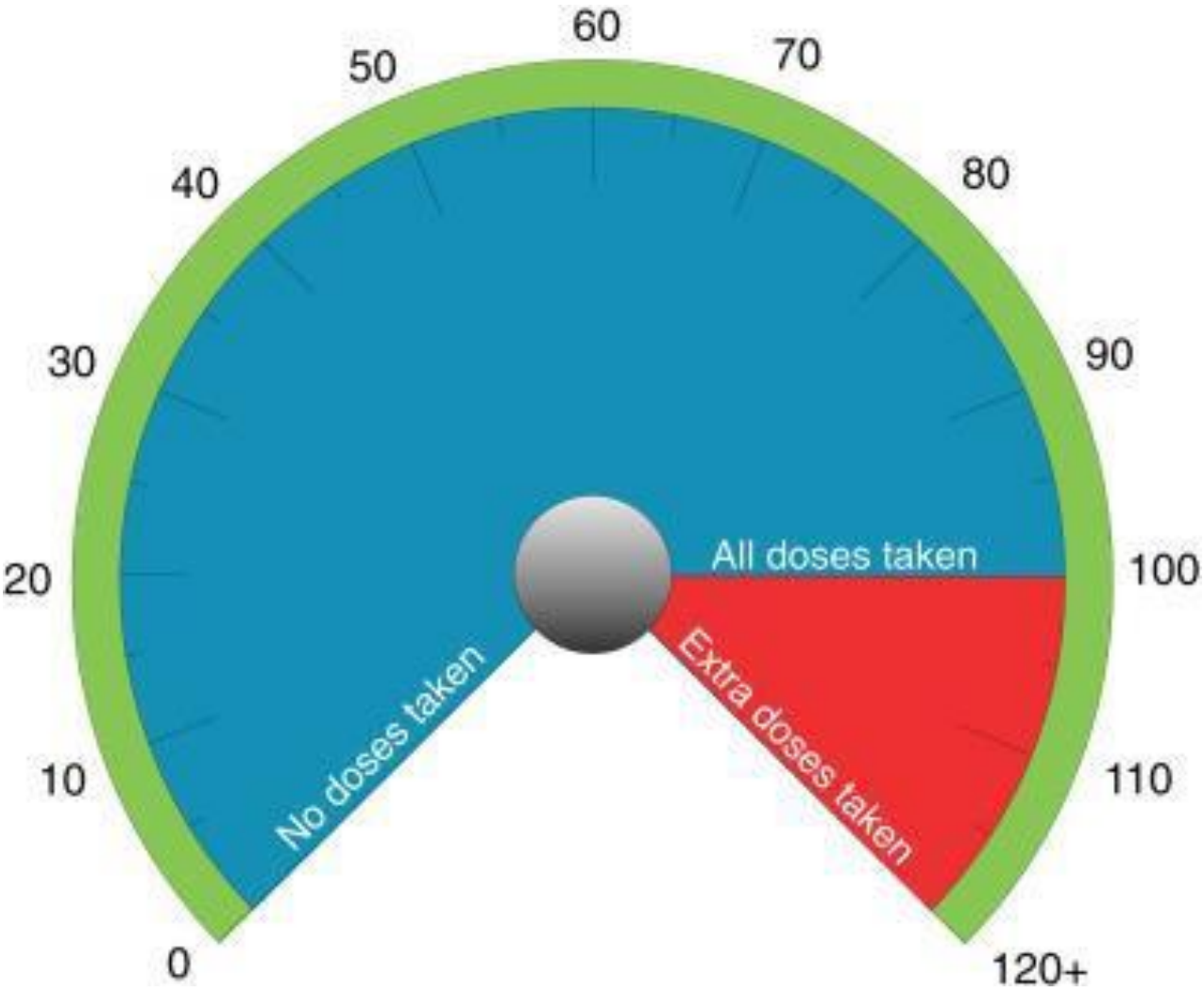
On how many of the last FOUR WEEKS, **was the complete dose injected** for this non-insulin injectable diabetes medicine as prescribed?

☐ **0 Weeks** ☐ **1 Week** ☐ **2 Weeks** ☐ **3 Weeks** ☐ **4 Weeks**

Please indicate on the scale below the number of weeks ***any injection was missed in the past four weeks*** for this non-insulin injectable diabetes medicine.

☐ **0 Weeks** ☐ **1 Week** ☐ **2 Weeks** ☐ **3 Weeks** ☐ **4 Weeks**

Think about the non-insulin injectable (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.



Diabetes Medicine Taking (Insulin only)

Please respond by checking either 'yes' or 'no' for each of the items in the box below. Respond here for only your insulin injectable (you will write that insulin name or just say "insulin" in the space below). You will have a chance to respond for each of your other insulin injectables (if any) on separate forms.

Name of injectable insulin: _____

Questions	Yes	No
Do you sometimes forget to inject your insulin?		
People sometimes miss injecting their insulin for reasons other than forgetting. Thinking over the past two weeks, where there any days when you did not inject your insulin diabetes medicine?		

Have you ever cut back or stopped injecting your insulin diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along your insulin?		
Did you inject all your insulin yesterday?		
When you feel that your symptoms are under control, do you sometimes stop injecting your insulin?		
Injecting insulin for your diabetes every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?		

How often do you have difficulties sticking to your treatment plan?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time.

On how many of the last SEVEN DAYS, **did you inject** your insulin as prescribed?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

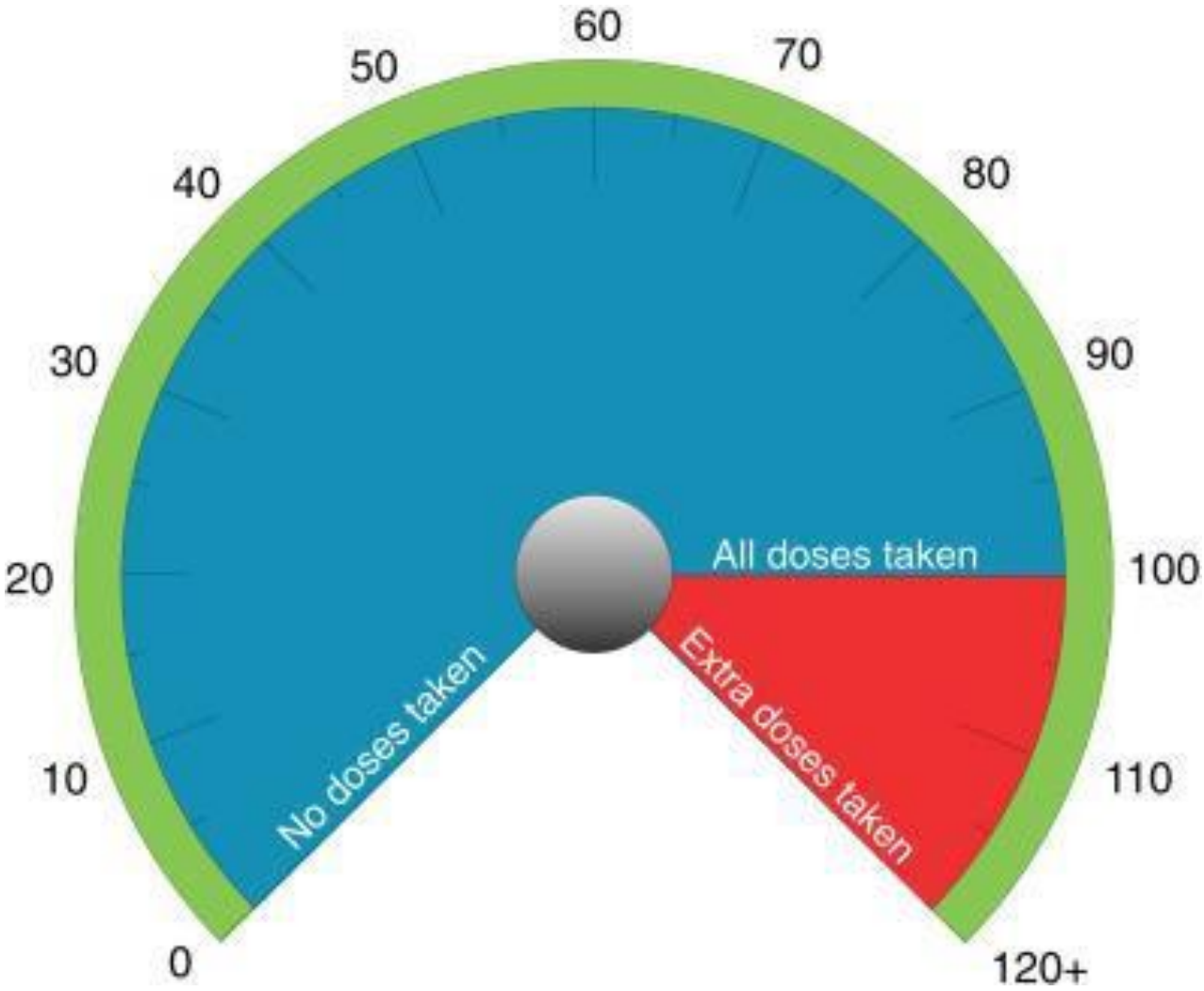
On how many of the last SEVEN DAYS, **was your recommended insulin units injected as** prescribed?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Please indicate on the scale below the number of days ***any injection was missed in the past week*** for your insulin.

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Think about the insulin (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.


0
10
20
30
40
50
60
70
80
90
100
110
120+
All doses taken
No doses taken
Extra doses taken

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Are you taking another type of insulin for your diabetes? Yes ☐ **No** ☐

If Yes, please complete the next set of questions.
Name of injectable insulin: _____

Questions	**Yes**	**No**
Do you sometimes forget to inject your insulin?		
People sometimes miss injecting their insulin for reasons other than forgetting. Thinking over the past two weeks, where there any days when you did not inject your insulin diabetes medicine?		
Have you ever cut back or stopped injecting your insulin diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along your insulin?		
Did you inject all your insulin yesterday?		
When you feel that your symptoms are under control, do you sometimes stop injecting your insulin?		
Injecting insulin for your diabetes every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?		

How often do you have difficulties sticking to your treatment plan?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time.

On how many of the last SEVEN DAYS, **did you inject** your insulin as prescribed?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

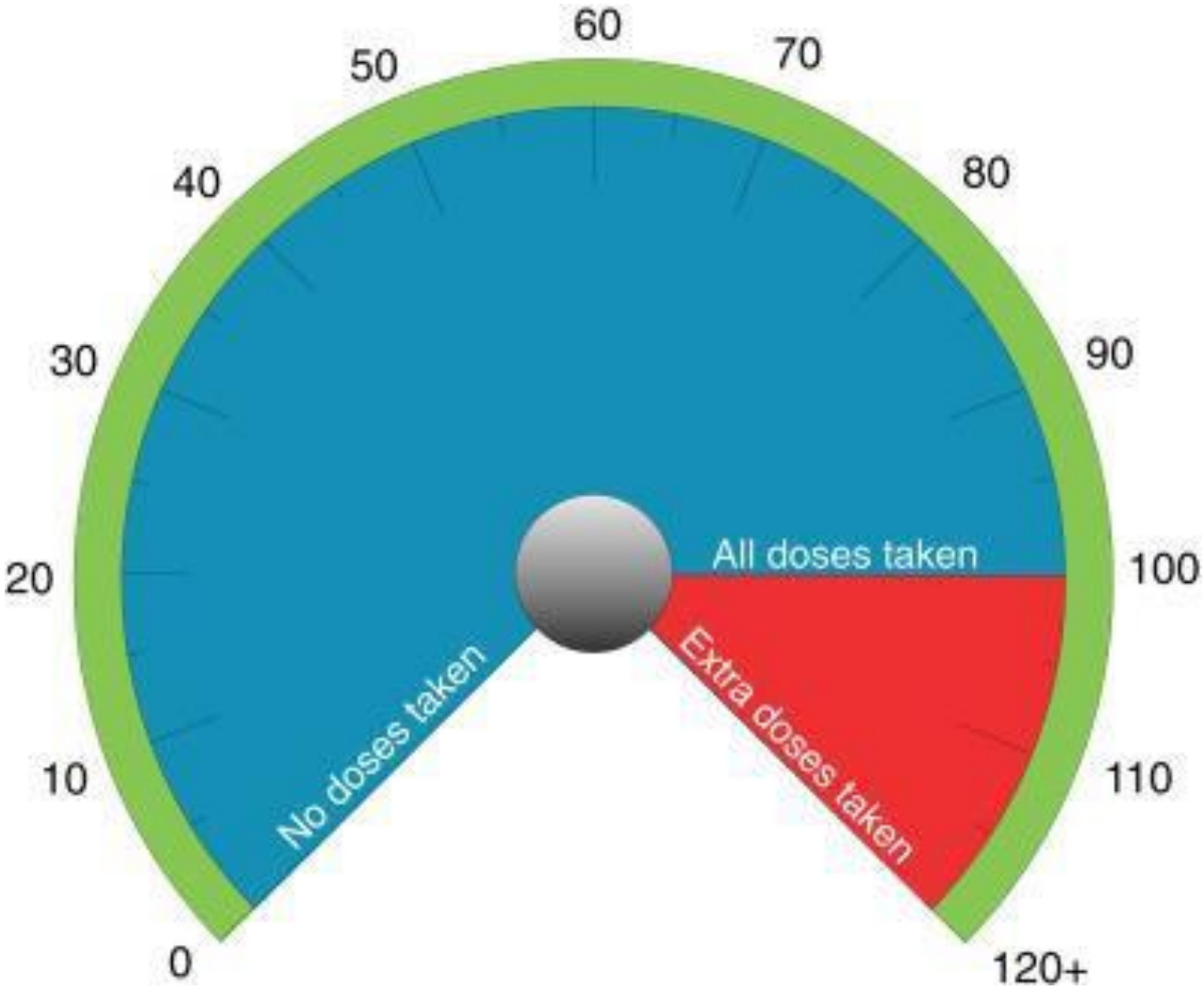
On how many of the last SEVEN DAYS, **was your recommended insulin units injected as** prescribed?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Please indicate on the scale below the number of days ***any injection was missed in the past week*** for your insulin.

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Think about the insulin (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.



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SECTION C

The questions in this section ask for your views about your general health. Please answer every question by marking one box per question. If you are unsure about how to answer, please give the best answer you can.

1. In general, would you say your health is:

❒	❒	❒	❒	❒
Excellent	Very good	Good	Fair	Poor

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, Limited A Lot	**Yes, Limited A Little**	**No, Not Limited At All**
2. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling or playing golf	❒	❒	❒
3. Climbing **several** flights of stairs	❒	❒	❒

During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

	Yes	**No**
4. **Accomplished less** than you would like	❒	❒
5. Were limited in the **kind** of work or other activities	❒	❒

During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes	**No**
6. **Accomplished less** than you would like	❒	❒
7. Didn't do work or other activities as **carefully** as usual	❒	❒

8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

❒	❒	❒	❒	❒
Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**

These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time **during the past 4 weeks.**

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
9. Have you felt calm and peaceful?	❒	❒	❒	❒	❒	❒
10. Did you have a lot of energy?	❒	❒	❒	❒	❒	❒
11. Have you felt downhearted and blue?	❒	❒	❒	❒	❒	❒

12. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

❒	❒	❒	❒	❒
All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None the time**

The next set of questions asks about your quality of life – in other words how good or bad you feel your life is.

Please put an **"X"** in the box that best indicates your response for each item.

What we want toknow is how you feel about your life now.

(I) In general, my present quality of life is:

❒	❒	❒	❒	❒	❒	❒
Excellent	Very good	Good	Neither good nor bad	Bad	Very bad	Extremely bad

Now we will like to know how your quality of life is affected by your diabetes, its management and any complications you may have.

(II) If I did not have diabetes, my quality of life will be:

❒	❒	❒	❒	❒
Very much Better	Much better	A little better	The same	Worse

Please respond to the more specific items on the page that follow. For each aspect of life described, you will find two parts:

For Part (a): Put an "X" in one box to show how diabetes affects this aspect of your life;

For Part (b): Put an "X" in one box to show how important this aspect of your life is to your quality of life.

3 (a) If I did <u>not</u> have diabetes, I will enjoy my leisure activities:

❒ Very much more ❒ Much more ❒ A little more ❒ The same ❒ Less

(b) My leisure activities are:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

4 Are you currently working, looking for work or would like to work?

Yes ❒ If **yes,** complete **(a)** and **(b)**

No ❒ If no, go straight to **Question 3**

(a) If I did <u>not</u> have diabetes, my work life would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) For me, having a work life is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

5 (a) If I did <u>not</u> have diabetes, local or long distance travel would be:

❒ Very much easier ❒ Much easier ❒ A little easier ❒ The same ❒ More difficult

(b) For me, local or long distance travel are:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

6 Do you ever go on vacation or want to go on vacation?

Yes ❒ If **yes,** complete **(a)** and **(b)**

No ❒ If no, go straight to **Question 5**

(a) If I did <u>not</u> have diabetes, my vacation would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) For me, vacations are:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

7 (a) If I did <u>not</u> have diabetes, physically I could do:

❒ Very much more ❒ Much more ❒ A little more ❒ The same ❒ Less

(b) For me, how much I can do physically is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

8 Do you have any family/relatives?

Yes ❒ If **yes,** complete **(a)** and **(b)**

No ❒ If no, go straight to **Question 7**

(a) If I did <u>not</u> have diabetes, my family life would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) My family life is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

9 (a) If I did <u>not</u> have diabetes, my friendship and social life would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) My friendship and social life are:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

10 Do you have or would you like to have a close personal relationship (e.g.husband, wife, partner)?

Yes ❒ If **yes,** complete **(a)** and **(b)**

No ❒ If no, go straight to **Question 9**

(a) If I did <u>not</u> have diabetes, my closest personal relationship would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) For me, having a personal relationship is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

11 Do you have or would you like to have a sex life?

Yes ❒ If **yes,** complete **(a)** and **(b)**

No ❒ If no, go straight to **Question 10**

(a) If I did <u>not</u> have diabetes, my sex life would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) For me, having a sex life is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

12 (a) If I did <u>not</u> have diabetes, my physical appearance would be:

❒ ❒ ❒ ❒ ❒
Very much better Much better A little better The same Worse

(b) My physical appearance is:

❒ ❒ ❒ ❒
Very important Important Somewhat important Not at all important

13 (a) If I did <u>not</u> have diabetes, my self-confidence would be:

❒ ❒ ❒ ❒ ❒
Very much better Much better A little better The same Worse

(b) My self-confidence is:

❒ ❒ ❒ ❒
Very important Important Somewhat important Not at all important

14 (a) If I did <u>not</u> have diabetes, my motivation would be:

❒ ❒ ❒ ❒ ❒
Very much better Much better A little better The same Worse

(b) My motivation is:

❒ ❒ ❒ ❒
Very important Important Somewhat important Not at all important

15 (a) If I did <u>not</u> have diabetes, the way people in general react to me would be:

❒ ❒ ❒ ❒ ❒
Very much better Much better A little better The same Worse

(b) The way people in general react to me is:

❒ ❒ ❒ ❒
Very important Important Somewhat important Not at all important

16 (a) If I did <u>not</u> have diabetes, my feelings about the future (e.g. worries, hopes) would be:

❒ ❒ ❒ ❒ ❒
Very much better Much better A little better The same Worse

(b) My feelings about the future are:

❒ ❒ ❒ ❒
Very important Important Somewhat important Not at all important

17 (a) If I did <u>not</u> have diabetes, my financial situation would be:

❒ ❒ ❒ ❒ ❒
Very much better Much better A little better The same Worse

(b) My financial situation is:

❒ ❒ ❒ ❒
Very important Important Somewhat important Not at all important

18 (a) If I did <u>not</u> have diabetes, my living situation and conditions would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) My situation and conditions are:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

19 (a) If I did <u>not</u> have diabetes, I would have to depend on others when I do not want to:

❒ Very much less ❒ Much less ❒ A little less ❒ The same ❒ More

(b) For me not having to depend on others is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

20 (a) If I did <u>not</u> have diabetes, my freedom to eat as I want would be:

❒ Very much greater ❒ Much greater ❒ A little greater ❒ The same ❒ Less

(b) My freedom to eat as I want is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

21 (a) If I did <u>not</u> have diabetes, my freedom to drink as I want (e.g. fruit juice, alcohol, sweetened hot and cold drinks) would be:

❒ Very much greater ❒ Much greater ❒ A little greater ❒ The same ❒ Less

(b) My freedom to drink as I want is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

Are there any other ways in which diabetes, its management and complications affect your quality of life, if so, please write what they are below.

The following questions are concerned with the treatment for your diabetes (including insulin, tabletes and/or non-insulin injectables)and your experience over the past few weeks. Please, answer each question by circling a number on each of the scales.

1. **How satisfied are you with your current treatment?**

Very satisfied	6	5	4	3	2	1	0 very dissatisfied

2. **How often have you felt that your blood sugars have been unacceptably high recently?**

Most of the time	6	5	4	3	2	1	0 none of the time

3. **How often have you felt that your blood sugars have been unacceptably low recently?**

Most of the time	6	5	4	3	2	1	0 none of the time

4. **How convenient have you been finding your treatment to be recently?**

Very convenient	6	5	4	3	2	1	0 very inconvenient

5. **How flexible have you been finding your treatment to be recently?**

Very flexible	6	5	4	3	2	1	0 very inflexible

6. **How satisfied are you with your understanding of your diabetes?**

Very satisfied	6	5	4	3	2	1	0 very dissatisfied

7. **Would you recommend this form of treatment to someone else with your kind of diabetes?**

Yes, I would definitely recommend treatment	6	5	4	3	2	1	0 no, I would definitely not recommend treatment

8. **How satisfied would you be to continue with your present form of treatment?**

Very satisfied	6	5	4	3	2	1	0 very dissatisfied

Please make sure that you have circled one number on each of the scales.

Over the <u>past 2 weeks</u>, how often have you been bothered by any of the following problems? Check one box for each item in the table below.

Questions	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things				
Feeling down, depressed, or hopeless				
Trouble falling/staying asleep, sleeping too much				
Feeling tired or having little energy				
Poor appetite or overeating				
Feeling bad about yourself – or that you are a failure or have let yourself or your family down				
Trouble concentrating on things, such as reading the newspaper or watching television				
Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual				
Thoughts that you would be better off dead or of hurting yourself in some way				

How difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

A. Not difficult at all B. Somewhat difficult C. Very difficult D. Extremely difficult

Which of the following diabetes issues are currently problems for you? Check the box that gives the best answer for you for each item in the table.

Questions	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
Feeling scared when you think about living with diabetes					
Feeling depressed when you think about living with diabetes					
Worrying about the future and the possibility of serious complications					
Feeling that diabetes is taking up too much of your **mental** energy every day					
Feeling that diabetes is taking up too much of your **physical** energy every day					
Coping with complications of diabetes					

Please check the box that best describes HOW CONFIDENT (or how sure) you feel that you could take your diabetes medicines exactly as you were told 100% of the time in the following situations.

How confident are you that you would continue to take your medicines exactly as prescribed when:

Questions	Definitely not Confident	Slightly Confident	Moderately Confident	Very Confident	Definitely Confident
You feel no support from your family and friends.					
You're feeling good.					
You're busy with other things.					
You are depressed.					
You can't remember when you took the last dose.					
You feel better with taking fewer medications.					
You can't schedule in a meal to take it with.					
You don't want to be reminded that you have diabetes.					
You are travelling away from home.					

Please indicate your response to the questions below on different factors that influences your diabetes.

1) Which of the following nutrients will have the most direct effect on your blood glucose?
    a. Fat
    b. Protein
    c. Vitamins
    d. Carbohydrates

2) If you skip a meal and are on blood glucose lowering medications, which of the following may occur?
    a. Your blood glucose may drop too low
    b. Your blood glucose will stay the same
    c. You may overeat at your next meal
    d. Both a and c

3) Some benefits of physical activity include which of the following?
    a. Weight loss

b. Increased insulin sensitivity
c. Increased HDL cholesterol
d. All of the above

4) Your body produces this hormone in order to regulate the amount of glucose in your blood.
   a. Testosterone
   b. Insulin
   c. Adrenaline
   d. Estrogen

5) When is the best time to check our blood glucose level?
   a. In the morning, when you are fasting
   b. Before a meal
   c. Two hours after a meal
   d. All of the above

6) Which of the following is generally the target range for A1c for people with diabetes?
   a. Anywhere between 8-10%
   b. Less than 7%
   c. 70-130 mg/dL
   d. Over 7%

7) Which of the following has an effect on blood glucose levels?
   a. Emotional stress
   b. Food
   c. Physical activity
   d. All of the above

8) Taking insulin means you have failed to manage your diabetes.
   a. True
   b. False

For each item below, check the box for whether the statement is ***true*** **or** ***false*** for how you feel it describes you.

	TRUE	FALSE
It is sometimes hard for me to go on with my work if I am not encouraged		
I sometimes feel resentful when I don't get my way		
Of a few occasions, I have given up on doing something because I thought too little of my ability		
There have been times when I felt like rebelling against people in authority even though I knew they were right		
No matter who I'm talking to, I'm always a good listener		
There have been occasions when I took advantage of someone		
I'm always willing to admit it when I make a mistake		
I sometimes try to get even rather than forgive and forget		
I am always courteous, even to people who are disagreeable		
I have never been irked when people expressed ideas very different from my own		
There have been times when I was quite jealous of the good fortune of others		
I am sometimes irritated by people who ask favors of me		
I have never deliberately said something that hurt someone's feelings		

Thank you for your participation. Your input is important to the study!!

Appendix D - Survey Booklet at Post-intervention and Follow-up Assessment

Name:_____ **Today's Date: _____**

Please respond to all of the questions that apply to you. Skip sections that do not apply (for example, skip questions on insulin taking if you are not taking insulin for your diabetes).
There is no right or wrong answer to the questions; your responses will help us understand how people with diabetes feel about their treatment and how they feel about living with diabetes.

Note: To be completed after 3 monthly meetings with your pharmacist.

SECTION A

Race/Ethnicity:_____**Gender**:_____**Age:** _____

Highest Education Level Completed

- ☐ Grade school
- ☐ Middle school/junior high
- ☐ High school
- ☐ College
- ☐ Trade school
- ☐ Post graduate
- ☐ Doctorate

Marital Status:

- ☐ Single
- ☐ Married or with partner
- ☐ Divorced
- ☐ Widowed

How long have you had diabetes?_____Years_____Months

Type of diabetes diagnosis _____

How long have you joined the EAMC Diabetes Disease Management?_____Years _____Months

In the **past 6 months,** how many times have you had to go to the Emergency Department (ER) because of problems related to your diabetes? _____

In the **past 6 months,** how many times have you had to stay overnight at the hospital because of problems related to your diabetes? _____

Have you been told by a doctor that you have any of the following? (Check all that apply)

- ☐ Diabetes
- ☐ High Blood Pressure
- ☐ High Cholesterol
- ☐ Liver problems
- ☐ Asthma/COPD
- ☐ GERD
- ☐ Dementia/Memory Loss
- ☐ Heart Disease
- ☐ Fibromyalgia
- ☐ Kidney Problems
- ☐ Gout
- ☐ Depression
- ☐ Circulation/numbness problems
- ☐ Mental Illnesses
- ☐ Other (Please specify) _____

SECTION B

Diabetes Medicine Taking (Oral medicines only on this form)

Please respond by checking either 'yes' or 'no' for each of the items in the box below. Respond here for only one of your oral diabetes medicines (you will write that medicine name in the space below). You will have a chance to respond for each of your other oral diabetes medicines (if any) on separate forms.

Name of this oral diabetes medicine: _____

Questions	**Yes**	**No**
Do you sometimes forget to take this oral diabetes medicine (pills)?		
People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past two weeks, where there any days when you did not take this oral diabetes medicine?		
Have you ever cut back or stopped taking your oral diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along this medicine?		
Did you take this medicine as prescribed yesterday?		
When you feel that your symptoms are under control, do you sometimes stop taking this oral medicine?		
Taking medicines every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan for this medicine?		

How often do you have difficulties sticking to your treatment plan for this medicine?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time

On how many of the **last SEVEN DAYS**, <u>was the entire prescribed daily amount</u> of this oral diabetes medicine taken?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

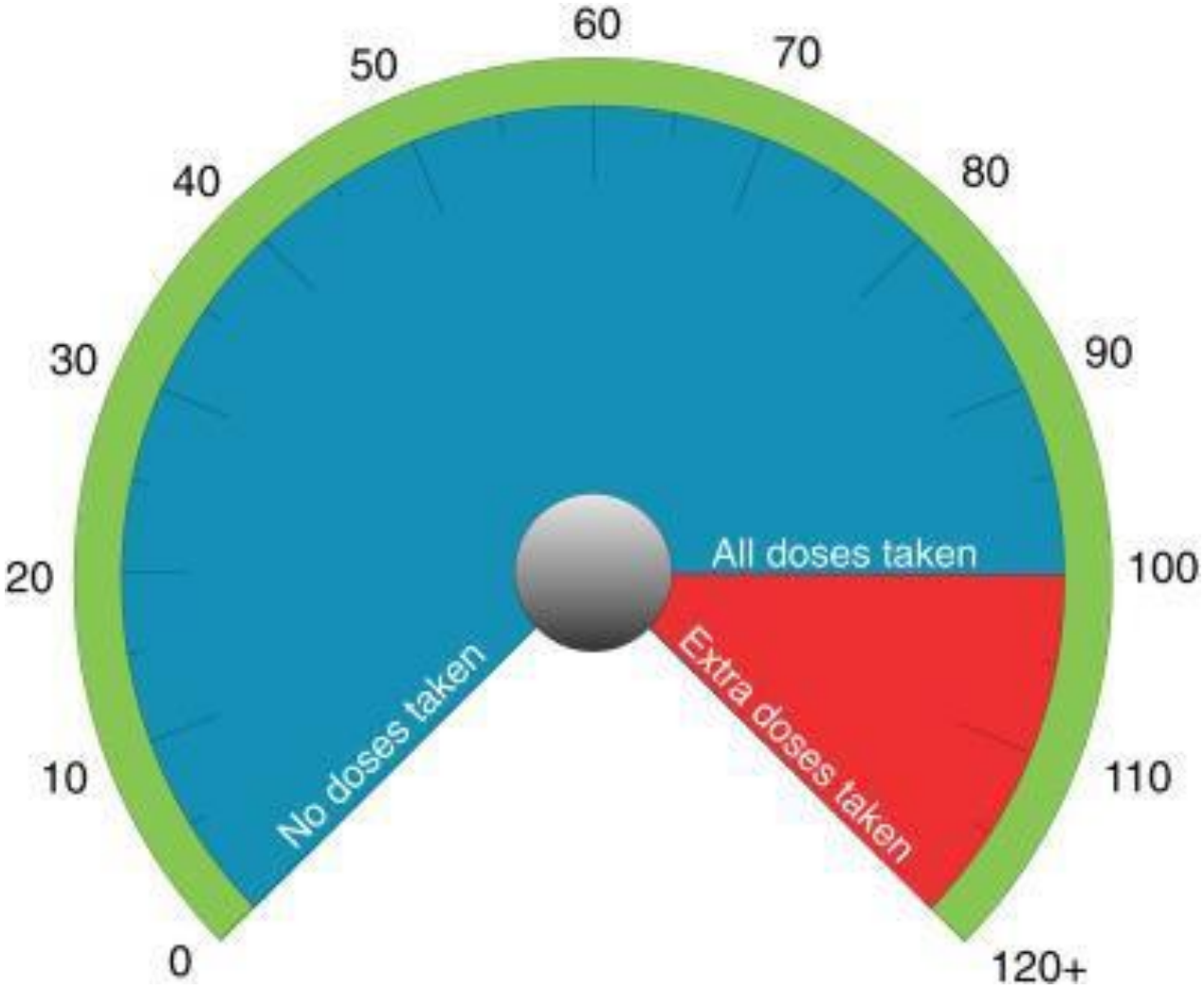
On how many of the **last SEVEN DAYS** <u>were the recommended number of pills per dose</u> taken for this oral diabetes medicine?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Please indicate on the scale below the number of days ***any dose was missed*** ***in the past week*** for this oral diabetes medicine.

☐ 0 Day ☐ 1 Day ☐ 2 Days ☐ 3 days ☐ 4 Days ☐ 5 Days ☐ 6 Days ☐ 7 Days

Think about the (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.



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Are you taking another oral diabetes medication? Yes ☐ No ☐

If Yes, please complete the next set of questions.
Name of other oral diabetes medicine: _____

Questions	**Yes**	**No**
Do you sometimes forget to take this oral diabetes medicine (pills)?		
People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past two weeks, where there any days when you did not take this oral diabetes medicine?		
Have you ever cut back or stopped taking your oral diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along this medicine?		
Did you take this medicine as prescribed yesterday?		
When you feel that your symptoms are under control, do you sometimes stop taking this oral medicine?		
Taking medicines every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan for this medicine?		

How often do you have difficulties sticking to your treatment plan for this medicine?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time

On how many of the **last SEVEN DAYS**, <u>was the entire prescribed daily amount</u> of this oral diabetes medicine taken?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

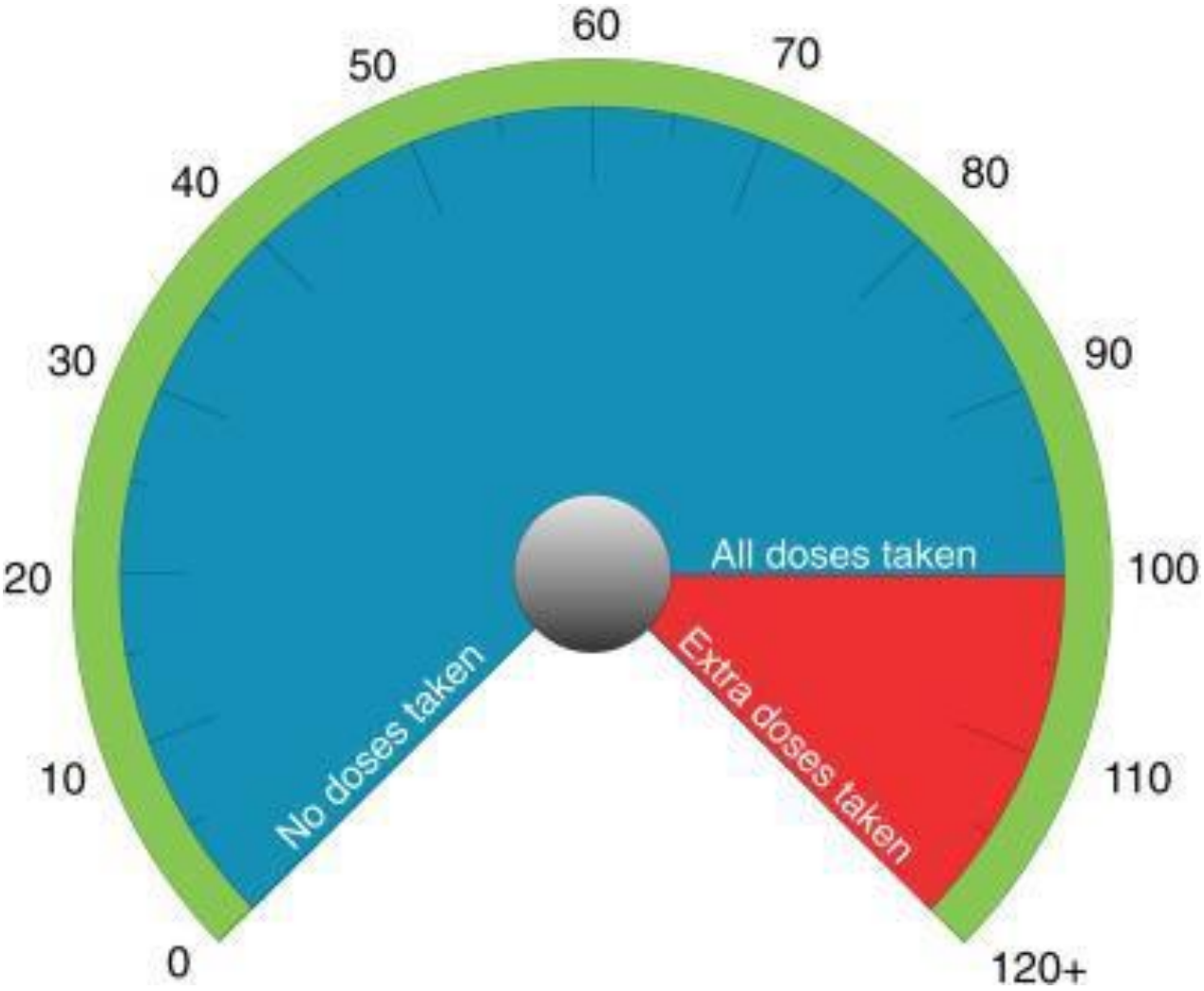
On how many of the **last SEVEN DAYS** <u>were the recommended number of pills per dose</u> taken for this oral diabetes medicine?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Please indicate on the scale below the number of days ***<u>any dose was missed</u> in the past week*** for this oral diabetes medicine.

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Think about the (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.



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Diabetes Medicine Taking (non-insulin injectable medicines)

Please respond by checking either 'yes' or 'no' for each of the items in the box below. Respond here for only one of your non-insulin injectable diabetes medicines (you will write that medicine name in the space below). You will have a chance to respond for each of your other non-insulin injectable diabetes medicines (if any) on separate forms.

Name of this injectable non-insulin diabetes medicine: _____

Does your treatment plan for this medicine require you to inject it daily or once a week?
___Daily
___Once a week
___Other (please specify) _____

Questions	Yes	No
Do you sometimes forget to take this non-insulin injectable diabetes medicine?		
People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past two weeks, where there any injections/doses you did not take when scheduled for this non-insulin injectable diabetes medicine?		
Have you ever cut back or stopped taking this non-insulin injectable diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along this injectable non-insulin diabetes medicine?		
Did you take all this non-insulin injectable diabetes medicines yesterday?		
When you feel that your symptoms are under control, do you sometimes stop taking this non-insulin injectable medicine?		
Taking non-insulin injectable diabetes medicines is a real inconvenience for some people. Do you ever feel hassled about sticking to the treatment plan for this medicine?		

How often do you have difficulties sticking to this treatment plan?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time

If your injection schedule is daily, respond to section A; if you injection schedule is weekly, respond to section B.

A. If your treatment plan requires you to inject this medicine every day, on how many of the last SEVEN DAYS, **did you inject** this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day **1 Day** **2 Days** **3 days** **4 Days** **5 Days** **6 Days** **7 Days**

If your treatment plan requires you to inject this medicine every day, on how many of the last SEVEN DAYS, **did you inject the complete dose** of this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day **1 Day** **2 Days** **3 days** **4 Days** **5 Days** **6 Days** **7 Days**

Please indicate on the scale below the number of days ***any injection was missed in the past week*** for this non-insulin injectable diabetes medicine.

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day 1 Day 2 Days 3 days 4 Days 5 Days 6 Days 7 Days

OR

B. If your treatment plan requires you to inject this medicine once a week, on how many of the last FOUR WEEKS, **did you inject** this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐

0 Weeks 1 Week 2 Weeks 3 Weeks 4 Weeks

On how many of the last FOUR WEEKS, **was the complete dose injected** for this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐

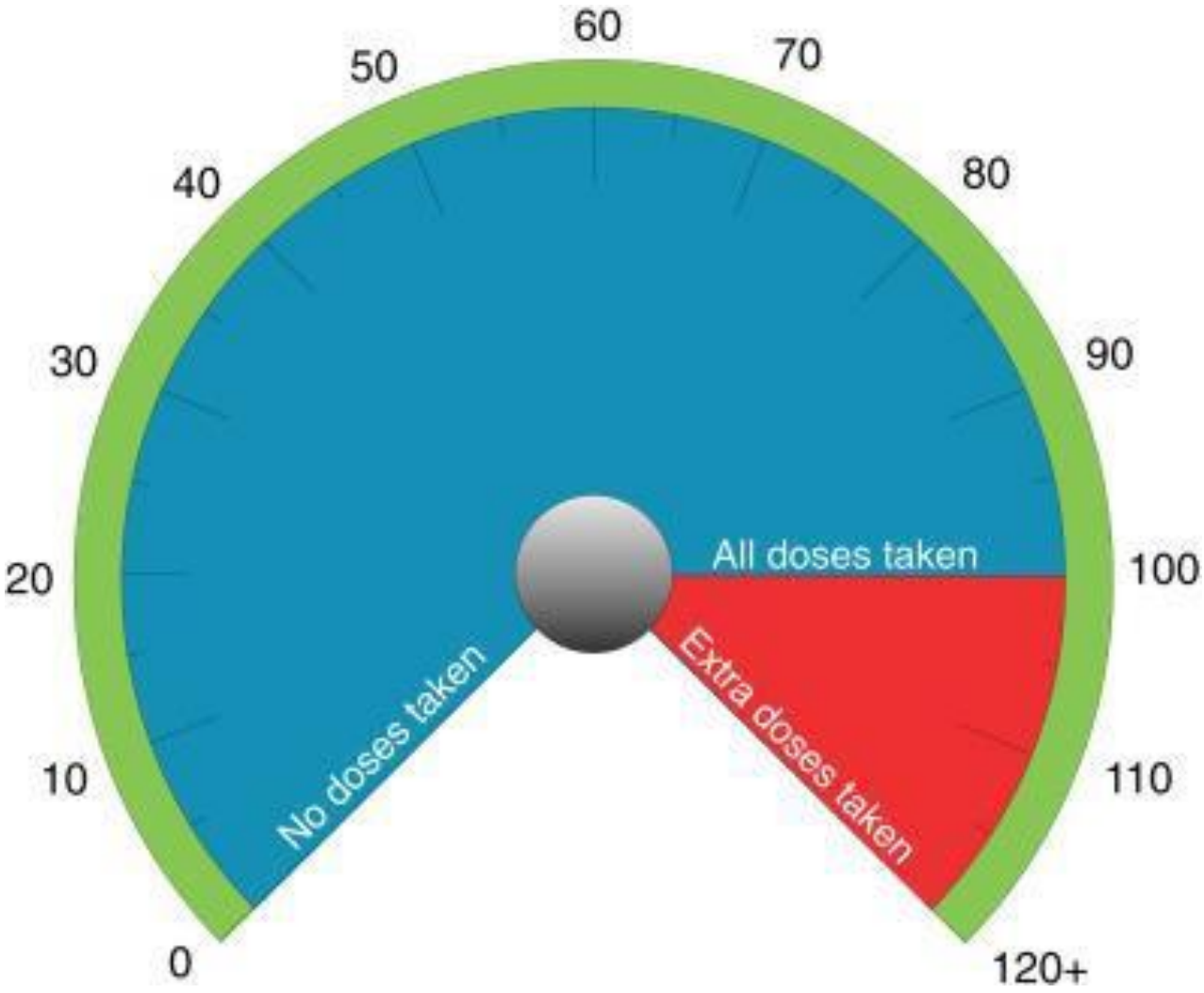
0 Weeks 1 Week 2 Weeks 3 Weeks 4 Weeks

Please indicate on the scale below the number of weeks ***any injection was missed in the past four weeks*** for this non-insulin injectable diabetes medicine.

☐ ☐ ☐ ☐ ☐

0 Weeks 1 Week 2 Weeks 3 Weeks 4 Weeks

Think about the non-insulin injectable (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.



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Are you taking another type of injectable non-insulin diabetes medication? ☐ **No** ☐

If Yes, please complete the next set of questions.

Name of this injectable non-insulin diabetes medicine: _____

Does your treatment plan for this medicine require you to inject it daily or once a week?
___Daily
___Once a week
___Other (please specify) _____

Questions	Yes	No
Do you sometimes forget to take this non-insulin injectable diabetes medicine?		
People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past two weeks, where there any injections/doses you did not take when scheduled for this non-insulin injectable diabetes medicine?		
Have you ever cut back or stopped taking this non-insulin injectable diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along this injectable non-insulin diabetes medicine?		
Did you take all this non-insulin injectable diabetes medicines yesterday?		
When you feel that your symptoms are under control, do you sometimes stop taking this non-insulin injectable medicine?		
Taking non-insulin injectable diabetes medicines is a real inconvenience for some people. Do you ever feel hassled about sticking to the treatment plan for this medicine?		

How often do you have difficulties sticking to this treatment plan?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time

If your injection schedule is daily, respond to section A; if you injection schedule is weekly, respond to section B.

C. If your treatment plan requires you to inject this medicine every day, on how many of the last SEVEN DAYS, **did you inject** this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 Day 1 Day 2 Days 3 days 4 Days 5 Days 6 Days 7 Days

If your treatment plan requires you to inject this medicine every day, on how many of the last SEVEN DAYS, **did you inject the complete dose** of this non-insulin injectable diabetes medicine as prescribed?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day 1 Day 2 Days 3 days 4 Days 5 Days 6 Days 7 Days

Please indicate on the scale below the number of days ***any injection was missed in the past week*** for this non-insulin injectable diabetes medicine.

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 Day 1 Day 2 Days 3 days 4 Days 5 Days 6 Days 7 Days

OR

D. If your treatment plan requires you to inject this medicine once a week, on how many of the last FOUR WEEKS, **did you inject** this non-insulin injectable diabetes medicine as prescribed?

☐ **0 Weeks** ☐ **1 Week** ☐ **2 Weeks** ☐ **3 Weeks** ☐ **4 Weeks**

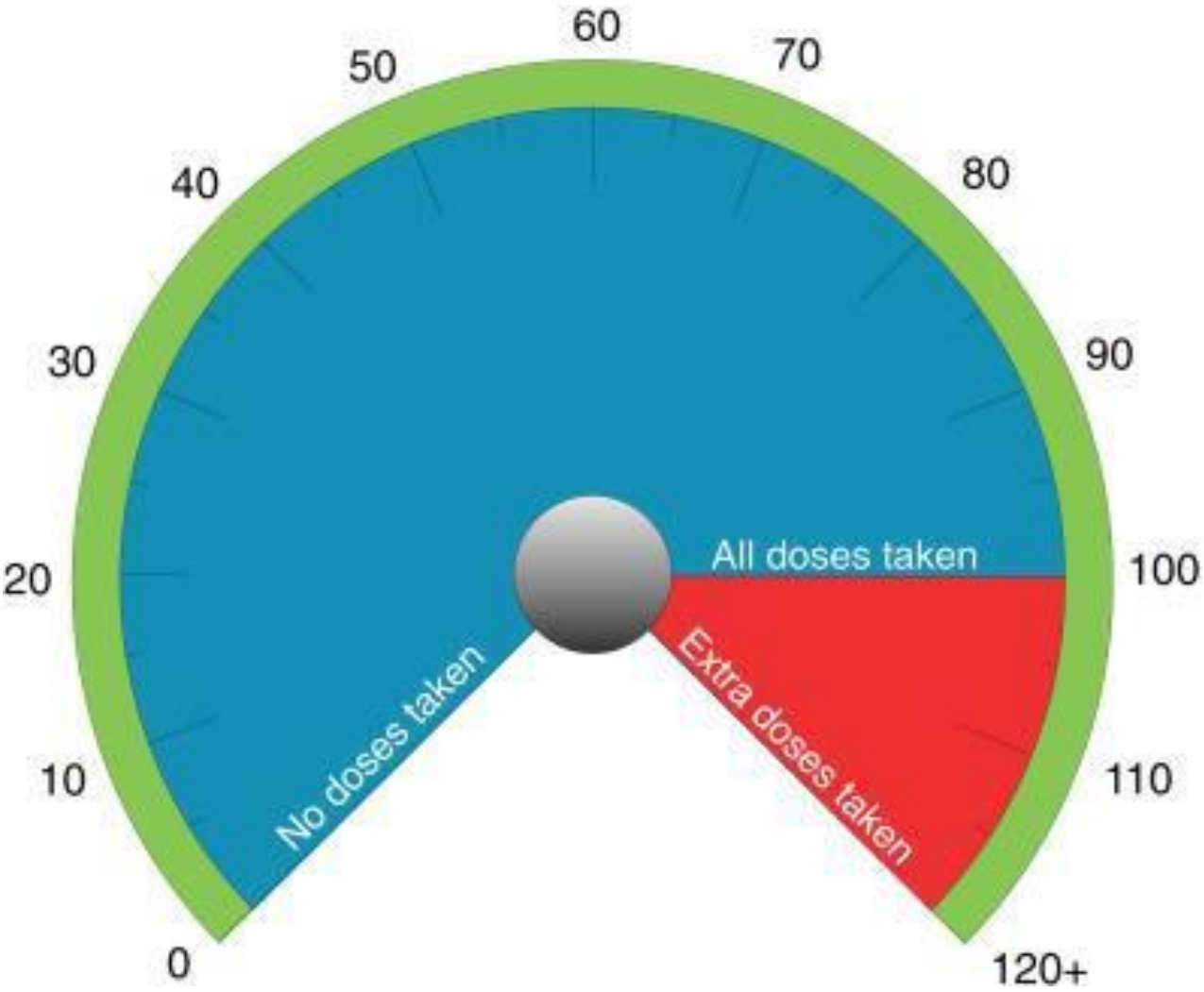
On how many of the last FOUR WEEKS, **was the complete dose injected** for this non-insulin injectable diabetes medicine as prescribed?

☐ **0 Weeks** ☐ **1 Week** ☐ **2 Weeks** ☐ **3 Weeks** ☐ **4 Weeks**

Please indicate on the scale below the number of weeks ***any injection was missed in the past four weeks*** for this non-insulin injectable diabetes medicine.

☐ **0 Weeks** ☐ **1 Week** ☐ **2 Weeks** ☐ **3 Weeks** ☐ **4 Weeks**

Think about the non-insulin injectable (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.



Diabetes Medicine Taking (Insulin only)

Please respond by checking either 'yes' or 'no' for each of the items in the box below. Respond here for only your insulin injectable (you will write that insulin name or just say "insulin" in the space below). You will have a chance to respond for each of your other insulin injectables (if any) on separate forms.

Name of injectable insulin: _____

Questions	Yes	No
Do you sometimes forget to inject your insulin?		
People sometimes miss injecting their insulin for reasons other than forgetting. Thinking over the past two weeks, where there any days when you did not inject your insulin diabetes medicine?		

Have you ever cut back or stopped injecting your insulin diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along your insulin?		
Did you inject all your insulin yesterday?		
When you feel that your symptoms are under control, do you sometimes stop injecting your insulin?		
Injecting insulin for your diabetes every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?		

How often do you have difficulties sticking to your treatment plan?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time.

On how many of the last SEVEN DAYS, **did you inject** your insulin as prescribed?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

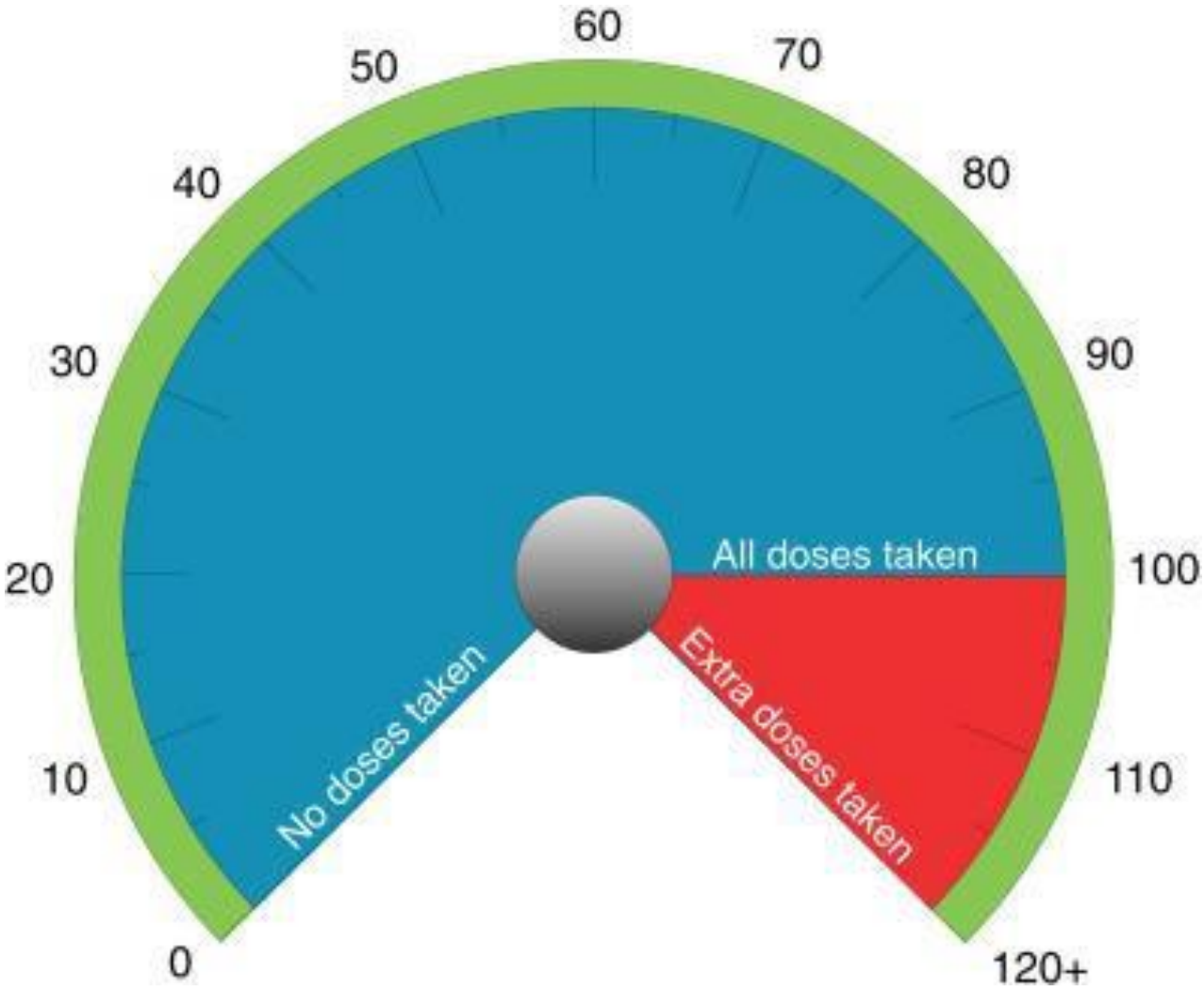
On how many of the last SEVEN DAYS, **was your recommended insulin units injected as** prescribed?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Please indicate on the scale below the number of days ***any injection was missed in the past week*** for your insulin.

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Think about the insulin (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.


0
10
20
30
40
50
60
70
80
90
100
110
120+
All doses taken
No doses taken
Extra doses taken

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Are you taking another type of insulin for your diabetes? Yes ☐ No ☐

If Yes, please complete the next set of questions.
Name of injectable insulin: _____

Questions	**Yes**	**No**
Do you sometimes forget to inject your insulin?		
People sometimes miss injecting their insulin for reasons other than forgetting. Thinking over the past two weeks, where there any days when you did not inject your insulin diabetes medicine?		
Have you ever cut back or stopped injecting your insulin diabetes medicine without telling your health care provider because you felt worse when you took it?		
When you travel or leave home, do you sometimes forget to bring along your insulin?		
Did you inject all your insulin yesterday?		
When you feel that your symptoms are under control, do you sometimes stop injecting your insulin?		
Injecting insulin for your diabetes every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?		

How often do you have difficulties sticking to your treatment plan?
A. Never/rarely **B.** Once in a while **C**. Sometimes **D**. Usually **E**. All the time.

On how many of the last SEVEN DAYS, **did you inject** your insulin as prescribed?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

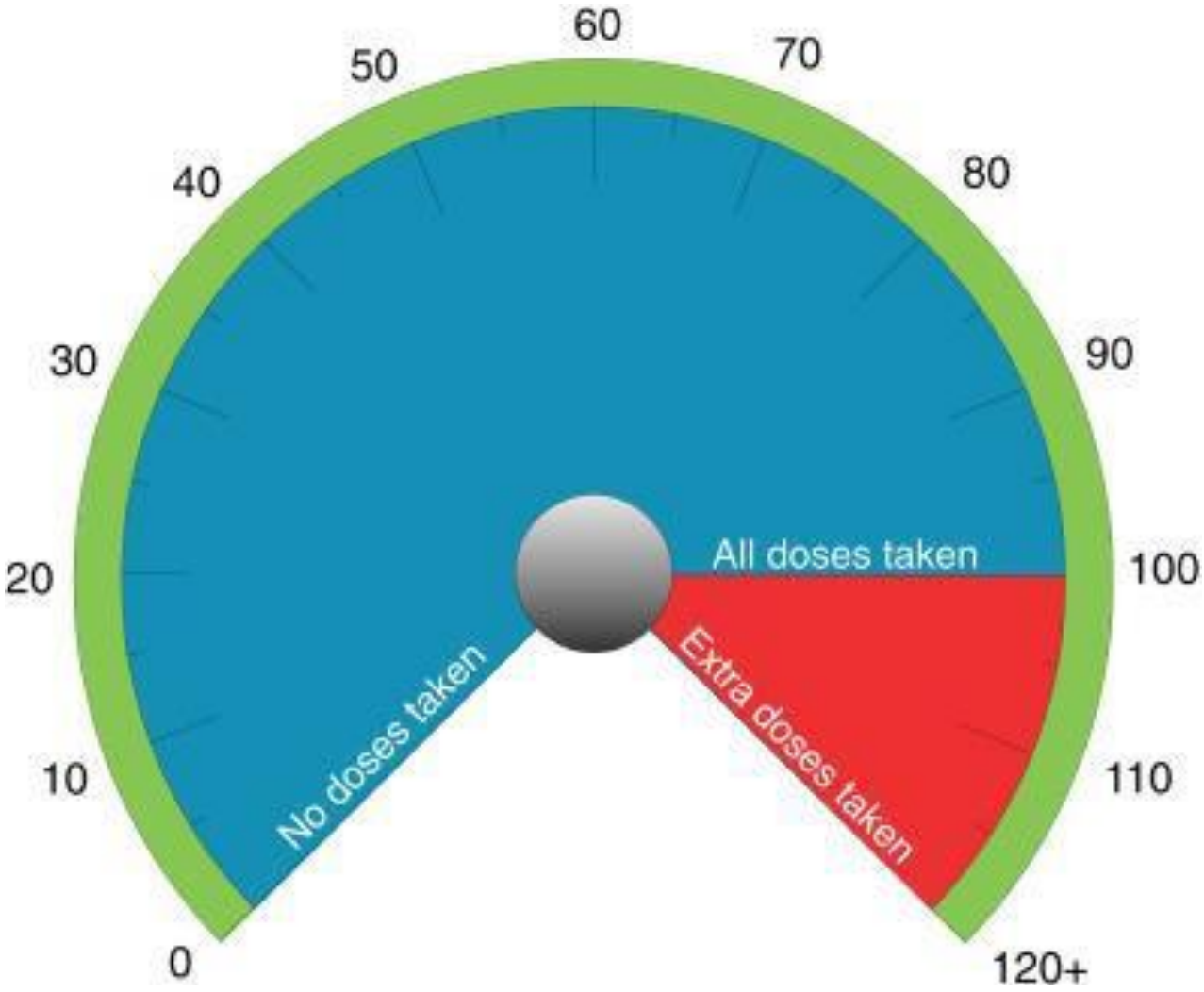
On how many of the last SEVEN DAYS, **was your recommended insulin units injected as** prescribed?

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Please indicate on the scale below the number of days ***any injection was missed in the past week*** for your insulin.

☐ **0 Day** ☐ **1 Day** ☐ **2 Days** ☐ **3 days** ☐ **4 Days** ☐ **5 Days** ☐ **6 Days** ☐ **7 Days**

Think about the insulin (_____) you are currently taking. Look at the picture below and think about how often you take your dose correctly as prescribed by your health care provider. Zero represents no doses taken, and 100 to 120+ represents extra doses taken.



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SECTION C

The questions in this section ask for your views about your general health. Please answer every question by marking one box per question. If you are unsure about how to answer, please give the best answer you can.

1. In general, would you say your health is:

❒	❒	❒	❒	❒
Excellent	Very good	Good	Fair	Poor

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, Limited A Lot	**Yes, Limited A Little**	**No, Not Limited At All**
2. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling or playing golf	❒	❒	❒
3. Climbing **several** flights of stairs	❒	❒	❒

During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

	Yes	**No**
4. **Accomplished less** than you would like	❒	❒
5. Were limited in the **kind** of work or other activities	❒	❒

During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes	**No**
6. **Accomplished less** than you would like	❒	❒
7. Didn't do work or other activities as **carefully** as usual	❒	❒

8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

❒	❒	❒	❒	❒
Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**

These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time **during the past 4 weeks.**

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
9. Have you felt calm and peaceful?	❒	❒	❒	❒	❒	❒
10. Did you have a lot of energy?	❒	❒	❒	❒	❒	❒
11. Have you felt downhearted and blue?	❒	❒	❒	❒	❒	❒

12. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

❒	❒	❒	❒	❒
All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None the time**

The next set of questions asks about your quality of life – in other words how good or bad you feel your life is.

Please put an **"X"** in the box that best indicates your response for each item.

What we want toknow is how you feel about your life now.

(I) In general, my present quality of life is:

❒	❒	❒	❒	❒	❒	❒
Excellent	Very good	Good	Neither good nor bad	Bad	Very bad	Extremely bad

Now we will like to know how your quality of life is affected by your diabetes, its management and any complications you may have.

(II) If I did not have diabetes, my quality of life will be:

❒	❒	❒	❒	❒
Very much Better	Much better	A little better	The same	Worse

Please respond to the more specific items on the page that follow. For each aspect of life described, you will find two parts:

For Part (a): Put an "X" in one box to show how diabetes affects this aspect of your life;

For Part (b): Put an "X" in one box to show how important this aspect of your life is to your quality of life.

2 (a) If I did <u>not</u> have diabetes, I will enjoy my leisure activities:

❒	❒	❒	❒	❒
Very much more	Much more	A little more	The same	Less

(b) My leisure activities are:

❒	❒	❒	❒
Very important	Important	Somewhat important	Not at all important

3 Are you currently working, looking for work or would like to work?

Yes ❒ If **yes,** complete **(a)** and **(b)**

No ❒ If no, go straight to **Question 3**

(a) If I did <u>not</u> have diabetes, my work life would be:

❒	❒	❒	❒	❒
Very much better	Much better	A little better	The same	Worse

(b) For me, having a work life is:

❒	❒	❒	❒
Very important	Important	Somewhat important	Not at all important

4 (a) If I did <u>not</u> have diabetes, local or long distance travel would be:

❒	❒	❒	❒	❒
Very much easier	Much easier	A little easier	The same	More difficult

(b) For me, local or long distance travel are:

❒	❒	❒	❒
Very important	Important	Somewhat important	Not at all important

5 Do you ever go on vacation or want to go on vacation?

Yes ❒ If **yes,** complete **(a)** and **(b)**

No ❒ If no, go straight to **Question 5**

(a) If I did <u>not</u> have diabetes, my vacation would be:

❒	❒	❒	❒	❒
Very much better	Much better	A little better	The same	Worse

(b) For me, vacations are:

❒	❒	❒	❒
Very important	Important	Somewhat important	Not at all important

6 (a) If I did <u>not</u> have diabetes, physically I could do:

❒	❒	❒	❒	❒
Very much more	Much more	A little more	The same	Less

(b) For me, how much I can do physically is:

❒	❒	❒	❒
Very important	Important	Somewhat important	Not at all important

7 Do you have any family/relatives?

Yes ❒ If **yes,** complete **(a)** and **(b)**

No ❒ If no, go straight to **Question 7**

(a) If I did <u>not</u> have diabetes, my family life would be:

❒	❒	❒	❒	❒
Very much better	Much better	A little better	The same	Worse

(b) My family life is:

❒	❒	❒	❒
Very important	Important	Somewhat important	Not at all important

8 (a) If I did <u>not</u> have diabetes, my friendship and social life would be:

❒	❒	❒	❒	❒
Very much better	Much better	A little better	The same	Worse

(b) My friendship and social life are:

❒	❒	❒	❒
Very important	Important	Somewhat important	Not at all important

9 Do you have or would you like to have a close personal relationship (e.g.husband, wife, partner)?

Yes ❒ If **yes,** complete **(a)** and **(b)**

No ❒ If no, go straight to **Question 9**

(a) If I did <u>not</u> have diabetes, my closest personal relationship would be:

❒	❒	❒	❒	❒
Very much better	Much better	A little better	The same	Worse

(b) For me, having a personal relationship is:

❒	❒	❒	❒
Very important	Important	Somewhat important	Not at all important

10 Do you have or would you like to have a sex life?

Yes ❒ If **yes,** complete **(a)** and **(b)**

No ❒ If no, go straight to **Question 10**

(a) If I did <u>not</u> have diabetes, my sex life would be:

❒	❒	❒	❒	❒
Very much better	Much better	A little better	The same	Worse

(b) For me, having a sex life is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

11 (a) If I did <u>not</u> have diabetes, my physical appearance would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) My physical appearance is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

12 (a) If I did <u>not</u> have diabetes, my self-confidence would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) My self-confidence is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

13 (a) If I did <u>not</u> have diabetes, my motivation would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) My motivation is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

14 (a) If I did <u>not</u> have diabetes, the way people in general react to me would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) The way people in general react to me is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

15 (a) If I did <u>not</u> have diabetes, my feelings about the future (e.g. worries, hopes) would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) My feelings about the future are:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

16 (a) If I did <u>not</u> have diabetes, my financial situation would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) My financial situation is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

17 (a) If I did <u>not</u> have diabetes, my living situation and conditions would be:

❒ Very much better ❒ Much better ❒ A little better ❒ The same ❒ Worse

(b) My situation and conditions are:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

18 (a) If I did <u>not</u> have diabetes, I would have to depend on others when I do not want to:

❒ Very much less ❒ Much less ❒ A little less ❒ The same ❒ More

(b) For me not having to depend on others is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

19 (a) If I did <u>not</u> have diabetes, my freedom to eat as I want would be:

❒ Very much greater ❒ Much greater ❒ A little greater ❒ The same ❒ Less

(b) My freedom to eat as I want is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

20 (a) If I did <u>not</u> have diabetes, my freedom to drink as I want (e.g. fruit juice, alcohol, sweetened hot and cold drinks) would be:

❒ Very much greater ❒ Much greater ❒ A little greater ❒ The same ❒ Less

(b) My freedom to drink as I want is:

❒ Very important ❒ Important ❒ Somewhat important ❒ Not at all important

Are there any other ways in which diabetes, its management and complications affect your quality of life, if so, please write what they are below.

For the past ≥3 months you have taking part in a diabetes study. At the start of your study you may have a change of treatment. Today we would like to know how your current treatment (including insulin, tablets and/or non-insulin injectables) has changed from your experience of treatment before the study began. Please answer each question by circling a number on each of the scales to indicate the extent to which you have experience changes. If you have experienced no change, please circle '0'.

1. **How satisfied are you with your current treatment?**

Much more satisfied now	3	2	1	0	-1	-2	-3	Much less satisfied now

2. **How often have you felt that your blood sugars have been unacceptably high recently?**

Much more of the time now	3	2	1	0	-1	-2	-3	Much less of the time now

3. **How often have you felt that your blood sugars have been unacceptably low recently?**

Much more of the time now	3	2	1	0	-1	-2	-3	Much less of the time now

4. **How convenient have you been finding your treatment to be recently?**

Much more convenient now	3	2	1	0	-1	-2	-3	Much less convenient now

5. **How flexible have you been finding your treatment to be recently?**

Much more flexible now	3	2	1	0	-1	-2	-3	Much less flexible now

6. **How satisfied are you with your understanding of your diabetes?**

Much more satisfied now	3	2	1	0	-1	-2	-3	Much less satisfied now

7. **How likely would you be to recommend this form of treatment to someone else with your kind of diabetes?**

Much more likely to recommend the treatment now	3	2	1	0	-1	-2	-3	Much less likely to recommend the treatment now

8. **How satisfied would you be to continue with your present form of treatment?**

Much more satisfied now	3	2	1	0	-1	-2	-3	Much less satisfied now

Please make sure that you have circled one number on each of the scale

Over the <u>past 2 weeks</u>, how often have you been bothered by any of the following problems? Check one box for each item in the table below.

Questions	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things				
Feeling down, depressed, or hopeless				
Trouble falling/staying asleep, sleeping too much				
Feeling tired or having little energy				
Poor appetite or overeating				
Feeling bad about yourself – or that you are a failure or have let yourself or your family down				
Trouble concentrating on things, such as reading the newspaper or watching television				
Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual				
Thoughts that you would be better off dead or of hurting yourself in some way				

How difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

A. Not difficult at all B. Somewhat difficult C. Very difficult D. Extremely difficult

Which of the following diabetes issues are currently problems for you? Check the box that gives the best answer for you for each item in the table.

Questions	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
Feeling scared when you think about living with diabetes					
Feeling depressed when you think about living with diabetes					
Worrying about the future and the possibility of serious complications					
Feeling that diabetes is taking up too much of your **<u>mental</u>** energy every day					
Feeling that diabetes is taking up too much of your **<u>physical</u>** energy every day					
Coping with complications of diabetes					

Please check the box that best describes HOW CONFIDENT (or how sure) you feel that you could take your diabetes medicines exactly as you were told 100% of the time in the following situations.

How confident are you that you would continue to take your medicines exactly as prescribed when:

Questions	Definitely not Confident	Slightly Confident	Moderately Confident	Very Confident	Definitely Confident
You feel no support from your family and friends.					
You're feeling good.					
You're busy with other things.					
You are depressed.					
You can't remember when you took the last dose.					
You feel better with taking fewer medications.					
You can't schedule in a meal to take it with.					
You don't want to be reminded that you have diabetes.					
You are travelling away from home.					

Please indicate your response to the questions below on different factors that influences your diabetes.

1) Which of the following nutrients will have the most direct effect on your blood glucose?
   a. Fat
   b. Protein
   c. Vitamins
   d. Carbohydrates

2) If you skip a meal and are on blood glucose lowering medications, which of the following may occur?
   a. Your blood glucose may drop too low
   b. Your blood glucose will stay the same
   c. You may overeat at your next meal
   d. Both a and c

3) Some benefits of physical activity include which of the following?
    a. Weight loss
    b. Increased insulin sensitivity
    c. Increased HDL cholesterol
    d. All of the above

4) Your body produces this hormone in order to regulate the amount of glucose in your blood.
    a. Testosterone
    b. Insulin
    c. Adrenaline
    d. Estrogen

5) When is the best time to check our blood glucose level?
    a. In the morning, when you are fasting
    b. Before a meal
    c. Two hours after a meal
    d. All of the above

6) Which of the following is generally the target range for A1c for people with diabetes?
    a. Anywhere between 8-10%
    b. Less than 7%
    c. 70-130 mg/dL
    d. Over 7%

7) Which of the following has an effect on blood glucose levels?
    a. Emotional stress
    b. Food
    c. Physical activity
    d. All of the above

8) Taking insulin means you have failed to manage your diabetes.
    a. True
    b. False

Thank you for your participation. Your input is important to the study!!