

THE IMPACT OF BRIEF INTERVENTION ON ADHERENCE TO MEDICATION
REGIMEN OF LOW-INCOME ADULTS WITH TYPE 2 DIABETES

A Thesis

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ABSTRACT

Patient nonadherence with medication regimen is a common problem facing health care providers treating adult patients with Type 2 diabetes. Poor glycemic control, diabetes related complications, and increased utilization and health care costs are among the outcomes of poor compliance with medical regimen. Prior research indicates moderate success with several techniques to improve medication adherence when used alone. However, the literature suggests a need for an intervention providing a multi-component technique, implementing self-motivating skills and follow-up prompts. Using a 15-minute single exposure intervention, the current study attempted to combine these two procedures (brief intervention including motivational interviewing with follow-up prompts) in an attempt to increase adherent behaviors in low-income adults with type 2 diabetes. Medication adherence was measured by HbA1c, which is a biological marker that is widely considered to be a reliable indicator of adherent behavior, as well as pharmacy records. Results indicate nonsignificant findings for both HbA1c and pharmacy refill measures.

INTRODUCTION

Prevalence and Demographics in the US

The number of diagnosed cases of diabetes mellitus is showing a significant increase in the US population. Approximately 6.2% of the population reported having diabetes in 2000 (Centers for Disease Control (CDC), 2000). In 1999 (CDC), approximately 450,000 deaths occurred among people with diabetes who were older than twenty-five. The CDC estimated that diabetes was responsible for 19% of all deaths in the United States at that time, making it the sixth leading cause of death.

Approximately 11% of adults diagnosed with diabetes take both insulin and oral medications, 22% take insulin only, 49% take oral medications only, and 17% do not take any medications (CDC, 1999). Diabetes cost the United States an estimated \$132 billion in 2002, \$91.8 billion as a result of direct medical costs, and \$40.2 billion due to indirect costs, such as disability, work loss, and premature mortality (Hogan, Dall, & Nikolov, 2002).

Within the diabetic population, type 2 diabetes is estimated to represent 90-95% of all cases (American Diabetes Association (ADA), 1994; CDC, 1999; Rubin & Peyrot, 2001). Factors such as race and age have been identified as placing some individuals at greater risk of developing type 2 diabetes. African-Americans along with Hispanic/Latino Americans, American Indians, and some Asian Americans and Pacific Islanders are at particularly high risk. The percentages of individuals within the African-American and Hispanic groups with diabetes are 13% and 10.2%, respectively.

With the requirement of an intricate self-care regimen, type 2 diabetes infringes on an individual's lifestyle, causing disruption in daily activities, and potentially financial

strain (Andrews & Friedland, 2000; Williams, Baker, Parker, & Nurss, 1998). The typical diabetic regimen includes increasing physical activity, weight loss, checking blood glucose multiple times per day, and taking one or more medications. Rubin and Peyrot (2001) describe the diabetes self-care regimen as complex, unremitting, and unpleasant. Yet, as difficult as the self-care regimen may be for diabetics, it is inarguably advantageous to the individual to adhere to their medical regimen. Adherence to medical regimen encompasses several factors (e.g. diet, exercise, and self-monitoring) and includes adherence to medication regimen. A discussion on the importance of medication adherence and its associated factors will follow.

Adherence

Medication adherence is inarguably a crucial component to successful treatment-outcome. Andrews and Friedland (2000, p.1) define medication adherence as “the act of taking medications as prescribed...a highly complex clinical behavior.” Recognized as one aspect of overall adherence to the prescribed medical regimen, optimal benefit from medication requires more from the patient than simply following physicians’ treatment plans. Practitioners and researchers alike recognize that patient adherence is associated with better outcome than patient compliance.

There are many ways to be nonadherent to a prescribed medication regimen. Examples include missing some of the prescribed doses or not taking them at all, taking doses at the wrong time, or taking the wrong dose. Another type of medication nonadherence is failure to follow medication instructions, such as taking medication with or without food or water. Finally, patients may fail to adhere to their medication regimen by not filling their prescriptions. In a study on adherence in an elderly population, 20%

of the patients did not present their prescription to a pharmacy within one month of its reception from a physician (Corlett, 1996).

Some researchers (Cameron & Best, 1987, Garcia & Cote, 2003) stress the importance of making a distinction between compliance and adherence. Cameron and Best suggest that compliance with the medical regimen concerns a more passive role regarding the actions of the patient (e.g. taking their medication). Adherence, however, refers to the patient's desire to fully participate with their medical regimen, and their positive attitude toward the regimen as well as collaboration with their health care provider (Garcia & Cote, 2003). For the current paper, we choose to use the term "adherence", although we recognize that adherence and compliance are often used interchangeably.

Methods for Assessing Patients' Adherence

Assessing patients' level of adherence, although difficult by any measure, can be considered to exist on a continuum. On one end of the spectrum are the "direct" or biological markers such as HbA1c for diabetics or urine analysis. On the other end of the spectrum are the "indirect" modes for obtaining information such as self-report and pharmacy data. Some argue that there is no definitive method, and advocate using multiple measures to assess patients' adherence. Methods for measuring adherence include biological markers, electronic monitoring, pill counts, pharmacy data, self-report, and daily medication diaries.

Biological Markers

Biological markers of adherence refer to physiological representations of a patient's adherence through blood or urine samples. For diabetics, HbA1c is considered to be the most reliable biological measure for collecting adherence data, and arguably the most reliable measure overall. This measure involves taking a blood sample, and allows health care providers to assess patients' levels of adherence for approximately the past three months (Kavanagh, Gooley, & Wilson, 1993). The blood sample allows health care providers to assess adherence by examining the amount of oxygen-carrying red blood protein, with glucose tightly bound to it. When a patient has not been following their medical regimen, HbA1c blood level will be elevated (Thomas, 1989).

Electronic Monitoring

A relatively new indirect method for obtaining adherence information is electronic pill monitoring. Next to biological markers, this method is considered to provide the most reliable information (Wagner, 2002). With this method, an electronic device is inserted into the cap of the prescription bottle. This device records the date and time of bottle opening. Health care practitioners can then download the electronic information for their records (Cramer, 1995). One drawback of this method is that it is unable to record the number of pills taken from the bottle at each time that it was opened. Electronic monitoring is also reported to be a costly measure of adherence (Andrews & Friedland, 2000).

Pill Counts

This method for measuring adherence requires that the patient return to clinic after a specified amount of time and bring with them their medications for their health

care practitioner to count. Cramer (1995) identifies problems with this methodology as not being able to use the data to assess for patients' adherence to time and dosage (e.g. not taking their medications at the prescribed time, or not taking the recommended dosages). The health care practitioner must also be aware that the patient can simply discard a specific amount of their medication before their appointment to make it appear that they took all their recommended dosages. Haynes, Wang, and Gomes (1987) suggest that medication adherence using pill counts can be increased by special pill packaging, with specific medication taking instructions placed on the package.

Pharmacy Data

Among other adherence measures are prescription fill and refill data obtained from pharmacies (Miller, Hill, Kottke, & Ockene, 1997). Pharmacy data can be used to assess adherence by knowing the frequency with which the medication needs to be filled, then comparing that information with the actual frequency that the prescription was filled. The researcher then infers, for example, that if the patient has not been to the pharmacy to refill their prescription, they have not been adhering to their medication regimen. Paes, Bakker, and Soe-Agnie (1997) found pharmacy data to be useful in examining overall patient medication adherence, and also adherence when comparing different dosing frequencies.

Self-Report

Another indirect way to assess for level of adherence to a medical regimen is to use self-report measures. Patient self-report involves the health care provider asking the patient to recall their medication taking practices from appointment to appointment. Many researchers and practitioners report that this method of obtaining adherence

information results in patient overestimation of adherence (Wagner, 2002). Cramer (1995) reported that this overestimation might be the result of patients telling their health care practitioners what they think their health care practitioner wants to hear. Andrews and Friedland (2000) reported that self-report is more accurate with assessing poor adherence than good adherence. Regardless, this method allows health care providers to get a rough estimate of their patients' adherence.

Daily Medication Diaries

Daily medication diaries are considered to be another form of self-report. With this method, the patient records their medication taking activities. In their 1984 study, Pederson, McLean, and Millingen used medication diaries that consisted of check marks placed by medications taken daily. Wagner (2002) reports that this method is associated with patient overestimations of adherence, and produces reliability of information similar to the standard self-report method.

Both direct and indirect measures of adherence are used to examine patient medication taking practices. There is a body of literature to support the benefit of using more than one method to examine medication adherence (Becker, Glanz, Sobel, Mossey, Zinn, & Mott, 1986; Pederson, McLean, & Millingen, 1984; Williams, Rodin, Ryan, Grolnick, & Deci, 1998).

Factors Pertaining to Adherence

There are many variables that have been associated with patient adherence to their medication regimen. Amongst those factors are psychosocial factors, economic factors, patient knowledge, and motivation.

Psychosocial Factors

Several psychosocial factors have been found to correlate with adherence to medication regimens. These include depression, stress, anxiety, social support, barriers and health beliefs, patient characteristics, economic factors, patient knowledge, and patient motivation.

Depression. Depression is one factor that has been found to negatively influence diabetic medication adherence (Ciechanowski, Katon, & Russo, 2000; Lustman, Griffith, & Clouse, 1997), and may contribute to decreased levels in glycosylated hemoglobin, a biological marker commonly known as HbA1c. Depression may attenuate medication adherence by inhibiting motivation and general self-care in individuals (Lustman, Griffith, & Clouse, 1997; Richardson, 2003).

Anxiety, Stress, and Social Support. In addition, stress (Shobhana, Begum, Snehalatha, Vijay, & Ramachandran, 1999), anxiety (Brownbridge & Fielding, 1994) and social support (Golin, DiMatteo, & Gelberg, 1996; Power et al., 2003) have been identified as factors impacting adherence for individuals with various chronic illnesses. Peyrot, McMurry, and Kruger (1999) report that it is important to address psychosocial issues, as there is a correlation with diabetics, between increased stress and decreased glycemic control.

Barriers and Health Beliefs. Positive health beliefs regarding adherence to medication taking have been found to be associated with good medication adherence (Garcia & Cote, 2003; Golin, DiMatteo, & Gelberg, 1996; Malcolm, Ng, Rosen, & Stone, 2003). Decreases in patients' numbers of perceived barriers have also been identified as contributing to patient adherence (Bond & Hussar, 1991; Miller et al., 1997; Paes,

Bakker, & Soe-Agnie, 1997; Rubin & Peyrot, 2001; Williams, Rodin, Ryan, Grolnick, & Deci, 1998).

Pertaining to diabetics, treatment-related barriers and negative emotions contribute to lack of success in reducing HbA1c (Weinger & Jacobson, 2001). The authors suggest that problems with adherence are cyclical in that poor adherence may lead to poor glycemic control, which creates treatment-oriented frustration (for the patient and the health care provider). This cycle perpetuates itself while creating greater problems with glycemic control and adherence.

Patient Characteristics. Research suggests that specific characteristics may put certain patients at-risk for nonadherence. Such characteristics include: younger age (Aljasem, Peyrot, Wissow, & Rubin, 2001; Power et al., 2003), minority status, primarily African-American (Aljasem, Peyrot, Wissow, & Rubin, 2001; Golin, DiMatteo, & Gelberg, 1996; Schectman, Bovbjerg, & Voss, 2002; Snodgrass, Vedanarayanan, Parker, & Parks, 2001), and lower levels of education (Power et al., 2003; Shobhana, Begum, Snehalatha, Vijay, & Ramachandran, 1999).

Economic Factors. There is some evidence that the economic cost associated with medication taking influences patient adherence. In their study, Mojtabai and Olfson (2003) report that in 2000, more than two million Americans receiving Medicare suffered cost-related problems with their medication adherence. They reported that many patients knowingly miss doses, take lower doses than prescribed, or fail to refill their prescriptions due to the associated costs. There is research to suggest that individuals of low socio-economic status (SES), have an increased risk for medication nonadherence (Apter, Reisine, Affleck, Barrows, & Zuwallack, 1998; Brownbridge & Fielding, 1994;

Schectman, Bovbjerg, & Voss, 2002; Shobhana, Begum, Snehalatha, Vijay, & Ramachandran, 1999), as not being able to afford their medications may contribute to patients' nonadherence. Snodgrass, Vedanarayanan, Parker, and Parks (2001) found decreased adherence in populations where patients have applied for Supplemental Security Income.

Patient Knowledge. Corlett (1996) suggests that two primary reasons for medication nonadherence are lack of knowledge regarding medication administration and failure to appreciate the importance of drug treatment in the management of the disease. Although no strong correlations between medication adherence and patient knowledge have been found to exist, many researchers and practitioners believe that patient education is still an important component of the treatment plan (Golin, DiMatteo, & Gelberg, 1996; Peck & King, 1982; Rubin & Peyrot, 2001; Shobhana, Begum, Snehalatha, Vijay, & Ramachandran, 1999).

Patient Motivation. Patient motivation has been identified as having a strong influence on adherence to medication regimens (Garcia & Cote, 2003; Peck & King, 1982). Models have been proposed that attempt to correlate stages of motivation with patient adherence (i.e. Prochaska and DiClemente's Transtheoretical Model). This research has been replicated by Trigwell, Grant, and House (1997), who found that patients' current stage of change was correlated with HbA1c measures in a population of 361 diabetics.

Pertaining to motivation to adhere to treatment recommendations, patient attrition is also considered to be a factor predisposing patients to medication nonadherence. Research has identified high attrition as a problem for providing interventions, especially

in the low SES African-American population (Rimmer, Silverman, Braunschweig, Quinn, & Liu, 2002). The authors identified treatment cost, transportation, and time as variables contributing to attrition. Given the high attrition in the low SES African-American population, a one-session treatment intervention is appealing. Healthcare providers should attempt to motivate their patients to attend their appointments to increase the likelihood that they will be adherent to their rest of their treatment plan.

Theoretical Explanations for Adherence/Nonadherence

Health Belief Model

Created by Hochbaum, Leventhal, Kegeles, and Rosenstock (1966), the health belief model (HBM) suggests individuals behave or adhere based on their readiness to act in such a way that would reduce the severity of their condition (Maiman & Becker, 1974). However, this action is based, in part, on their attitudes or beliefs regarding their perceived susceptibility or vulnerability. In fact, HBM suggests that the individual's perception of reality has greater value than the actual reality concerning behavior change (Hurley, 1990).

According to HBM, behavior change requires three steps. The first step is the assessment of an individual's readiness for behavior change. The second step involves weighing the pros and cons for behavior, after the individual has acquired enough information to understand what the behavior modification will entail. Lastly, internal and/or external cues are developed which serve to prompt the individual to initiate behavior change (Bloom Cerkoney & Hart, 1980).

In health care settings, patients weigh the recommendations of their health care provider against their estimations of the potential outcomes of both adherence and non-

adherence. Concerning the relationship between HBM and decision making, HBM states that motivation, both internal and external is necessary to produce change, but requires significant endorsement of the procedure required to produce the change (Maiman & Becker, 1974; Streecher, Champion, & Rosenstock, 1997).

Positive correlations exist between patients' adherence and their health beliefs (Becker, Maiman, Kirscht, Haefner, Drachman, & Taylor, 1979). It has been suggested that health beliefs have a causal relationship with adherence. Becker et al. also suggest that by addressing patients' perceptions about their illness and treatment regimens, physicians may potentially be able to predict their patients' level of adherence. Therefore, to improve adherence, they recommend implementing strategies to modify current maladaptive health beliefs and perceptions by addressing patient's attitudes regarding their illness and current regimens.

Rosenstock (1975) outlines six characteristics that contribute to a person's adherence. The first characteristic is patient motivation (i.e. the patient must be aware of their health and interested in improving their behaviors). The second characteristic is the patient's perceived susceptibility to a particular illness. The patient must be aware that they are vulnerable to the particular issue of concern. Third, the patient must have a certain perceived severity. This means that they realize that, depending on their actions, their illness will impact them in a certain way. Perceived benefits of professional intervention is the fourth characteristic. The patient must believe that their illness will improve if they choose to adhere to their prescribed medical regimen. The fifth characteristic is the patient's perceived barriers to taking action. It is important that the patient believe that the benefits of changing their behavior outweigh the costs of their

behavior staying the same. Lastly, the patient must consider knowledge of the medical condition and prescribed regimen to be important (e.g. what their medications are, why they need to adhere to their medical regimen, and the specific behaviors to be performed in order to adhere to their medical regimen).

After a review of the current literature on disease models and their applicability in explaining the various influences which contribute to adherence in diabetic patients, Gentili, Maldonato, Grieco, and Santini (2001) asserted that the health belief model is particularly applicable to adherence issues in individuals with diabetes. They asserted that health care providers must not only provide direct treatment interventions, but they must also address patients' concerns and potential barriers to adherence regarding their medication regimens.

Transtheoretical Model

The transtheoretical model seeks to integrate several existing models. In addition, Prochaska et al. (1994) concluded from their study using 3,858 patients with one of 12 problem behaviors (i.e. cocaine use, failure to have mammography screenings, condom use, etc.), that the transtheoretical model was highly effective in promoting positive health behaviors when paired with other models. It is regarded as an eclectic approach to psychotherapy (Prochaska & Norcross, 1999). This model attempts to preserve and combine major principles that are considered effective in behavior change by encouraging treatment programs to be creative and tailored.

One way in which this is done is by addressing patients' individual needs. Patients have unique variables that contribute to or impair their ability to adhere to their medication regimen (e.g. adapting their medication regimen to their particular schedule).

Utilizing processes of change, which are behaviors performed by individuals to change their thinking and behavior, is another principle that is integrated into the transtheoretical model. Stages of change, which are attitudes at any given time about change, can also be an effective tool used from within the transtheoretical framework to get patients to become more aware of where they are in terms of readiness to make behavior modifications. Lastly, motivational interviewing, a brief, directive, client-centered approach that brings about behavior change through dealing with ambivalence to change, is an effective technique to move patients through the stages of change by incorporating processes of change to prompt individuals to become more active in their behavioral conduct.

In essence, this model suggests that tailoring to individual needs will be achieved by matching the individual's process of change with their stage of change. Norcross, Prochaska and DiClemente (1995) (as cited in Prochaska & Norcross, 1999) report that this can easily be accomplished using some of the techniques outlined by Miller and Rollnick's motivational interviewing. Processes of change involve the actions that people perform to modify their behavior. The stages of change are a theoretical measure of where the patient is regarding their attitudes about behavior change. These include precontemplation where the patient is not thinking about behavior change, contemplation where the patient begins to think about behavior change, and preparation where the patient prepares to make the behavior change. Once they begin behavior modifications, they are in the action stage. Lastly, in order to sustain the modifications that they have made, patients go into the maintenance phase, where one of the focuses is relapse prevention.

Prochaska, DiClemente, and Norcross (1992) state that to increase the likelihood that individuals will choose to decrease their maladaptive behaviors, in addition to addressing patients' attitudes regarding behavior modification, interventions (i.e. processes of change) that are behaviorally focused must be incorporated into individuals' self-management regimens. They found that the processes of change, which produced the most significant results, were the more behavioral change processes (i.e. counterconditioning where the patient substitutes alternatives for problem behaviors). In other words, patients' treatment must depend on the matching of their stage of change (e.g. precontemplation, contemplation, preparation, action, or maintenance) with the appropriate process of change.

Increasing Adherence

As previously discussed, medication adherence is becoming an increasing problem for persons with type 2 diabetes in the United States. Many methods exist for assessing medication adherence. Likewise, there are several known factors that influence medication adherence. Thus, researchers and practitioners must use this information to create interventions that will improve medication adherence. When developing an intervention, considerations for the intervention include: how many components to include in the intervention, certain design components, and the degree of interpersonal involvement with the health care practitioner to be included.

Applicability of Multi-Component Intervention Designs

When attempting to increase medication adherence, deciding how many interventions to implement is an important consideration. Single interventions have been used historically, yielding mild to moderate effects. Currently, more multi-component

interventions are used to maximize treatment effectiveness. Single interventions that have been used in the past are often combined with one another to enhance the intervention. These single interventions can be behavioral, psychosocial, or a combination of the two.

Single Interventions

In an early review of the literature, Haynes, Wang, and Gomes (1987) stated that there were no known single interventions with significant long-term effects on adherence. Examples of single interventions include self-monitoring (Baker & Kirschenbaum, 1993; Edmonds et al., 1985), counseling by health care practitioners (Levine, et al., 1979), special unit dose reminder pill packaging (Becker et al., 1986), phone follow-ups (Taylor, Houston-Miller, Killen, & DeBusk, 1990), patient education (Morisky et al., 1983), and tailoring (Prochaska, DiClemente, Velicer, & Rossi, 1993; Rimer et al., 1999). Haynes et al. suggest that many of the treatments that have been tried alone may yield positive results when linked with one another. In a more recent review, Miller et al. (1997) arrived at a similar conclusion.

Combining Behavioral Interventions

Several studies support that medication adherence can be enhanced by combining single interventions. These combinations can occur as behavioral strategies only, or in tandem with psychosocial interventions. Takala, Niemela, Rosti, and Sievers (1979) found an increase in adherence to blood pressure medication by using combinations of single-interventions that were strictly behavioral. Those interventions included oral and written instructions regarding medication regimens, a follow-up card with blood pressure

readings, medications prescribed, and the time of the next appointment, as compared to the control group, which received only oral instructions.

The findings of Skaer, Sclar, Markowski, and Won (1993) suggest that multiple behavioral interventions improve medication adherence. In addition, they found a positive correlation between increased adherence and the number of behavioral strategies that were implemented. In addition, the groups receiving multiple interventions obtained significant results regarding reduction in physician, laboratory, and hospital service utilization, as compared to the single intervention and usual care groups.

Combining Behavioral and Psychosocial Interventions

There is support to suggest that multiple interventions are even more effective when psychosocial interventions are implemented along with behavioral interventions. Cramer (1995) outlines four strategies (i.e., education, planning of dosing regimens, improved communication, and clinic visits) that may produce more significant results when paired with one another. Education that involves both the patient and their family has been tested. Likewise, the planning of dosing regimens by using a pill box or the use of checklists for medication times has been researched. Cramer emphasizes the importance of strong communication between the health care provider and the patient, including a discussion of the diagnosis and treatment plans. Lastly, the scheduling of clinic visits can be adjusted to minimize waiting times as well as scheduling more frequent visits. The author reported that adherence improves by 10% five days before a physician visit; therefore, more frequent appointments can also improve patient adherence.

There is support in the literature for the efficacy of using patient counseling to increase patient motivation for medication adherence as a component of the intervention (Morisky et al., 1990; Pederson, McLean, & Millingen, 1984). These psychosocial interventions can be used to increase patients' knowledge about their medications and address barriers to medication taking.

Peyrot, McMurry, and Kruger (1999) report that multicomponent approaches should include patient training and improved management of psychosocial issues. They assert a direct relationship between medication adherence and psychological health. They suggest that with people with diabetes, stress and coping impact metabolic control through psychological (i.e. patients having difficulty with adherence while managing stressors of their daily lives) and physiological (i.e. the increase of hepatic production of glucose as a reaction to the release of hormones that respond to stress) processes. Therefore, it appears that better management of psychosocial issues pertaining to daily living is more conducive to patient adherence with their medical regimen.

Design Considerations for Adherence Interventions

Once the interventions to be used have been decided upon, researchers must determine how they will be implemented. There are several considerations to keep in mind when creating an intervention plan. They are time, cost, simplicity, brevity, and demographic tailoring.

Time

In medical settings, interventions are designed to be effective relative to time and cost efficiency. It is important that interventions be provided in as little time as possible for medical staff efficiency. Current attempts to achieve this goal are being explored by

health care providers in order to move towards brief assessments that use computer technology, and assessments and interventions provided to the patient by individuals other than the patients' immediate medical staff (Glasgow & Eakin, 1998).

Cost

In addition to time efficiency, Glasgow and Eakin (1998) also showed that low cost measures for encouraging adherence are becoming more widespread.

Recommended strategies include 1) the use of low-cost reminders to patients regarding appointments and medication refills, 2) physician reminders regarding the importance of adherence, and 3) referrals to other health care professionals who can assist the current medical team in providing services and enhancing adherence with the medical regimen.

Simplicity

It appears that successful interventions are not necessarily complex interventions. In their research on improving self-management in persons with diabetes and effective methods for training health care workers to assist patients, Doherty, Hall, James, Roberts, and Simpson (2000) concluded that it may be more effective for a medical team to begin with a minimal amount of sub-components of change as opposed to attempting to promote behavior change using more complex interventions. Although this may not necessarily be ideal in that the practitioner would be addressing fewer problems at one time, it may be simply more practical. It may also be easier to train a staff to complete a small portion of an intervention at one time. Trainers can teach the staff at a more basic level, requiring less training. Based on their findings, Doherty et al. concluded that training interviewers is best when kept simple (i.e. fewer components in the intervention).

Brevity

In addition, especially when an intervention involves more than one interviewer, it is best to condense the sessions with patients to primary skills because the interventions will be easier to teach and reliability will most likely be higher. Doherty et al. (2000) reasoned that the more brief an intervention, the easier it is to instigate it in multiple health care settings with multiple trainers. They also concluded that the techniques for behavioral modification (which present the same factors in motivational interviewing) are easily taught to potential trainers as well as easily received by patients.

Miller and Rollnick (2002) state that brief interventions of one to three sessions are as effective as more extensive treatments. They point out that brief interventions, using the principles of motivational interviewing, are more beneficial to the patient than no treatment at all. Other studies have asserted that by using brief motivational interviewing, patients can be influenced to change within a matter of minutes (Resnicow, DiIorio, Borrelli, & Hecht, 2002).

Demographic Tailoring

In designing effective interventions, health care providers would benefit from considering the particular population for which they are designing the intervention. The results of a study by Brantley et al. (1999) suggest that preventative programs must be created for patients with special tailoring, based on their targeted racial, gender, and/or age groups. Their research regarded prevalence of risk behaviors (e.g. smoking, high dietary fat, and sedentary lifestyle) in a predominantly African-American, low SES population. Thus, in a low SES, African-American population, race and ethnicity and SES should be considered when designing and intervention. For example, for such a

population, transportation difficulties and the need for a low cost intervention should be considered.

Patient-Centered Multicomponent Interventions Targeting Motivation

When designing an intervention aimed at behavior change, a baseline measure concerning the individual's current activities and motivation to change should be acquired. Part of this assessment involves evaluating the degree to which patients are considering making behavioral changes. Individuals who spend less time thinking about behavior change are less likely to re-evaluate their current behaviors (Prochaska & DiClemente, 1983). Included in the evaluation of motivation for change, are the identification of past attempts for behavior change, and the variables contributing to success or failure (Hoppe, Farquhar, Stoffelmayr, & Helfer, 1988). Research has examined the effects of counseling and conducting interpersonal interviews with patients in an attempt to enhance their motivation towards adherence. Miller and Rollnick (1991) have developed a brief intervention (Motivational Interviewing) that can be used to help motivate individuals to change maladaptive behaviors.

Brief Counseling

In a study on smoking cessation, patients in a primary care setting who received brief patient-centered, behavior-oriented counseling were more likely to change their behaviors and move towards smoking cessation than participants who were only provided brief advice to stop smoking (Ockene et al., 1991). This type of counseling is used to promote patient involvement in behavior change, and addresses many of the same issues as motivational interviewing. The subjects were divided into three groups with the first group receiving only advice to stop smoking. The second group received the advice as

well as a counseling intervention that covered five areas: motivation to change, past experiences with attempting to modify the behavior, current concerns, resources available to assist the patient in making the change, and interest in developing a plan for changing the behavior. The third group was provided the advice, the counseling intervention, and nicotine-containing gum (NCG). The NCG group was the most successful. Their findings suggested that this group was twice as likely as those in the advice only group to abstain from smoking for three months. The counseling group was 1.6 times more likely than the advice only group to abstain from smoking for three months. Thus, the researchers concluded that the brief patient-centered intervention was more effective because it reduced defensiveness and supported the patient-health care provider relationship.

Motivational Interviewing

Rollnick (2002) identifies the “spirit” of motivational interviewing (MI) as the use of exploration as opposed to exhortation, and support rather than persuasion and argumentation, as methods for creating an environment for behavior change. Using core techniques of MI, including reflective listening, rolling with resistance, agenda setting, and increasing self-motivation, has shown that motivational interviewing can be useful in a variety of settings and across different populations (Miller & Rollnick, 1991).

Reflective listening is designed to promote patient rapport. The primary goal is to communicate to the patient acceptance of them, regardless of their stage of change or current maladaptive behaviors. Employing empathy and reflectively listening will help the interviewer establish a better picture of the patient’s current situation. Rolling with resistance is a technique for discussing with the patient potential consequences and

outcomes of behavior change, without debating with them or arguing. The interviewer introduces new perspectives and potential solutions without demanding that the patient implement them. Instead, the patient's ideas can be considered and incorporated into the treatment plan. Agenda setting promotes patient action and provides direction for the client as well as the interviewer. Lastly, supporting patient self-efficacy will place the decision-making and implementing behavior change on the patient. It will be the patients' belief in themselves that will ultimately lead to successful outcomes.

Motivational Interviewing and Adherence. Motivational interviewing, as it attempts to increase patient autonomy and self-management as well as self-efficacy, has been identified as having the potential to increase adherence in primary medical settings because of its potential brevity (Noonen & Moyers, 1997). More specifically, MI may potentially increase adherence with medical regimen in adults with diabetes (Clark & Hampson, 2001; Senecal, Nouwen, & White, 2000; Stott, Rees, Rollnick, Pill, & Hackett, 1996), and adults with psychosis (Kemp, Kirov, Hayward, & David, 1998).

Motivational Interviewing in Clinical Settings. Looking to the future, motivational interviewing has the potential to be provided on a regular basis in diabetes clinics. In order for this to be efficient, motivational interviewing will have to be taught to medical teams, which may include members other than physicians and psychologists. Concerning the training of others to provide interventions to promote behavior change, Resnicow, DiIorio, Borrelli, and Hecht (2002) stated that a strength of motivational interviewing is that it can be used effectively after minimal training not only by psychologists, but by other members of the health care profession as well. But

ultimately, it is imperative that the intervention be created so that one or more members of the medical team can learn to provide it to patients.

Motivational Interviewing and Potential Implications. Noonen and Moyer (1997) in their review of MI research to date suggest that several variables should be examined in future research using motivational interviewing. They suggest that MI be used with populations that are in a position to be receiving advice from health care professionals, and to have their motivation to comply with the information that has been provided to them examined. In addition, the length of the intervention to achieve maximum effectiveness has remained unclear. This information is especially important in medical settings where interactions between the medical staff and their patients can be very limited. Lastly, researchers have suggested that MI may not be appropriate for all populations. Examining effectiveness in a low income, predominantly African American population may provide further insight.

In summary, diabetes is a medical condition of growing concern for the U.S. population. Two theoretical models have been proposed to address adherence and nonadherence. Adherence to the diabetic medication regimen is a factor of concern for physicians and may be measured in a variety of ways, such as HbA1c and self-report. Research indicates that multi-component designs to improve adherence are more effective than single component experiments. It appears that principles of motivational interviewing, when provided in brief and concise sessions, have the ability to produce behavior change in patients with diabetes, especially when paired with other techniques, such as the use of follow-up prompts.

The purpose of the present study was to examine whether a brief intervention using the core principles of motivational interviewing and a follow-up prompt would be associated with greater patient adherence with medication than usual care in a low income, predominantly African-American population. Adherence to the medication regimen was determined by analyses of serum HbA1c, an indicator of adherence over 2-3 months, and pharmacy records of patient medication refills.

Hypotheses

1. It was hypothesized that patients receiving motivational interviewing and a follow-up prompt (Treatment Group) would show a significant improvement in adherence, as indicated by a decrease in HbA1c levels, as compared to a group receiving usual care (Control Group).
2. It was hypothesized that patients receiving motivational interviewing and the follow-up prompt (Treatment Group) would evidence higher percentages of diabetic medication prescription refills as compared to those receiving usual care (Control Group).
3. Individual differences among patients in the Treatment Group (i.e. age, race, marital status, etc.) were examined to determine potential predictors of adherence to medication regimen. No hypotheses were proposed.

METHOD

Participants

Participants were recruited from the Diabetes Clinic at Earl K. Long Medical Center (EKL). Adults with type 2 diabetes who were currently taking diabetic medication were approached for participation in this study. Patients were excluded from this study if they had been diagnosed with Type I diabetes, were not currently medicated for diabetes, not able to provide an address where they would be residing for three months after the initial assessment, or if their oral comprehension was below the 5th grade level as determined by the Woodcock Johnson-Oral Comprehension test (Woodcock, McCrew, & Mather 2001). Patients were also excluded if they were determined to be depressed, as measured by the Beck Depression Inventory-PC (Beck, Guth, Steer, & Ball, 1997). Depressed patients were offered a referral to the Adult Psychology Department.

Measures

Demographic Questionnaire

A self-report demographics questionnaire was administered to participants. This questionnaire included: name, hospital number, date of diagnosis of diabetes, date of birth, sex, age, race, marital status, education level, employment status, current medications, location of prescription refill, and the frequency with which they have been instructed to take their medication(s) (See Appendix A).

Woodcock-Johnson-Oral Comprehension

The Woodcock-Johnson III-Test of Achievement (Woodcock, McCrew, & Mather, 2001) was used to ensure that the patients understood the conversation and instructions that were given to them during the brief intervention. This test has been

shown to have a reliability coefficient of .89 for adults. In order to participate in this study participants had to demonstrate that they have at least a 5th grade oral comprehension level. The suggested starting point for grade 5 is Item 13. For this study, questions began with Item 7, which is a grade 3 to 4 comprehension level. Patients were required to answer items 7-13 correctly to participate. Patients who failed to pass this test were not permitted to participate in this study.

Beck Depression Inventory-PC

The Beck Depression Inventory for Primary Care (BDI-PC) (Beck, Guth, Steer, & Ball, 1997) is an abbreviated version of the original BDI and consists of seven items. Steer, Cavalieri, Leonard, and Beck (1999) used the BDI-PC to screen outpatients with more chronic and comorbid medical diagnoses. Their results indicated a mean score of 6.55 for the patients who were diagnosed with Major Depressive Disorder. They suggest a cutoff score of 5 to 6 and above to minimize the potential of falsely classifying a nondepressed person as being depressed.

HbA1c as a Biological Marker of Adherence

Patients' adherence to their medication regimen was determined by measuring their glycosylated hemoglobin levels (HbA1c). This measure is widely accepted as an outcome measure of a patient's adherence to their medical regimen over a 2-3 months period (Peyrot, McMurry, & Kruger, 1999; Goldstein et al., 1982). HbA1c reports the amount of oxygen-carrying red blood protein that has glucose tightly bound to it. It provides a measure of average blood concentration of the glucose (Kavanagh, Gooley, & Wilson, 1993). The normal range of HbA1c is 4-6% in individuals without diabetes. In individuals with diabetes, an acceptable range is generally considered to be between 4

and 8%. The range for most nondiabetics is between 5.4% and 7.4% (Hurley, 1990). At Earl K. Long, patients' HbA1c levels are measured approximately every three months during their regularly scheduled visits to the Diabetes Clinic. Patient HbA1cs were obtained from their medical charts.

Procedure

The primary investigator identified which patients were attending the diabetic clinic for a routine 3-month follow-up visit and approached them for participation in this study. If the patient met the demographic requirements for participation, the study was explained, including time commitment and the possibility of receiving a follow-up letter. A form (See Appendix B) requiring their consent to participate was presented and confidentiality was explained. The consent form informed participants that their address would be documented, their medical chart would be examined, and their HbA1c levels would be recorded. Participants were also provided with the experimenters' contact information should they have further questions or wish to know the results of the study. After they were placed in a physician's examining room, the Woodcock Johnson was administered. If patients failed to pass the 5th grade level of the oral comprehension subtest of the Woodcock-Johnson, they were thanked for their time and their participation in this study was terminated. Patients that passed the oral comprehension test were given the BDI-PC. Individuals who scored a 6 or above on the BDI-PC were excluded from participation. Those that endorsed suicidal ideation on item 6 were assessed for suicide potential. The appropriate referrals were made for these patients to receive further assessment and possible treatment.

Eligible patients were randomly assigned to the experimental or control group using a random numbers table. A brief, structured (See Appendix C), approximately 15-minute intervention was performed with participants assigned to the experimental group, and included a discussion of the importance of taking their medications, activity management (i.e. incorporating medication taking into one's daily routine), anchoring medication use (i.e. taking medication at the same time every day), using cues and reminders (i.e. placing bottles that need refilled near keys where they can be a reminder to have refilled), the use of self-monitoring, and self-reinforcement. The investigator attempted to discuss with the patient the feasibility that they could make the behavior changes necessary to become more adherent with their medication regimen. Barriers to adherence with medication regimen were addressed and the patient was encouraged to problem-solve with the investigator. Following the interview, patients were given a handout that provided them with ideas to help them remember to take their medications and to refill their prescriptions, as well as to motivate them to become more active in their diabetes management and discuss their diabetes with their physician (See Appendix D).

Patients randomly assigned to the control group were given usual care. They were asked a few questions about their current medication regimen (See Appendix E). This assisted the researcher in developing a baseline measure of their adherence, as well as controlling for exposure to the researchers. They were then thanked for their time and the session was terminated.

One week following the interview, the investigator sent a reminder letter to the experimental group, reminding them that they needed to refill their prescriptions and that

they should attend their follow-up appointment in two months. They received one of these letters each of the three months until their next scheduled appointment. For both of the groups, HbA1c levels were extracted from the medical charts of the participants following their next lab visit. If patients failed to attend the diabetes clinic within six months, they were excluded from the study. Patients attending the Diabetes Clinic are scheduled in 3-month intervals at which time they are given blood tests, and measures of HbA1c levels are recorded. Therefore, barring failure to attend a scheduled appointment, HbA1c levels were available for the date that the intervention was administered, as well as upon their three and/or six month follow-up appointment.

The brief intervention was delivered by the author, Kathleen Kendra, a graduate student in the doctoral clinical psychology program at Louisiana State University-Baton Rouge. In addition to reviewing the literature on motivational interviewing, a brief manual, which outlines the basic principles of motivational interviewing (See Appendix F) was created for purposes of synthesis of information and review.

Independent Variables

1. Treatment versus usual care.

Dependent Variables

The outcome variable to be ascertained was adherence to medication regimen, which was assessed by conducting chart and medication record reviews.

1. HbA1c: This measure was obtained from the medical charts of each of the participants. It was acquired by recording the results of the patient's blood tests following the three-month treatment period.

2. Percentage of medication refills: Many of the patients at Earl K. Long Memorial Hospital have their diabetes medication prescription(s) filled at the EKL pharmacy. Records were obtained for each participant as to whether or not they had their prescriptions filled each month following their enrollment in the current study. Results were recorded as the percentage of refills prescribed following the onset of participation in this study.

Estimated Sample Size

Based on previous studies, in which findings reported a .8 improvement in HbA1c at best, the effect size was set at -.8. Setting the effect size at -.8 suggested that 70 participants in each group were needed to achieve a power level of .80. A total of 140 subjects were desired.

RESULTS

Descriptive Data

A total of 157 participants were invited to participate in this study. Eight subjects who were approached elected not to participate. Ten participants of the 157 initial subjects were excluded because they had not had an HbA1c measure in at least the past three months. In addition, 7 subjects were excluded for not meeting the Woodcock-Johnson 5th grade level requirement and/or scoring above a 5 on the BDI-PC. One hundred and forty individuals entered the study. Thirty-three of those 140 individuals could not complete the study, as they either did not return or were not scheduled by their physician for follow-up lab work within six months. A total of 107 individuals completed the study.

The average years of diabetes diagnosis for the 107 participants was 10.27 years. The sample was predominantly female (81.8%), and African American (83.3%). Participants were more likely to be married (35.4%) or single (29.3%). Approximately 83.5% percent had a high school degree or GED equivalent. The vast majority of participants were currently unemployed (76.8%). No subjects endorsing suicidal ideation on the BDI-PC endorsed plan or intent.

Prior to testing the study hypotheses, descriptive statistics (e.g., means and standard deviations) were obtained on all experimental variables (i.e., demographic variables, HbA1c, pharmacy refill data) (See Table 1). A two-sample nonparametric test was conducted to determine whether the Treatment Group differed demographically (i.e., marital status, sex, and ethnicity) from the Control Group. No significant differences were found between the groups for marital status $\chi^2(1, N = 107) = 1192.5, p > .05$, sex

$\chi^2(1, N = 107) = 1151.5, p > .05$, or ethnicity $\chi^2(1, N = 107) = 989.5, p > .05$. One tailed t-tests revealed no significant differences between groups for age, $t(105) = .571, p > .05$, years diagnosed, $t(104) = .637, p > .05$, education, $t(104) = .661, p > .05$, or BDI score $t(105) = .264, p > .05$.

Table 1
Means and standard deviations of experimental variables for control and experimental groups. N=107

Variable	Experimental n=50		Control n=57	
	Mean	SD	Mean	SD
Years diagnosed	10.86	8.34	9.74	8.96
Age	57.52	9.80	56.42	9.24
Education (yrs)	11.27	2.29	10.94	2.51
HbA1c Pre	7.71	1.33	8.43	2.13
HbA1c Post	7.62	1.56	7.96	1.79
BDI score	1.26	1.37	1.60	1.59

Hypothesis #1: Effects of Motivational Interviewing and Follow-up Prompt

To test Hypothesis 1 that patients receiving motivational interviewing and a follow-up prompt (Treatment Group) would show a significant decrease in HbA1c compared to controls, a t-test was conducted on group means of HbA1c scores at 3 months subsequent to the initial treatment contact. Although the participants were randomly assigned the experimental or control group, Levene's Test for Equality of Variances suggested that the Treatment Group was significantly different from the Control Group at baseline, $t(102) = -1.07, p < .05$. However, neither of the two groups yielded a significant change three months after initial contact, with the experimental group (N=50) showing a .09 decrease in HbA1c at three months post intervention, $t(49) = .27, p > .05$ (See figure 1). The Control Group (N=57) showed a significant decrease of .47 in HbA1c three months after enrollment in this study $t(56) = 1.11, p < .05$. These

findings indicate that the intervention was unsuccessful in reducing HbA1cs for this sample.

Hypothesis #2: Effects of Intervention and Follow-up Prompt on Pharmacy Refills

To test Hypothesis 2 that patients receiving motivational interviewing and a follow-up prompt (Treatment Group) would obtain a higher percentage of prescription refills compared to controls, a t-test was conducted on group means of the percentage of refills across the 3 months of treatment (see Table 2). Of the 107 participants, 60 (56.1%) reported that they filled their medications at the EKL pharmacy. High percentages of pharmacy prescription refills were obtained from both the treatment (85.54%) and control (89.73%) groups. The two groups did not significantly differ in percentage of prescription refills $t(58) = .25, p > .05$.

Additional Analyses

To determine the relationship between medication adherence and demographic variables within the Treatment Group, simple, zero order correlations were computed for demographic variables, HbA1c, and percentages of pharmacy refills. No significant relationships were established between race, years diagnosed, sex, age, marital status, education and employment, and HbA1c pre and post and pharmacy refills.

To test whether the group with the brief intervention and follow-up mailed appointment reminder would yield a higher percentage of appointment attendances than the control group, mean percentages were extracted from both the treatment (M=90.92%) and control (M=87.62%) group (see table 2). An independent sample t-test showed that there was no significance between the two groups in terms of percentage of appointment attendance $t(105) = .37, p > .05$.

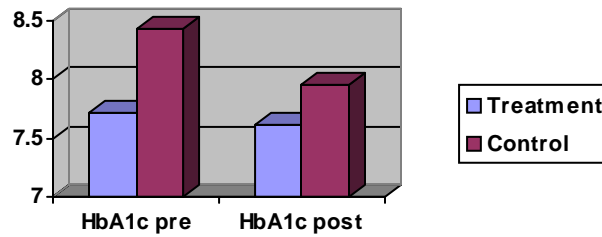


Figure 1: Hba1c means at baseline and three months following initiation of study for treatment and control group.

Table 2: Means for number of appointments attended versus appointments scheduled, percentage of appointments attended, and percentages of pharmacy refills collected for treatment and control groups.

Group	Mean number of appointments attended	Mean number of appointments scheduled	Mean percentage of appointments attended	Mean percentage of pharmacy refills collected
Treatment	2.47	2.76	90.92	85.54
Control	2.24	2.58	87.62	89.73

Reliability Between Interviews

The Motivational Interviewing Skill Code (MISC) (Miller, 2000) was used to verify reliability between interviews. The MISC is a rigorous coding system that requires at least three passes through a single session. Each statement made by the therapist is then categorized by content (e.g. reflective statement, informational statement, etc.), and frequencies of the statements are recorded. The primary “elements” of motivational interviewing (i.e. acceptance, egalitarianism, empathy, genuineness, warmth, and spirit) are rated on a scale from 1-7. The statement codings are reported in terms of how many times that element is used throughout the interview (e.g. number of facilitative

statements, number of filler statements, etc.). Approximately eleven percent of the experimental sessions were taped and then thoroughly coded using the MISC.

Reliability for the six elements of motivational interviewing was examined using means and standard deviations. Acceptance, warmth, and spirit yielded 100% reliability with zero variance between ratings. The scores for empathy and genuine also provided minimal variance with minimum ratings of 6 ($M=6.67$, $SD=.52$). The scores for egalitarianism yielded a smaller mean ($M=5.33$) and larger standard deviation ($SD=.82$).

Regarding the statements made by the interviewer, no directive or confrontational statements were recorded in any of the sessions. Confidence intervals were used to assess for reliability in frequencies of interviewer statements. The structure technique was used twice, but only in one of the interviews. For the rest of the interpretations, confidence intervals were evaluated as rounded integers, as decimals were not used in coding. One additional question was asked outside of the confidence interval ranges for advice and facilitation. Two additional questions were asked in an interview concerning providing information. Five questions beyond the higher confidence interval range were asked in one of the interviews. In one of the interviews, zero filler statements were made, which was below the lower confidence interval range. This was also true for the support technique. The data suggests that for affirmation, emphasizing control, raising concern, reflecting, reframing, and warning, all of the interviews were within the same confidence interval range.

DISCUSSION

This study attempted to explore the effects of a brief intervention and follow-up prompt on HbA1c in individuals with type 2 diabetes. The goal of this study was to determine whether a 15-minute brief intervention using the principles of motivational interviewing would be sufficient to contribute to significant decreases in HbA1c when paired with a mailed appointment reminder, versus usual care controls. A general overview of the findings of the current study will be presented, followed by a discussion of the research hypotheses, a review of the limitations of the current study, and concluding remarks and indications for future research.

Effects of Brief Intervention and Follow-up Prompt on HbA1c

Research question #1 addressed the effects of a brief intervention and follow-up prompt on HbA1c as compared with controls. For the Treatment Group, the initial HbA1c was within the fair to moderate range for diabetics. Thus, to make a significant decrease in HbA1c would be more difficult than if HbA1c were more poorly controlled. This can be likened to a well-known principle of weight loss. For example, the more weight an individual has to lose, the easier it often is for them to initially lose weight. Likewise, individuals who are attempting to lose smaller amounts of weight often struggle because they are already closer to their target range. In addition, it is the individual with less weight to lose that is in greater short term danger of having setbacks because recommended lifestyle changes may not be as drastic (e.g. restricting 200 calories from a 1200 calorie/day diet versus 200 calories from a 3000 calorie/day diet). This same idea serves to explain one possible reason why the Control Group experienced greater nonsignificant decreases in HbA1c. Again, as mentioned previously, a random

sampling numbers table was used to delegate individuals to either the treatment or control group, so the significant difference between the two groups remains a very unusual finding.

Attempting to achieve significant results using participants recruited from hospital clinic waiting rooms addresses a significant problem facing adherence researchers. The low SES, predominantly African American population is inarguably an important population to research, as this population is at risk for acquiring chronic disease and dealing with related complications (Aljaseem, Peyrot, Wissow, & Rubin, 2001; Apter, Reisine, Affleck, Barrows, & Zuwallack, 1998; Brownbridge & Fielding, 1994; Schectman, Bovbjerg, & Voss, 2002; Golin, DiMatteo, & Gelberg, 1996). When designing interventions with this population the goal is often to increase adherence in less adherent individuals. However, a sample taken from a hospital waiting room may be a confound when targeting nonadherent individuals, as appointment attendance is considered to be one indirect measure of adherence (Newell, Bowman, & Cockburn, 1999). Therefore, those individuals sampled from a waiting room are more likely than their nonattending counterparts to have better controlled and more stabilized HbA1c levels.

Effects of Brief Intervention and Follow-up Prompt on Pharmacy Refills

Both the treatment and control group averaged high percentages of pharmacy refills for their diabetes medication, 85.54% and 89.73% respectively. Medication taking for type 2 diabetics has been shown to be associated with diabetes related complications, an identified important area for research (Bartlett, 1988; Newman, Bowman, & Cockburn, 1999; Peck & King, 1982). However, the current study did not support such

findings. Instead, both groups appeared to achieve sufficient levels of pharmacy refills. However, the pharmacy data analyzed was only EKL pharmacy data. On an aside, the researcher would like to note that at the time that the study began, the EKL pharmacy raised its medication co-payment. Thus, several subjects reported that they used to get their medications filled at the EKL pharmacy, but were no longer doing so due to the raised cost. It can only be speculated that non-EKL pharmacy refill percentages might be lower than EKL because of the effort and inconvenience associated with getting to the pharmacy, as opposed to using the EKL pharmacy while already on the premises for physicians' appointments. However, pertaining to the pharmacy data for the current study, it appears that patients that use the EKL pharmacy do not perceive medication refills to be a barrier to diabetic adherence. These high percentages of medication refills indicate that patients are very accurate with their current medication taking practices.

Mailed Appointment Reminders and Follow-up Prompts

The mean number of percentage of appointments attended throughout the study period were also very high, with the Treatment Group (M=90.92%) resulting in a slightly higher overall attendance rate, as compared with the Control Group (M=87.2). As the difference between the groups was not significant, we are unable to conclude that the mailed appointment reminders had any effect on appointment attendance. Other studies have suggested that there exists a potential for these low cost reminders to yield significant differences in appointment attendance (Glasgow & Eakin, 1998; Skaer, Sclar, Markowski, & Won, 1993), however this hypothesis was not supported by the current study. Once again, the sample being studied was comprised of a group of individuals that have a history of attending appointments (at least one- the day that they were recruited),

thus these reminders may have merely reinforced their appointment attendance, or even have been redundant to their own procedures for remembering their appointments.

Limitations

Several issues must be considered when interpreting the data presented in the current study. The first limitation is that this study lacked participants sufficient for a thorough data analysis. Although 157 subjects were willing to participate in the study, 43 individuals had to be excluded because either there was no initial or no follow-up HbA1c data.

There are three points of interest pertaining to this issue. First, nine individuals, upon medical chart review, were identified as having attended their physician's appointment, but following the appointment, did not walk across the parking lot from the clinic to the main hospital to have their lab work done. This will be discussed further in a subsequent section. Second, at least six patients were identified through their medical charts as not having a physician's referral to have lab work done, and thus there were no initial and/or follow-up HbA1c available. One participant was excluded because he had not had lab work completed in over a year, but the physician continued to record that the patient's DM II was "under good control". Lastly, for the remaining excluded participants, it is unclear why initial and/or post HbA1c data was unavailable. This speaks to the need for standardization of medical care, as well as the need for interventions targeting not only appointment adherence, but also addressing the importance for patients to have their lab work done.

Conclusions and Implications for Future Research

In summary, it appears that the 15-minute interview with follow-up prompt failed to produce greater medication adherence than usual care. However, there are a few points of interest worth commenting on. Most of the existing literature is comprised of brief interventions that include at least one follow-up intervention (Clark & Hampson, 2001; Ockene et al., 1987; Rimmer, Silverman, Braunschweig, Quinn, & Liu; Weinger, & Jacobson, 2001). However, the results of the current study indicate that perhaps a one-time brief intervention may not be sufficient to motivate patients to make behavioral modifications. Future one-time brief interventions may wish to investigate the effects of a longer intervention.

Returning back to the aforementioned concept of researching the already adherent population, the Stage of Change model suggests that over time, it is the individuals in the contemplation stage that are going to achieve the best results (Prochaska, DiClemente, & Norcross, 1992). As the current study recruited patients that were attending appointments and had been diagnosed with diabetes for at least one year, it is likely that the sample was largely comprised of individuals in the action or maintenance stage. Thus, behavioral patterns may have been more firmly established with this population than with a sample of individuals currently preparing for or contemplating behavior change. Future studies may wish to examine the effects of a brief intervention on people with type 2 diabetes, comparing individuals in preparation and contemplation with those in action and maintenance. In addition, studies targeting nonadherent individuals, investigating current medication taking practices and barriers to medication refills and appointment attendance may provide significant insight for the adherence literature.

Another surprising finding resulted from this study. It appears that in this sample, although medication taking and appointment attendance (along with glucose monitoring, diet, and exercise) have been areas of concentration in the literature, there may be a gap in the research. There does not appear to be much research dedicated to the study of HbA1c testing adherence. The findings from this study indicate that health care providers may not be discussing the importance of having lab work done regularly with their patients. Another possibility is that not all physicians regularly prescribe HbA1c testing. However, one study suggested that 75% of health care providers recommend regular HbA1c testing, compared to about 50% of those patients who actually completed the testing (Lawler & Viviani, 1997). Regardless, barriers to HbA1c testing in the diabetic population appear to warrant further investigation. Likewise, further studies may wish to investigate lab attendance for individuals with type 2 diabetes in clinics where the lab is in clinic, versus in hospital settings where the patient has to leave the clinic to have their lab work done.

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APPENDIX A: DEMOGRAPHICS

Name: _____

EKL#: _____

Date of Diabetes Diagnosis: _____

Date of Birth: _____

Sex: M F

Age: _____

Marital Status: Single Married Separated Divorced Widowed

Race: Caucasian African-American Other: _____

Education Level: _____

Employment: Y N

Diabetes Medications Currently Taking: _____

Place Where Diabetes Medications Are Filled: _____

Frequency of Medication Administration: _____

APPENDIX B: CONSENT TO PARTICIPATE IN A RESEARCH STUDY

EKL# _____

Full approval by IRB received _____

Title of Study:

The Impact of Brief Intervention on Adherence to Medication Regimen of Low-Income Adults with Type II Diabetes

Performance Sites:

We expect about 140 participants to be gathered from one site. Participants will be acquired and additional information will be gathered from Earl K. Long Hospital in Baton Rouge, Louisiana.

Investigators Involved in This Study:

Principle Investigator: Phillip J. Brantley, PhD
(225) 763-3046

Co-Investigator: Kathleen E. Kendra, BS
(225) 354-2008

Purpose of the Study:

The purpose of this study is to use the combination of an interview technique and a follow-up prompt procedure in an attempt to promote greater adherence to diabetes medication regimen.

Description of the Study:

Dr Brantley will be directing this study. This study will take place over approximately three months. The expected time for patients' direct involvement in this study is approximately 30 minutes. The thirty minutes with the treatment group will be used to employ a motivational technique. The control group will be asked questions about their current medication regimen. Both groups will receive usual care from their diabetes physician.

Benefits of Participation in this Study:

No benefits are promised from your participating in this study. A potential benefit of your participation is that increased adherence to you medication regimen will improve your current health condition, or encourage you to think about making behavior modifications to your adherence to you medication regimen.

Risks to the subject:

No known risks are identified as potential outcomes of your participation in this study. Medical treatment is not made available to research participants by Earl K. Long Adult Psychology. Should you endure medical illness or injury due to your participation in this study, you will be referred to the appropriate medical staff.

Alternatives to Participation in the Study:

If you choose not to participate in this study at this time, there will be no alternatives offered to you. Should you decide to participate in this study, you may withdraw at any time without consequence.

Subject’s Right to Privacy:

The research team will make every effort within their ability to maintain the confidentiality of the information provided by you and a review of your medical chart. It is possible that the result of this study will be published, however your personal information will not be made available to anyone that is not a member of the research team for the current study.

Release of Information:

The medical records related to the study are available to both Adult Psychology and the Food and Drug Administration.

Financial Information:

- A. Participation in this study will not result in any extra charges above and beyond those routinely incurred by other patients with diabetes
- B. The costs of all drugs, visits, procedures and study related and unforeseen complications must be met by subjects.
- C. Subject Payment: None

Signatures:

This study has been discussed with me and all my questions have been answered. I understand that additional questions regarding the study should be directed to investigators listed on page one of this consent form. I understand that if I have questions about subjects’ rights, or other concerns, I can contact the Chancellor of LSU Medical Center, at (504) 568-4801. I agree with the terms above, acknowledge I have been given a copy of the consent form and agree to participate in this study. I understand that I have not waived any of my legal rights by signing this form.

Signature of Subject

Date

Signature of Witness

Date

The study subject has indicated to me that the subject is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above the subject has agreed to participate.

Signature of Reader

Date

Signature of Person Administering Consent

Date

Signature of Principal Investigator

Date

APPENDIX C: MANUAL FOR INCREASING PATIENTS' ADHERENCE TO
MEDICATION REGIMEN

NAME: _____

EKL#: _____

INTERVIEWER: _____

DATE: _____

Manual for Increasing Patients' Adherence to Medication Regimen-Adapted from Miller and Rollnick (1991).

Introduction:

“Taking your medications as your doctor has recommended may be one of the most difficult parts of being a diabetic. It can be very hard to remember when to take each dose, to make sure you have your medications with you when you need them, and to continue taking them even when you do not feel sick. It is very easy to slowly begin taking your medication less often and to make it seem less and less important, both in your mind as well as in your daily routine.”

Inquire about the patient's current attitudes and behaviors regarding medication adherence:

“On a scale from one to ten, with one being that you never or almost never take your medications and ten being that you always or almost always take your medications, how would you rate your current medication taking behaviors such as taking your medications as often as your doctor has told you to?”

“On that same scale from one to ten, how confident are you that if you decided to improve the way you take your medications that you could do it?”

Inquire about current medication regimen:

“What is your current medication schedule?”

-When do you take them?

-How often do you refill your prescriptions?

-Where do you get your prescriptions refilled?

-How do you remind yourself to take your medications?

Identifying challenges to medication adherence:

“What are some of the most challenging problems that you have with taking your medications as your doctor recommends?”

Reflect:

“It sounds like some of the biggest problems you have with taking your medications as your doctor recommends are _____, _____, _____, etc. What are some ways that you could think of that would make taking your medications as your doctor has told you to less of a problem for you?” Note: if patient has trouble generating ideas for problem solving, prompt them with one idea and attempt to get them to add ideas of their own.

Summarize the discussion:

“It sounds like you have been having difficulty taking your medications as prescribed partly due to _____, _____, _____, etc. But you have also said that you think that if you started to _____, you would be more likely to take your medications as your doctor has prescribed. Can you think of anything else that we just talked about that I missed?”

“On a scale from one to ten, with one being that you never or almost never take your medications and ten being that you always or almost always take your medications, how confident or sure do you feel that you, based on what we have talked about, can improve the way with which you take your medications?”

NAME: _____

EKL#: _____

INTERVIEWER: _____

DATE: _____

The following form is to be filled out by the motivational interviewer during their brief intervention session with the patient. A copy of this list may be made and given to the patient at their request.

EXPLORING GOALS: In the space below, write down what the patient identifies as their general goals. Ask them to list them in a hierarchical fashion, if possible.

Now, ask the patient how these goals are impacted by or related to their medication adherence.

DECISIONAL BALANCE: In the space below, record what the patient identifies as the pros and cons for maintaining their current behaviors

Pros

Cons

In the space below, record what the patient identifies the pros and cons for behavior change regarding adherence to medication regimen

Pros

Cons

PLAN OF ACTION: In the space below write down a few suggestions generated by the patient about how they can improve their medication adherence. Prompts to use may include, e.g. what are some of the important reasons you would make a behavior change? The first steps you plan to use to make a behavior change are..., People that may be able to help you to change are..., and I hope that my plan will have these positive results.

APPENDIX D: GUIDE FOR IMPROVING MEDICATION TAKING

Why is medication taking important?

You doctor has prescribed diabetes medications to you help you control you blood sugar. The more you take your medications as prescribed, the more well-controlled your blood sugar will be. In other words, you will be less likely to have diabetes related problems such as blindness and heart problems which can lead to: strokes, gangrene leading to amputations, high blood pressure, and gum problems. Diabetic problems can also cause kidney failure and nerve damage.

Become an active participant in the management of your diabetes

In addition to taking your medications as prescribed, you will benefit from having them filled on a regular basis. You will also benefit from attending all of your appointments at the Diabetes Clinic to allow you doctor to help you manage your diabetes. Make sure that you fully understand how and when you need to take your medications. Do not hesitate to ask your doctor when something that he or she says is unclear to you.

Find strategies to help you remember to fill your prescriptions:

- Mark the date on your calendar
- Post the date on your refrigerator
- Keep a note near where you keep your medications that has the date that you need to refill your prescriptions on it
- Be creative! Write down some of your own ideas to help you remember to refill your prescriptions below:

Find strategies to help you remember to take your medications:

- Keep your medications somewhere that you will see them and be reminded to take them (e.g. on your kitchen table, by your television, etc.)
- Buy a tiny alarm clock or a watch with an alarm on it, and set it to go off the next time you need to take your medications
- Try to take your medications at the same time each day (e.g. before or during meals, when you are getting ready for work, bed, etc.). Do not hesitate to discuss times for medication taking that may be best for your health as well as easy for you to remember with your physician.
- Be creative! Write down some of your own ideas to help you remember to take your medications below:

APPENDIX E: CONTROL INTERVIEW

NAME: _____

EKL#: _____

INTERVIEWER: _____

DATE: _____

Introduction:

“Thank you for your willingness to participate in this study. I would like to take a couple minutes and ask you a few questions about how you currently take you diabetes medications.”

Inquire about current medication regimen:

“What is your current medication schedule?”

-When do you take them?

-How often do you refill your prescriptions?

-Where do you get your prescriptions refilled?

APPENDIX F: BRIEF MOTIVATION INTERVENTION ADAPTED FROM MILLER AND ROLLNICK

Brief Motivational Intervention Adapted from Miller and Rollnick (1991)

In their 1991 book, Miller and Rollnick state that the most influential impact of a brief intervention is to motivate the patient to change their current maladaptive behaviors. The intent of the principles of motivational interviewing (MI) is to provide practical utilization for assisting people in helping others change their behavior. Not only is MI for patients who present with the desire for change, it is also useful in promoting change or even contemplation about change in people who have been identified as being resistant or ambivalent about change. MI asserts that making changes is up to the individual. The role of the motivational interviewer is to use basic strategies in persuading the patients to derive for themselves that changing their maladaptive behaviors is in their best interest. This type of intervention is based on principals that are in stark contrast with the historical interventions that instructs patients or uses confrontational techniques.

Miller, in 1983, outlined five basic principles that guide the motivational interview. The first principle is the *expression of empathy*. Following Carl Rogers, the expression of empathy entails showing the patient warmth, using techniques such as reflective listening and the idea of accepting the patient without judging, blaming, or criticizing. The second strategy to be employed is the *development of discrepancy*. The concept of cognitive dissonance is applicable here. The interviewer guides the patient to the realization that the patient's current behaviors may be incongruent with their broader goals. It is essential that patients are able to generate this list of incongruencies themselves, as they will be more likely to detect the discrepancies. A technique to help them realize these discrepancies is known as the *decisional balance* exercise. The decisional balance can be presented to the patient as a pro/con or cost/benefit analysis. It contains statements that the patient made regarding their perception of their motivations to change their possible reasons for sustaining their current behaviors.

The third principle of motivational interviewing is to *avoid argumentation*. To confront patients in an oppositional manner is counterproductive, as it is likely to make them defensive and more resistant to change. The fourth principle, *rolling with resistance*, is especially applicable to these patients. Motivational interviewers are advised to avoid providing their own opinions, but rather, offer new perspectives. It is made clear to patients that the session is for their benefit, and it is up to them to decide how much they wish to get out of it. Patients are encouraged to actively work with the interviewer to problem-solve and answer their own questions and deal with their barriers.

Lastly, the guidelines come full circle as the first and fifth principles are designed to *improve self-efficacy*. Increasing the patients' self-efficacy serves the purpose of encouraging individuals to change by suggesting that they will be successful if they apply effort to make the desired behavior changes. It is important that patients understand that they are responsible for their behavior modification. Miller and Rollnick (1991) suggest that motivational interviewing can be successfully used to assist patients who are ready to change, and to help those that may not currently be ready to change or are in a maladaptive behavioral pattern to become "unstuck" and to start the change process.

General Strategies:

1. Ask open-ended questions:

- Tell me briefly about your diabetes. (Prompts: How do you feel about living with diabetes?
What are some lifestyle changes you make since you were diagnosed?)
- Tell me about your current medication regimen.
- What do you like about it? What are some problems you have with medication adherence?

2. Listen reflectively. Identified by Miller and Rollnick (1991) as "roadblocks", avoid maladaptive strategies such as ordering, warning, providing solutions, preaching, criticizing, and shaming.

3. Affirm. The motivational interview is designed to provide support to the patient. This can be conveyed by using empathy and through statements of appreciation and understanding.

Examples include:

- It must be difficult to have to make so many lifestyle changes accompanying the diagnosis of diabetes. I must say, if I were in your position, I would also find that difficult.
- It seems like you are a really strong person. I can see that adjusting to attending appointments and relying on others for treatment would be difficult.
- Living with diabetes is not easy. I can understand how you may become frustrated with the adjustments.
- Having to comply with a complex medication regimen is not easy. I can understand how total adherence could seem overwhelming.

4. Summarize. This technique is to be used throughout the motivational interview. To summarize, attempt to link together statements that have already been made. For example:

It sounds like you are worried about your ability to take your medications as directed. You have mentioned that it is difficult for you to remember to take your medications, and that sometimes it seems like more trouble than it is worth. What are some concerns that you have about taking your diabetes medications?

5. Elicit Self-Motivational Statements. It is up to the patient to decide whether or not to make behavior changes. It is also important for them to be able to identify changes to be made, and why they think they would like to make the changes. This is called problem recognition.

Examples of desirable statements include:

- I guess I didn't realize before that I had a problem with medication adherence.
- Maybe I am not as good as I could be about taking my diabetes medications.

Expression of concern is also a way that patients can communicate with the interviewer that they are contemplating making behavior changes. Examples include:

- I am worried about my medication adherence.
- I feel very frustrated by my diabetes/medications.

A third type of motivational statement is the intention to change. These statements can be direct or implicit. Examples include:

- I think it's time for me to think about taking my medications more regularly.
- I feel that I have to do something about this.

Lastly, self-motivational statements can suggest optimism about making behavior changes. This reflects the patient's self-efficacy. Examples include:

- I think I can do it.
- I am going to improve my medication adherence.

There are multiple ways to elicit self-motivational statements. The motivational interviewer can ask for them directly, using open-ended questions (e.g., What makes you think there could be a problem with your current medication taking practices?). The interviewer may also attempt to elicit elaboration from the patient. This may encourage patients to make more self-motivational statements. To do this, the interviewer may ask for specific examples or directly encourage the patient to provide more details. The interviewer may also wish to use extremes to help the patient think about the extent of the consequences of their behaviors (e.g., What are your worst fears about what might happen if you don't take your medications?).

Among the more active approaches for eliciting self-motivational statements are exploring goals and creating a decisional balance. Both techniques involve the patient listing reasons for changing as well as reasons and consequences for choosing not to work on changing behaviors. Exploring goals involves identifying goals that are the most important to the patient. Once goals are identified, discrepancies between the patient's current behavior and ideal behavior become clearer to the interviewer and the patient. Likewise, the decisional balance, as previously discussed, allows the patient to see the

positives and negatives for behavior change as related to adhering to diabetes education. Lastly, the interviewer should discuss with the patient how to begin the change process. This requires the patient and the interviewer to work together in generating a plan of action that is realistic.

VITA

The author, Kathleen Kendra received her Bachelor of Science degree from California Polytechnic State University-San Luis Obispo (2001). Currently, she attends Louisiana State University's doctoral program for clinical psychology. Research interests include adherence and motivation in patients diagnosed with HIV/AIDS and diabetes. Her clinical experience includes two and a half years of assessment and therapy at Earl K. Long Memorial Hospital, treating patients in primary care and internal medicine, and patients diagnosed with HIV and AIDS. She also received assessment and treatment experience with the pediatric psychology department at Earl K. Long. Kathleen will earn her Master of Arts degree in clinical psychology in December of 2004.