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EFFECT OF OCCUPATIONAL THERAPY IN PROMOTING MEDICATION ADHERENCE IN PRIMARY CARE: A RANDOMIZED CONTROL TRIAL

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Effect of Occupational Therapy in Promoting Medication Adherence in Primary Care: A Randomized Control Trial

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Abstract

Hypertension (HTN) and type 2 diabetes mellitus (T2DM) are common chronic diseases addressed in primary care settings (Wang et al., 2018). Poor medication adherence creates inferior outcomes in both populations (Doggrell, 2010; Stewart et al., 2014). This randomized controlled trial using a pretest-posttest control group design examined whether the addition of an occupational therapy intervention to usual care by a clinical pharmacist compared to usual care alone affected medication adherence rates among adults with uncontrolled HTN and/or T2DM. Twenty-nine participants were recruited from a primary care clinic after being referred to the clinical pharmacist to improve HTN or T2DM management. Data from the seven-item Adherence to Refills and Medication Scale (ARMS-7), stages of change measure, pill count, blood pressure and/or hemoglobin A1c were collected. Both groups were found to be similar across all demographic characteristics. The proportion of adherent participants (as measured by the ARMS-7, blood pressure, and pill count) increased in both groups but between groups changes were not statistically significant. A post hoc comparison of mixed ANOVA results for ARMS-7 measurements indicated that the occupational therapy intervention was having a unique effect as compared to the control. Effect scores for pill count (d = .55) also suggested that the occupational therapy intervention was positively affecting adherence. While analyses of blood pressure and A1c values were limited by missing data points, both groups demonstrated improvement in these areas. Occupational therapists can be utilized to positively influence medication adherence in a primary care setting.

Keywords: hypertension, diabetes, adherence, occupational therapy

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Traci A. Garrison

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The commonly stated goal of primary care is to address health needs in a holistic manner across the lifespan (World Health Organization [WHO], 2019). The primary care model includes prevention, wellness, and treatments for both acute and chronic illnesses (Client Protection and Affordable Care Act, 2010). Recent estimates state that approximately 133 million Americans live with a chronic disease, and over one-quarter of the United States population lives with multiple chronic diseases (National Health Council [NHC], 2014; U.S. Department of Health and Human Services, 2010). Individuals with chronic disease have higher rates of disability, lower levels of independence, an increased burden of care, and lower quality of life scores (Bobitt, Aguayo, Payne, Jansen, & Schwingel, 2019). It is estimated that 75-95% of all healthcare costs in the United States are due to chronic conditions (Centers for Disease Control and Prevention, 2013; NHC, 2014). Chronic disease management can create many challenges for the client and healthcare team. Recent findings show that these issues are best served by a client-centered and strong interprofessional approach (Bobitt et al., 2019; Gorina, Limonero, & Álvarez, 2019).

The WHO has recently focused on four main chronic diseases categories. These include cancers, chronic respiratory disease, cardiovascular disease, and diabetes (WHO, 2018a). Hypertension (HTN) earned specific focus by the WHO (2018a) within the category of cardiovascular disease, as it has been declared a global public health crisis due to its devastating contributions to heart disease, stroke, and kidney failure (WHO, 2013). Type 2 diabetes (T2DM) was also highlighted as an area of concern due to its growing numbers on the global stage, its concomitant mortality and morbidity, and associated rising healthcare costs (Danaei et al., 2011; WHO, 2018a).

In the United States alone, 75 million individuals are defined as hypertensive, and this number is expected to rise (Merai et al., 2016; Reboussin et al., 2017). While HTN is predictive of the development of disease and disability, it can be managed through lifestyle changes and medication (Will et al., 2016). Unfortunately, approximately half of all individuals who are prescribed antihypertensive medications do not take them correctly, resulting in uncontrolled HTN, subsequent poor health outcomes, and increased societal costs (Stewart et al., 2014; WHO, 2003; Will et al., 2016). While many studies have examined various approaches to address adherence, no single method has been identified as successful (Geboers et al., 2015; Nieuwlaat et al., 2014).

Similar to HTN, type 2 diabetes also demonstrates increasing numbers; they have risen from 108 million in 1980 to 422 million in 2014 (WHO, 2018b). It is also known to be the primary cause of blindness, kidney failure, heart attacks, stroke, and lower limb amputation (WHO, 2018b). It is also a multifaceted disease that often requires significant lifestyle change and management of several medications to achieve optimal health outcomes (Bailey & Kodack, 2011). Unlike many chronic conditions, the client with T2DM has a variety of treatment options available. Despite the variety of options, roughly only half of clients with T2DM achieve optimal blood glucose levels, and two-thirds of clients with T2DM die from subsequently developed cardiovascular disease (Bailey & Kodack, 2011). Like HTN, poor medication adherence is one of the primary factors creating inferior outcomes in the T2DM population (Doggrell, 2010). Better adherence to prescribed medication schedules has been shown to improve glycemic control and decrease the physical and financial costs of the disease, including the reduction of hospital readmission rates (Doggrell, 2010; Jiang et al., 2016).

Occupational therapists are uniquely suited to assess and address the wide variety of factors that influence a clients' willingness and ability to adhere to a prescribed medication regimen. Specifically, practitioners are equipped to assess and treat issues related to cognition, neuromuscular control, and integrating medications into clients' daily routines (American Occupational Therapy Association [AOTA], 2014). Additionally, the practitioner can address deficits that result from the disease process, such as memory difficulties, or side effects from the medications, such as tremors (AOTA, 2017).

Research, while limited, supports the occupational therapist's role in addressing medication management and adherence (Schwartz & Smith, 2016). The Integrative Medication Self-Management Intervention (IMedS) is an occupational therapy intervention recently designed to improve client adherence to medications. The IMedS has been tested in a randomized Phase I feasibility study. This feasibility study found that medication adherence could be influenced by the IMedS (Schwartz & Smith, 2016). A qualitative analysis of the use of the IMedS also showed that the intervention facilitated new medication habits and routines (Schwartz et al., 2017).

The efficacy of the IMedS needs to be studied with a larger sample size to better understand its ability to improve medication adherence. The purpose of this study was to determine whether the addition of the IMedS to usual care, as compared to usual care alone, would affect medication adherence rates among community-dwelling adults with HTN and/or T2DM. To meet this purpose, this study addressed the following objectives:

1) to determine if the addition of the delivery of the IMedS by an occupational therapist to usual care improves medication adherence rates, as measured by the Adherence to

Refills and Medication Scale (ARMS-7), pill count, and blood pressure and/or hemoglobin A1c;

2) to determine whether the administration of the IMedS in addition to usual care influences an individual's readiness for change as measured by the stages of change measure; and
3) to explore whether participant demographics (e.g., gender, age, ethnicity, assist at home, comorbidities, and number of medications) influence medication adherence rates.

Findings from this study provide insights into the role of the occupational therapist addressing medication adherence in a primary care population, information for the continued refinement of the use of the stages of change measure to medication adherence, and further the data available related to the relationships between participant characteristics and adherence. Expanded understanding of these topics better enables the healthcare team to increase adherence with the goals of improving the health of clients with HTN and/or T2DM and reducing associated healthcare costs.

Literature Review

Primary healthcare can provide an ideal setting to develop self-care management skills in clients with chronic conditions (WHO, 2019). A multidisciplinary approach has been shown to be effective in improving self-care related to chronic disease management (Kuhmmer et al., 2016; WHO, 2002). Hypertension and T2DM are two chronic diseases often addressed in primary care in the United States (Nguyen, Makam, & Halm, 2016; Wang et al., 2018).

Medication adherence is a key factor in improving disease management for HTN and T2DM (Doggrell, 2010; Jiang et al., 2016; Khayyat et al., 2019; Will et al., 2016). Medication

adherence has been defined as the extent to which clients take their medication as prescribed (Ho, Bryson, & Rumsfeld, 2009). Poor adherence—sometimes described as non-compliance—is explained as a person not following the prescribed dosage or schedule ordered by his or her medical provider (Robnett, Dionne, Jacques, LaChance, & Mailhot, 2007). Understanding these diseases, their impact on individuals and populations, and barriers and supports for adherence, affects the development of effective interventions.

Hypertension or high blood pressure has been designated as a global public health issue by the WHO. Worldwide 1.56 billion individuals are projected to be diagnosed as hypertensive by 2025 (Jarari et al., 2015; WHO, 2013). Hypertension is of particular concern because of its contribution to the development of heart disease, stroke, kidney failure, early mortality and disability, and increased use of healthcare resources (Merai et al., 2016). The global rise in HTN is thought to be related to a growing aging population, unhealthy diets, sedentary lifestyles with associated weight gain, and persistent stress (WHO, 2013).

Individuals have historically been considered to be hypertensive if their systolic blood pressure is ≥ 140 mm Hg, their diastolic is ≥ 90 mm Hg, or if they are prescribed medications to lower their blood pressure (Merai et al., 2016). The American College of Cardiology Foundation and the American Heart Association recently suggested that target systolic blood pressure should be adjusted to < 130 mmHg (Reboussin et al., 2017). In the United States alone, 16 million adults are being treated for HTN, an estimated 11.5 million are unaware of their HTN, and 7 million are aware but not treating the disease (Merai et al., 2016). While HTN is linked to many detrimental health outcomes, individuals often do not identify warning signs or experience symptoms. The lack of obvious symptoms often delays the initial diagnosis of HTN and

negatively influences an individual's understanding of the need for treatment (Merai et al., 2016; WHO, 2013).

Evidence suggests that antihypertensive medications can reduce the risk of the negative health outcomes associated with HTN (James et al., 2014). Unfortunately, previous research has found that half of individuals stop taking their antihypertensive medications within one year of initial prescription (Vrijens, Vincze, Kristanto, Urquhart, & Burnier, 2008). The American Medical Association provides guidelines for prescribing antihypertensive medications from four different drug classes. These guidelines also note that more than one antihypertensive drug is often required to achieve blood pressure control (James et al., 2014). As the number of medications increases, so does the difficulty of correctly managing and affording all medications. When clients require multiple medications—often known as polypharmacy—medication rates decrease (Tajeu et al., 2016). While polypharmacy is a challenge, the benefits of multiple medications can often outweigh the drawbacks. The answer is not always to reduce the number of medications, but to find ways to better manage the medications (Munger, 2010; Vrettos, Voukelatou, Katsoras, Theotoka, & Kalliakmanis, 2017).

Though chronic diseases present significant challenges to both the individual and the healthcare system at large, many chronic diseases can be prevented or managed by improving self-care skills (Lorig et al., 1999). In addition to blood pressure medications, individuals with HTN are often instructed to make lifestyle changes related to diet and exercise. One large randomized trial found that adjusting diet and exercise, along with proper medication use, yielded the best outcomes for blood pressure control (Appel et al., 2003). A systematic qualitative review of adherence studies revealed a more complex picture that identified consistent challenges to adequately studying and understanding adherence issues related to diet,

exercise, and medication management, as well as the interaction of these self-management behaviors (Jin, Sklar, Min Sen Oh, & Chuen Li, 2008). While improving diet, exercising, and taking prescribed medications is expected to reduce blood pressure, many people with HTN find it difficult to adjust longstanding eating and activity habits. Coupling these changes with new medication routines further increases the demand on individuals to make more extensive changes to daily habits and routines (McDonald, Blackwell, & Meurer, 2006).

Similar to HTN, T2DM also presents as a complex disease, the treatment of which often involves the management of a multitude of self-care behaviors. As the number of individuals with T2DM has risen, so has a myriad of treatment choices; protocols, guidelines, and algorithms related to diabetes medications have been established to meet a range of client needs under diverse circumstances (Bailey & Kodack, 2011). The chronic nature of T2DM and demands of managing self-care behaviors, including diet, activity level, blood sugar testing, and multiple medications, makes achieving optimal glycemic control a test of discipline for every client and an educational challenge for the healthcare team. The complexity of options and demanding nature of these diseases requires individuals to alter both dietary and daily habits in order to adhere to the medical provider's recommended course of action for managing the disease (McDonald et al., 2006; Sontakke, Jadhav, Pimpalkhute, Jaiswal, & Bajait, 2015). Osborn, Mayberry, and Kim (2016) examined the roles of these self-care behaviors and found medication adherence to be the only statistically significant self-care behavior to improve glycemic control in clients with T2DM and low socioeconomic status. While pharmacists and medical providers are often experts in developing optimal plans for disease management, the client's understanding and adoption of appropriate self-care behaviors are critical links to successful adherence (Gorina et al., 2019; Tajeu et al., 2016). Osborn et al. (2016) concluded that a key element to achieving

successful medication management is defining a process that creates supports and removes barriers for individuals to correctly manage their medications.

Medication Adherence

Medication adherence is the extent to which clients take their medication as prescribed (Ho et al., 2009), while poor adherence is when a person does not follow the prescribed treatment ordered by the medical provider (Robnett et al., 2007). The topic of medication adherence has also been studied under the term compliance, but adherence has become the preferred term secondary to the passivity implied by the term compliance. Medication adherence infers a cooperative alliance between the provider and the client (Osterberg & Blaschke, 2005).

Measurement. Previous studies measured adherence via a variety of direct and indirect approaches (Lam & Fresco, 2015). Direct measures include measurements of the drug in blood or urine and observation of an individual taking the medication. While direct measures theoretically increase measurement objectivity, the metabolization of the drug may affect measurement accuracy. Additionally, direct measurements are often intrusive and expensive (Osterberg & Blashke, 2005).

Indirect measures include measures related to refills (medication possession ratios or proportion of days covered), pill counts, electronic medication packaging devices, self-report measures in the form of questionnaires or interviews, and comparison of blood pressure readings or hemoglobin A1c (HbA1c) measurements (Lam & Fresco, 2015; Nieuwlaat et al., 2014; Stewart et al., 2014). Indirect measures also have their limitations and strengths (Lam & Fresco, 2015). Indirect measures of refills are readily available from database reviews but offer no guarantee that medications are being taken correctly (Osterberg & Blashke, 2005). Counting the number of pills that are present at consecutive appointments offers a cost-efficient and simple

method that has been shown to have high accuracy. Counting pills may be inaccurate when clients stockpile surplus medications or when medications have been misplaced. Pill counting also does not confirm whether the pills removed from the bottle were taken as prescribed (Lam & Fresco, 2015; Osterberg & Blashke, 2005). Electronic dispensing devices have been demonstrated to be accurate, but they are expensive and often too heavy to travel with an individual (Lam & Fresco, 2015). While self-report measures are inexpensive, easily administered, have high clinical utility, and have been found to provide reasonably accurate estimates of adherence, there are always the concerns that come with the subjective analysis of one's own performance (Lam & Fresco, 2015; Nguyen, La Caze, & Cottrell, 2014; Osterberg & Blashke, 2005).

Factors influencing adherence. Methods of medication adherence assessment have been widely used to identify factors that influence adherence. Due to the interactive complexity of the factors known to influence adherence, the factors have been divided into (a) client, (b) provider, and (c) health system (Hugtenburg, Timmers, Elders, Vervloet, & van Dijk, 2013; Neiman et al., 2017). Client factors have been further subdivided into intentional (e.g., active decision to not take the medication because of beliefs, side effects, cost, etc.) and unintentional factors (e.g., forgetting to take the medication, misunderstanding the instructions, etc.) (Ho et al., 2009; Neiman et al., 2017). A large survey (N = 24,000) found that approximately 30% of participants were intentionally non-adherent, leaving the majority of reasons in the unintentional category (Gadkari & McHorney, 2012). Provider factors refer to the complex dosing of medications and lack of communication between the client and provider and between prescribing providers (Neiman et al., 2017). Healthcare system factors include a lack of access to care, limited client-centered education materials, and prohibitive financial cost (Neiman et al., 2017).

Individual client characteristics have also been studied to determine if they have an influence on adherence. Studies have linked adherence to education level, age, gender, race or ethnicity (Holmes et al., 2012), socioeconomic status (Kripalani et al., 2015), comorbidities (Rolnick, Pawloski, Hedblom, Asche, & Bruzek, 2013), number of medications (Holmes et al., 2012f), and number of unique providers (Holmes et al., 2012). Whittle et al. (2016) concluded that many of these studies were flawed in their methods and have low generalizability. These authors found in their own large randomized control trial of hypertensive therapies that while client characteristics can be significantly associated with adherence, the association does not fully explain adherence and should be thoughtfully examined when used to inform future efforts to improve adherence (Whittle et al., 2016). Though demographics are often analyzed in adherence studies, Whittle et al.'s (2016) conclusion agrees with previous work by DiMatteo (2004) which looked at demographic factors across multiple studies and found they had only a small effect on adherence.

Interventions. The variety of identified factors influencing adherence make creating effective interventions difficult. Demands of managing self-care behaviors, including diet, activity level, and multiple medications, make achieving optimal blood pressure and glycemic control a test of discipline for every client and an educational challenge for the medical team (Alhalaiqa, Deane, & Gray, 2013; Schroeder, Fahey, & Ebrahim, 2008). Identifying an accessible process within the medical team that will create individualized supports for and remove barriers to successful medication management has also been shown to be difficult (Alhalaiqa et al., 2013; Schroeder et al., 2008).

Systematic reviews related to medication adherence reveal that efforts to improve adherence in individuals with HTN and T2DM have included interventions delivered by nurses,

pharmacists, physicians, and multidisciplinary healthcare teams (Cramer, 2004; Sapkota, Brien, Greenfield, & Aslani, 2015; Schroeder et al., 2008). A systematic review of the interventions specifically used to address adherence to antihypertensive medications concluded that simplifying dosing regimens improved adherence, but not necessarily blood pressure levels (Schroeder et al., 2008). Schroeder et al. (2008) also found the use of motivational strategies and complex, multi-faceted approaches to be promising but suggested that more research was needed (Schroeder et al., 2008). A systematic review of the interventions used thus far to address T2DM adherence concluded that none consistently improved adherence across this population (Sapkota et al., 2015). A separate systematic review focusing on medication adherence across a variety of diagnoses found the most effective medication management interventions were multifaceted with frequent client interactions (Nieuwlaat et al., 2014). These complex interventions included personalized ongoing support with in-depth education and/or counseling and frequent support from allied health professionals or caregivers (Nieuwlaat et al., 2014). In a qualitative study of individuals with HTN who underwent adherence training, the researchers found that client-centered interventions that focused on eliminating barriers to adherence and improving beliefs and attitudes toward medication ultimately improved adherence, lowered blood pressure, and reduced the risk of associated health concerns (Alhalaiqa et al., 2013). These results indicate a scripted and globally applied approach will not be effective in addressing medication adherence. A solution appears to lie in an intervention that is client-centered and addresses the specific strengths and barriers that exist within the individual, their environment, and the medication management activities required of them.

Occupational therapy practitioners are well-suited for this role as they are equipped to use everyday life activities (occupations) to improve or enable participation in roles, habits, and

routines in a variety of settings (e.g. home, community, work, etc.). Occupational therapy practitioners are specifically trained to examine the activities an individual needs or wants to do, the environmental context(s) in which the occupation occurs, and the contributing personal factors required for success (e.g., body functions, values, beliefs, psychosocial functions, cognition, etc.), while also assessing the relationship that exists between all of these elements to either support or impede success (AOTA, 2014). They also promote medication adherence as they address self-care occupations and assess and intervene in specific and global aspects of the medication management process (AOTA, 2017).

Medication management for the occupational therapy practitioner refers to the "daily systems and processes of taking medications as prescribed" (Schwartz & Smith, 2017, p. 1). These processes include interacting with prescribing providers, navigating pharmacy systems, understanding instructions for proper medication administration, and maintaining these habits over the prescribed time (AOTA, 2017). The occupational therapist is well suited to identify and address challenges in a client's medication management processes. For instance, it falls in the occupational therapy practitioner's scope of practice to address cognitive deficits, such as decreased memory or problem-solving; to adjust schedules to integrate proper timing of medications into an individual's daily habits and roles; to identify community resources to support acquisition of medications; to provide environmental adaptations to enable proper medication adherence (e.g., alarms suited for the client with cognitive, visual, or hearing deficits, external and internal cue training, devices for adapting medication bottles to address coordination, sensory, or range of motion deficits, etc.); and to support occupational engagement to improve overall health and wellness (AOTA, 2014; Cole, 2011).

The occupational therapist's role in primary healthcare has been developing over recent years. In 2014, the AOTA released a statement advocating for the occupational therapist's position in primary care and outlining the occupational therapy practitioner's roles in primary care. Included in this statement was a discussion of specific roles related to the management of chronic conditions. Medication management is highlighted as an area of intervention in primary care with specific emphasis on how the occupational therapy practitioner supports clients in achieving lifestyle modifications by incorporating medication management and other healthcare activities into the client's roles and routines (AOTA, 2014).

To allow for proper implementation and assessment of outcomes, interventions benefit from a manualized approach. The IMedS is an occupational therapy manualized intervention based on theory, current occupational therapy practice, and best evidence on the topic of medication adherence (Schwartz, 2015). It consists of a three-step process that leads the client from the reflection of past performance, to goal setting, and onto strategy identification and implementation. This intervention guides the client through identifying strategies in the following six areas: altering the medication management activity, advocacy, assistive technology, environmental modifications, and securing refills on time (Schwartz et al., 2017). A Phase I study indicated promise for the effectiveness of an occupational therapy intervention being applied to issues of medication adherence and concluded that the IMedS should be further tested to support the use of evidence-based occupational therapy interventions (Schwartz & Smith, 2016).

The development of the IMedS was partially informed by the transtheoretical model (Schwartz, 2015). This model has been effectively used to improve health behaviors (Werch, Ames, Moore, Thombs, & Hart, 2009). Also known as the stages-of-change model, the

transtheoretical model defines five linear stages that a client progresses through during behavior change: precontemplation, contemplation, preparation, action, and maintenance (Prochaska, DiClemente, & Norcross, 1993). The application of the transtheoretical model or stages-of-change model to medication adherence in a hypertensive population has previously shown that behavior change interventions should be aligned with the individual's current stage of change in order to improve effectiveness but no known research has examined how an intervention influences individual progression through the stages (Chang, McAlister, Taylor, & Chan, 2003; Willey et al., 2000). Research has recently found that a person's self-identified position along the stages of change continuum is predictive of adherence in a T2DM population (Arafat et al., 2019).

Significance of the study

To this point, limited research has been conducted regarding the occupational therapy practitioner's role and effectiveness in the medication management process. Yuen (1993) and Sanders and Van Oss (2013) assert that occupational therapy practitioners are well-positioned to utilize their understanding of addressing performance deficits and developing daily routines to promote medication adherence. Fricke and Unsworth (2001) found that clients and practitioners alike identified maintaining the ability to manage medications as a high priority for supporting independent community living. Schwartz and Smith (2016) provided more objective information in their randomized, feasibility study of whether an occupational therapy-specific intervention could help individuals with chronic health conditions improve their medication adherence. The conclusions of this Phase I study were that occupational therapy practitioners can positively influence adherence and that further research is needed (Schwartz & Smith, 2016). The subsequent qualitative analysis of this Phase I study found that the occupational therapy

intervention group participants reported greater improvements in medication adherence and to have implemented twice as many new adaptive strategies as the standard of care group (Schwartz et al., 2017).

The individual, medical team, and community at-large are affected by the challenges of improving medication adherence and the real consequences of poorly managed chronic disease, as they contribute to personal, medical, and societal costs (Schroeder et al., 2008; WHO, 2013; WHO, 2016). Though the factors influencing adherence are well-documented, no clear means to improve adherence have been identified (Nieuwlaat et al., 2014). Research has demonstrated that there are a variety of viable methods available to assess adherence and client-centered interventions that allow for individualized problem solving have the potential to positively affect adherence (Nieuwlaat et al., 2014; Nguyen et al., 2014; Schroeder et al., 2008). The occupational therapy practitioner is well positioned as an established healthcare professional in the medical team to offer skilled interventions to address improving medication management (Schwartz & Smith, 2017). A better understanding of the occupational therapist's role in addressing medication management assists in defining the occupational therapist's role in this area on the interdisciplinary medical team, refining interventions for adherence, and the adjustment or development of future occupational therapy interventions.

Method

Study Design

This randomized controlled trial using a pretest-posttest control group design took place from June 9, 2018, through April 30, 2019, at Jordan Valley Community Health Center (JVCHC) in Springfield, Missouri. Prior to participant recruitment, the study was approved by the Institutional Review Board (IRB) at the University of Indianapolis and reliance agreements were

ratified between Missouri State University and University of Missouri-Kansas City (UMKC). The legal department at JVCHC provided a letter of cooperation.

Participant Selection

A convenience sample of adults (age 18 years and older) with HTN and/or T2DM being treated at the JVCHC by the clinical pharmacist were recruited for the study until the required number of participants was achieved. The JVCHC protocol guides medical providers to consult the clinical pharmacist if clients with a hypertension diagnosis have an elevated blood pressure on two different readings for his/her specific age and diagnosis situation and/or when a client's HbA1c is > 9% or the client is newly diagnosed with T2DM. Clinic clients were considered eligible for inclusion in the study if they were 18 years or older, had a confirmed diagnosis of HTN and/or T2DM, and they provided written informed consent. Clients were excluded if they had a medical power of attorney and/or were unable to provide their own informed consent.

An a priori sample size estimation was conducted using G*Power, version 3.1 (Faul, Erdfelder, Lang, & Buchner, 2009). In the absence of known means, standard deviations, or minimal clinically important difference information for the ARMS-7, it was determined to use a moderate effect size of .30 based on an assessment of a systematic review and meta-analysis examining interventions for adherence in individuals with hypertension (Conn, Ruppar, Chase, Enriquez, & Cooper, 2015). The calculation was based on using repeated measures ANOVA, within-between interaction test with two groups and two measurements and the following parameters: two-tailed test, alpha of .05, a conservative power of .95, and a moderate effect size of .30. From the calculation, it was estimated that a minimum of 32 participants were needed to detect a possible statistically significant effect. After five months of limited recruitment, clients

who otherwise met the inclusion criteria with T2DM (with or without HTN) were subsequently added to the inclusion criteria with IRB approval.

Instrumentation

Adherence to Refills and Medication Scale. The ARMS-7 (Appendix A) consists of seven questions that provide a self-report of medication adherence (Kripalani et al., 2015). Permission was granted by the author for the use of the ARMS-7 (Appendix E). The ARMS-7 is a reliable and validated instrument that was developed using individuals with cardiovascular disease, including hypertension. The measure requires a response to questions about medication adherence based on a four-point scale. Scores on the ARMS-7 range from 7 to 28. The instrument was designed to be flexible and, in this study, higher values will indicate better adherence (Kripalani, Risser, Gatti, & Jacobson, 2009). The ARMS has also demonstrated a higher correlation with medication refills as compared to the extensively used 4-item scale by Morisky, predictive validity with blood pressure control, and had been shown to be appropriate across literacy levels (Kripalani et al., 2009; Kripalani et al., 2015; McNaughton, Jacobson, & Kripalani, 2014).

Stages of Change Measure. Participants readiness for change was measured by a single-item measure that has demonstrated a strong correlation $r = .91$ with other stages of change scales that have multiple-items (Cook & Perri, 2004). This one-item measure is simple, free to use without permission, and eliminates confusion that can occur with multi-item scales (Cook & Perri, 2004) (Appendix F).

Pill count. Pill count is an objective, simple, and inexpensive measurement of how many pills remain in an individual's bottle as compared to refill timing and the number that should remain (Hawkshead & Krousel-Wood, 2007). A percentage of adherence can be calculated by

dividing the number of doses taken by the number of doses that should have been taken multiplied by 100 (Hawkshead & Krousel-Wood, 2007). In a study focusing on hypertension, Hamilton (2003) found significant correlations between pill count and adherence measured by more expensive electronic monitoring systems ($r = .29 – .39$; $p < .01$). Though it requires the assumption that missing pills were ingested by the intended recipient and should be combined with other measures of adherence, pill count is widely considered a gold standard for measuring adherence (Prado, Kupek, & Mion, 2007).

Blood pressure. Accurate blood pressure readings are integral to assessing and monitoring hypertension. Comparison of blood pressure readings over time has been utilized as a method of assessing adherence in a population with HTN (Lam & Fresco, 2015). Use of the manual auscultatory method is regarded as the most accurate non-invasive method of measuring blood pressure as compared to automated devices (Chen, Chen, Feng, Chen, & Zheng, 2017). Significant differences have been found between manual and automated measurement devices ($p = .003$) particularly regarding systolic blood pressure. The guidelines for the proper administration of a manual blood pressure measurement to be used in this study are outlined in Appendix D (Pickering et al., 2005).

Hemoglobin A1c. The hemoglobin A1c (HbA1c) blood test provides a value that represents a person's average blood glucose level over a 3-month period (National Institute of Diabetes and Digestive and Kidney Diseases, 2019). Research from quality assurance assessments has shown the HbA1c to test to provide a reliable result (Penttilä et al., 2016). The HbA1c test is used in conjunction with other clinical correlates to both diagnose T2DM and for prognostication for complications of the disease (Sherwani, Khan, Ekhzaimy, Masood, &

Sakharkar, 2016). The HbA1c test results have been used in previous studies to evaluate medication adherence (Bailey & Kodack, 2011; Kelly et al., 2016).

Charlson Age-Comorbidity Index. To better assess the impact of comorbid conditions, once all data were collected comorbidities were weighted via the validated Charlson age-comorbidity index (CACI) (Charlson, Szatrowski, Peterson, & Gold, 1994). The formula for the CACI score considers the age of the individual and ranks comorbidities based on identified risk of contributing to mortality (Charlson et al., 1994). The CACI was originally validated for individuals who had elective surgery and had either hypertension or diabetes. While the index is useful in providing information about the degree of illness an individual has the authors encourage studies with smaller numbers to also examine comorbidities and age separately (Charlson et al., 1994). These analyses were also completed for this study.

Procedures

Recruitment and informed consent. As the standard of care in the clinic, clients identified as having uncontrolled HTN or T2DM are given a referral to the clinical pharmacist by the participant's primary care provider. At this consultation, the pharmacist confirmed the client's uncontrolled HTN and/or T2DM diagnosis via the electronic medical record (EMR) and proceed through the JVCHC protocol for HTN or diabetes. The pharmacist then informed the client about the study and inquired of his or her interest in participating in the study. If the client indicated interest, the pharmacist began the informed consent process or introduced the primary researcher (T.G.) who then completed the informed consent process.

Group assignment (randomization). Participants who completed the consent process were consecutively and randomly assigned to either the TAU group or a TAU plus occupational therapy group. Group assignment was performed using sequentially numbered, identical, opaque,

sealed white envelopes. The clinical pharmacist or primary researcher selected the first envelope in the sequence and recorded the participant's group assignment in the EMR and a study binder that was locked in a secure filing cabinet at JVCHC. Participants' information was also deidentified at this time and given a study participant number. If the participant was assigned to the group receiving occupational therapy, the clinical pharmacist initiated a referral to occupational therapy for the participant. The primary researcher then recorded the additional demographic information and assessment information described herein on a password-secured laptop using participant identification numbers.

Data collection. Once consent was received, the primary researcher collected demographic data specific to age, gender, race/ethnicity, number of prescribed medications, the availability of a caregiver to assist with medications, and diagnosed comorbidities. The comorbidities were scored via the CACI as described above. This information was transferred to a password secured electronic spreadsheet matched only to the participant's study number. Medication adherence was measured by the primary researcher or the pharmacist via administration of the self-report ARMS-7 instrument during the participant recruitment process and subsequently measured via pill count and blood pressure readings and/or HbA1c levels from the EMR. The participant's current stage of behavior change was assessed via the single-item stages of change measure. The primary researcher or the clinical pharmacist recorded this information within the participant's EMR. The primary researcher or the clinical pharmacist collected the outcome data from all participants a minimum of two times during either the pharmacy or occupational therapy intervention sessions. Outcome measures were sought at the initial visit and at each subsequent visit. The number of visits varied based on participant need and participation (Table 2). All assessments and reassessments occurred at JVCHC. Scores were

recorded in the participant's EMR. After data collection was complete, all scores were transferred to a study data collection form utilizing a participant number and no personal identifying information to allow for data analysis. This document was password protected and secured on the primary researcher's password protected laptop.

Intervention. If the participant was assigned to the TAU group, he/she received an intervention from the clinical pharmacist at JVCHC. This is the standard practice in the clinic. The aforementioned protocols were utilized to ensure that all members of the TAU group received a similar intervention experience. In general, the TAU process consisted of the clinical pharmacist providing education about the pathophysiology of the diagnosis, an interview related to diet, exercise, and social history related to the diagnosis, a discussion about medication adherence, and setting self-management goals related to managing the disease. The pharmacist may also adjust medications as needed. The TAU process for clients with hypertension is described in detail in Appendices B (HTN) and C (diabetes).

If the participant was assigned to the occupational therapy intervention group, the intervention was guided by the IMedS. Use of motivational interviewing with a focus on health literacy were utilized throughout the IMedS intervention as participants were guided through self-identifying personal medication management goals and self-selecting personalized strategies to improve adherence. The full manual is available for review at the referenced website (Schwartz, n.d.). The occupational therapy intervention was also informed by the administration of the medication management subtask of the Performance Assessment of Self-Care Skills (PASS) (Rogers, & Holm, 1989).

Data Screening and Analysis

The raw data were transferred to a password protected Excel spreadsheet by the primary researcher and reviewed for accuracy. Data analyses were completed using IBM® SPSS® for Windows, Version 24 (IBM Corp., Armonk, NY). Descriptive statistics were conducted, and the results were used to describe the sample and baseline characteristics of the experimental and control groups (Table 1 and Table 2). Nominal data are presented as frequency and percentage while interval and ratio data are reported as mean and standard deviation or median and interquartile range, dependent on whether the data are normally distributed. To determine if participants in both groups were similar in demographic and baseline characteristics, comparisons were conducted using Fisher's exact test for nominal data and either an independent *t*-test or non-parametric Mann-Whitney U test for interval and ratio data, dependent on whether or not the data were normally distributed as determined by the Shapiro-Wilk test.

Results

Originally, 32 participants, enrolled in the study; however, three participants did not return after the initial appointment. Data for these three participants were eliminated from analysis, leaving a total sample size of 29. Due to randomness in the assignment to groups, there were 12 participants in the control group and 17 participants in the experimental group.

Participant Characteristics

The final sample size of 29 participants was nearly equally divided between male (51.7%) and female (48.3%). The sample included four ethnic groups with the large majority being Caucasian (75.9%). The mean age for the total sample was 51.59 years (*SD* = 10.08). Further details regarding demographic characteristics are found in Tables 1 and 2. As previously

described, the experimental and control groups were found to be similar across all demographic characteristics.

Gender Distribution

Gender distribution varied somewhat between the groups. The control group was 66.7% (n = 8) male, but the experimental group was 41.2% male (n = 7). A Fisher's exact test was performed to evaluate whether there was an association between group and gender and to test for potential gender differences between groups. There was no statistically significant association between group and gender as assessed by Fisher's exact test, two-sided, p = .264. Gender was therefore assumed to be equally distributed between groups. Further demographic details can be found in Table 1.

Age Distribution

An independent-samples t-test was then performed to test for equivalencies in age between the control group and the experimental groups. There were no outliers in the data, as assessed by inspection of a boxplot. Age for each level of group was normally distributed, as assessed by Shapiro-Wilk's test ($p > .05$), and the assumption of homogeneity of variances was met, as assessed by Levene's test for equality of variances (p = .105). Results revealed no significant differences in age between the experimental group (M = 52.00, SE = 2.81) and the control group (M = 51.00, SE = 2.30), $t(27) = 0.26$, p = .798 (Table 2). Age was assumed to be equivalent between the experimental and control groups.

Ethnicity

The sample contained four self-defined ethnic groups with Caucasian being the largest (75.9%). A chi-square analysis was not able to be performed to test for equivalence in the distribution of ethnicity because there were fewer than five participants per group. Frequencies

for each group are available in Table 1. A review of the tabled data revealed a similar pattern and frequency between groups indicating that ethnicity was equally distributed between groups and the sample was weighted toward Caucasian participants. These percentages are similar to those found in the census data for the surrounding area (U.S. Census Bureau, 2010).

Number of Medications

An independent-samples t-test was performed to determine if there were differences in the number of medications prescribed between the control group and the experimental group. There were no outliers in the data, as assessed by inspection of a boxplot. The number of medications for each group was normally distributed, as assessed by the Shapiro-Wilk test ($p > .05$), and there was homogeneity of variances, as assessed by the Levene's test for equality of variances ($p = .052$). Results revealed no significant differences in number of medications between the experimental group ($M = 8.18$, $SE = 0.91$) and the control group ($M = 6.75$, $SE = 1.48$), $t(27) = 0.87$, $p = .393$ (Table 2). The number of medications was assumed to be equivalent between groups.

In-Home Assistance

The presence of assistance at home was evaluated and a review of percentages revealed that 35.3% of the experimental group had assistance at home while 75.0% of the control group had available assistance to manage their medications (Table 1). A Fisher's exact test was performed to see if there was an association between group and the presence of assistance for medication management. No statistically significant association was found between group and assistance at home as assessed by Fisher's exact test, two-sided, $p = .060$. Therefore, assistance at home was considered to be equivalent between groups.

Number of Documented Comorbidities

An independent-samples t-test was performed to determine if there were differences in the number of documented comorbidities between the control group and the experimental group. An inspection of a boxplot demonstrated no outliers in the data. These results were found to be normally distributed as assessed by Shapiro-Wilk test ($p > .05$), and there was homogeneity of variances, as assessed by Levene's test for equality of variances ($p = .818$). Results revealed no significant differences in number of comorbidities between the experimental group ($M = 3.41$, $SE = 0.33$) and the control group ($M = 2.75$, $SE = 0.37$), $t(27) = 1.31$, $p = .201$ (Table 2).

Charlson Age-Comorbidity Index (CACI) Scores

Comorbidities were also weighted based on the CACI. A Mann-Whitney U test was completed to determine if there were differences in CACI scores between the experimental and control groups because these scores were not normally distributed, as assessed by Shapiro-Wilk's test ($p < .05$). Median CACI scores for the control group (1.50) and experimental group (2.00) were not statistically significantly different, $U = 85.00$, $z = -0.81$, $p = .471$, using an exact sampling distribution for U (Dineen & Blakesley, 1973). This result, combined with the above analysis of the actual number of comorbidities, indicates no significant difference between groups based on overall comorbidities. In general, the experimental and control groups were deemed sufficiently homogenous in composition such that further analysis would proceed without the need for any adjustment to the groups.

Differences Between Groups

Adherence as measured by the ARMS-7. Included in the first objective of the study was to determine whether the addition of the delivery of the IMedS by an occupational therapist to usual care resulted in better medication adherence, as measured by the self-report, seven-

question ARMS-7 instrument. A difference score was created between the final and the initial ARMS-7 score. The assumption of normality was met for the difference score (Shapiro-Wilk's, $p > .05$). An independent-samples t-test was performed. Results revealed no significant differences in the ARMS-7 change score between the experimental group ($M = 1.33$, $SE = .70$) and the control group ($M = 0.86$, $SE = .67$), $t(20) = 0.42$, $p = .678$

A mixed ANOVA was used to test whether the ARMS changed differentially by group. The three times of ARMS measurement as the within factor and control versus experimental group as the between factor. There was a significant main effect for ARMS, $F(2, 23) = 6.11$, $p = .007$, eta = .35, but there was not a significant interaction between ARMS and group belonging, $F(2, 23) = 2.24$, $p = .129$, eta = .16. Both groups improved similarly.

The means plot revealed a V shape for the experimental group that bore further analysis (Figure 1) because of its dissimilarity to the pattern of change in the control group. Despite the overall interaction being non-significant, the means for the experimental group were explored separately with a post hoc repeated measures t-test. The test was significantly different for the post hoc comparison for time two and time three for the ARMS-7 measurement, $t(14) = 3.41$, $p = .004$, $d_c = .65$. The effect size was reported using Dunlap's correction for intercorrelation of the measurements (Dunlap, Cortina, Vaslow, & Burke, 1996), instead of Cohen's d (Cohen, 1988), which tends to over-report the true effect. The limited power of the test, owing to the relatively small sample size, however, was not sufficient to find this in the initial analysis. Ultimately, participants in the experimental group arrived at a self-assessed adherence rate slightly greater than the control group (Figure 1).

Adherence as measured by pill count. Determining whether the addition of the delivery of the IMedS by an occupational therapist to usual care improves medication adherence as

measured by a pill count was also included in the first objective. An ANOVA analysis was not completed on the individual pill counts due to multiple missing data points and an observed negative skew. A difference score between the first and final pill counts was calculated. Because some participants were also taking more medications than prescribed, yielding percentages above 100%, the participant's pill count percentage (e.g., 119%) was subtracted from 100 and then the absolute value of that calculation was subtracted from 100 again. The assumption of normality for the change score was not met (Shapiro-Wilk's, $p < .05$). A Mann-Whitney U test was used to assess for differences between groups. The difference score was not significantly different between the experimental and control groups for pill count, $U = 46.00$, $z = -1.28$, $p = .215$.

The mean pill count percentages for the difference score were noted to demonstrate a sizeable difference with the experimental group having a mean of 20.57 and the control group a mean of 7.89. An effect size calculation was completed using Measure of the Effect (MOTE), version 0.0.0.9100, to examine mean differences on a standardized scale (Buchanan, Scofield, & Valentine, 2017). This calculation revealed $d = 0.55$, indicating a medium effect size for the occupational therapy intervention on pill count in the experimental group (Cohen, 1988). Correlation analyses, including a review of scatterplots, were completed to assess the relationship between the ARMS-7 scores and the pill count scores. Due to missing pill count data, the statistical analyses were limited and no conclusions could be drawn.

Adherence as measured by blood pressure. Also included in the first objective of the study was to determine whether the addition of the delivery of the IMedS by an occupational therapist to usual care improves blood pressure, as measured by the mean arterial pressure (MAP) within the experimental group. The mean values for the experimental group and the control group across time can be seen in Table 3. The assumption of normality was violated

(Shapiro-Wilk's, $p < .05$) for the data. The data were also found to be positively skewed and with multiple outliers.

A difference score was calculated between the final MAP and the initial MAP scores. The difference was assessed with a Mann-Whitney U test. The median difference score was not significantly different between the experimental (*Mdn* = -4.00) and control groups (*Mdn* = -8.33), $U = 60.00$, $z = -1.17$, $p = .259$. In line with previous analyses, the effect size was calculated and found to be -0.31 indicating a small effect size for the control group intervention on the difference in MAP as compared to the intervention group (Figure 2).

Adherence as measured by hemoglobin A1c. The A1c values could not be compared between groups due to an inequality of relevant participants (experimental: $n = 10$; control: $n = 1$). Overall, 9 out of 10 participants in the experimental group demonstrated a desired decrease in their A1c (*M* = -1.09, *SD* = 1.85) and the one participant in the control group decreased by .80 units. Considering the previously designated standard of change of at least 0.50 standard deviation of improvement, half of the participants in the intervention group demonstrated a significant improvement in their A1c (Norman, Sloan, & Wyrwich, 2003).

Readiness for change as measured by the stages of change measure. The second objective of the study was to determine whether the administration of the IMedS in addition to usual care influenced an individual's readiness for change, as measured by the stages of change (SOC) measure. The SOC score was not normally distributed, therefore a nonparametric Friedman test (alternative to a repeated measures ANOVA) was used to determine if there was a difference in stage of change scores across the three measurement times. The Friedman ANOVA statistic, X^2 (2, $N = 25$) = 1.50, $p = .472$ indicated that there was not a statistical difference in

SOC scores across the three measures at an alpha .05 level. Descriptive statistics for each of the measurements are listed in Table 4.

Demographic influence on adherence. The final objective was to explore whether participant demographics (e.g., gender, age, race/ethnicity, assist at home, comorbidities, and number of medications) impact medication adherence rates. Various correlation analyses were completed based on the level of measurement. Full results are found in Table 5. No relationship was found between the individual change scores for the adherence measures of the ARMS-7, pill count, or MAP and the demographic factors, other than for the number of medications and the ARMS-7 ($r = .49$, $p = .019$). This indicates a positive linear association of the number of medications and an improvement in the ARMS-7 score. Using a Type I Error correction the p-value was adjusted to .017. Using this criterion, this relationship would not be considered significant.

Analyzing the relationship between individual adherence measurements and demographics can provide some insights but should be viewed with caution as the literature indicates that adherence should be measured in multiple ways (Kreyes, 2016; Lam & Fresco, 2015; Pednekar et al., 2019). Coupling the statistics from this study that demonstrate no significant difference in demographics between the control and experimental groups with the cumulative measurements of adherence may also indicate that participant demographics are not significantly impacting medication adherence rates.

Discussion

The purpose of this study was to meet three objectives. The first objective was to use at least three different medication adherence measures to evaluate the influence of the addition of the IMedS to usual care on adherence as compared to usual care alone. The second objective was

to determine whether the administration of the IMedS influenced an individual's readiness for change. The third objective was to explore the influence of demographics on adherence. The first and third objectives were met, but the second objective was impeded by a lack of sensitivity of the stages of change measure.

The randomization process provided groups that were evenly matched on the identified demographic areas. As suggested by the literature, multiple methods were used to assess adherence for both groups (Kreyes, 2016; Lam & Fresco, 2015; Pednekar et al., 2019). The proportion of adherent participants increased in both groups but was not significantly different between groups for the change scores calculated for the ARMS-7, MAP, and pill count. This finding corroborates previous work by Doggrell (2010) that found no clear preference for an intervention from any specific profession.

While three outcome measures were used, as previously discussed, each has its own limitations which may have influenced study findings. This study agrees with previous findings that individuals tend to overestimate their level of adherence with the initial ARMS-7 score mean being 26/28 (Kelly et al., 2016; Nyugen et al, 2014). This provided a challenge for distinguishing an inclusion criterion based on the ARMS-7 because clients rarely self-identified as non-adherent. If adherence is truly high, there is no need for intervention, and if change does occur it will be so slight that it would likely go undetected (Doggrell, 2010). However, assessments and discussions completed during the intervention process would often show that participants were unaware or unwilling to acknowledge non-adherent behaviors. While blood pressure provides an objective measurement, it varies throughout the day and can be influenced by extraneous variables such as recent caffeine intake, timing of exercise, stress, a participant's decision to not take the medicine when going into public due to side effects (e.g., increased urination), or the

duration of use of antihypertensive medications (Mancia et al., 1983). Pill count data was limited by the participants' willingness to allow the researcher to count their pills, forgetting to bring their pills, and by combining pills from multiple bottles.

Recent literature suggests that a composite adherence reference standard should be developed and validated (Kreyes, 2016). This standard would use the results from several imperfect measurements to calculate a more accurate composite score rather than using only a comparison of the individual scores. Kreyes (2016) also included suggestions to address missing data. Such a validated score would have yielded more clarity in this study.

Outcomes may also be affected by time in care. Conn (2015) previously concluded that the most effective adherence measures addressed multiple components and were delivered over several days. While the IMedS process intends to address many areas, intervention time was often limited by having to share appointment time between the pharmacist and the occupational therapist, or the participant needing to attend another appointment, or both. Several participants in both groups missed appointments due to a lack of transportation or other individual stressors.

Analysis of how individual outcome measures changed across groups yielded interesting findings. These results could be better evaluated with a larger sample size. The significant main effect found for the ARMS-7 and the significant difference found for the post hoc comparison for time two and time three for the ARMS-7 measurement indicated that the occupational therapy intervention was having a unique effect as compared to the control (Figure 1). These findings may suggest that participants in the experimental group receiving occupational therapy services may change in their adherence rates in a different manner as compared to the control. The combination of motivational interviewing and a collaborative analysis of habits and roles improved the participants' ability to identify missed doses or habits of non-adherence. This

increased awareness appeared to create the drop in self-reported adherence as patients reported their actual adherence more accurately. In these cases, participants were also noted to verbalize a heightened understanding and commitment to making changes in their daily habits related to medication adherence. Once the participants identified the need for improving their adherence and implemented self-selected strategies, their adherence rose to just above that of the control group.

Standardized mean difference effect sizes (*d*) were calculated for the pill count and MAP outcomes to further reflect the post-intervention difference between the treatment and control participants. These effect sizes, though limited by sample size, provide information for clinical application and may be useful in future research to strengthen power analyses. The pill count outcomes were further evaluated for differences across time and group due to the differences identified in the mean percentage change between the occupational therapy group ($M = 20.6\%$) and the control group ($M = 7.9\%$). The comparison of the two interventions yielded a medium difference between the two ($d = 0.55$), suggesting that the occupational therapy intervention was positively affecting adherence as measured by pill count. This difference supports previous IMedS research that medication adherence is responsive to occupational therapy (Schwartz & Smith, 2016). These findings also expand upon previous research that demonstrated the intervention can be effective in a lab setting, by now showing the IMedS approach can be useful in a primary care clinic.

Effect size analysis of the MAP change score yielded $d = -0.31$, indicating the control group saw a larger change for blood pressure as compared to the intervention group. Since both groups were receiving an intervention by the clinical pharmacist for adjustment of medications and counseling, it seems the difference may be due to small variations between groups or

individual factors that influence blood pressure that were not tracked in the study (e.g., caffeine intake, stress level, etc.). Though not statistically significant, the intervention group demonstrated an older mean age, was managing more medications, had less assistance at home, and had a higher number of comorbidities. The control group also started with a higher mean MAP, which may have made it easier to detect change. While remaining cautious due to the number of missing data points for MAP, both groups saw an overall decrease in MAP, indicating that the interventions were having the desired effect in this hypertensive population.

While A1c could not be compared between groups because of the inequality of participants with T2DM, it is notable that 90% of participants in the experimental group demonstrated a desired decrease in their A1c (M = -1.09, SD = 1.85), or half of the group when using the standard of change of one half of the standard deviation reduction in A1c. These participants received both the pharmacy and occupational therapy intervention. Future research should focus on whether the occupational therapy intervention was necessary to produce this change.

The literature supports the approach taken by the IMedS as administered by an occupational therapist. In a systematic review of medication adherence interventions, Conn et al. (2015) reported that the intervention components showing the most promise were those addressing the link between habits and adherence behaviors, providing adherence feedback, self-monitoring of blood pressure, the use of pill boxes, and motivational interviewing. The occupational therapist's clinical process inherently views a client through their individualized daily occupations, habits, and routines, which has also been identified as a key component of effective adherence interventions (Längst et al., 2015). The occupational therapist also used the pill count information as objective feedback to increase self-awareness of habits that were

promoting or limiting adherence. Participants also employed combinations of environmental supports like taking blood pressure at home; use of pill boxes; and establishing environmental cues such as checklists, alarms, and smartphone applications. The occupational therapist's interventions also included assessing and treating cognitive and coordination limitations affecting the medication management process. Motivational interviewing throughout the intervention appeared to be key for prolonged use of new strategies, as it helped the individual identify areas for improvement and strategies that best fit their unique contexts.

The single-item stages of change scale lacked the sensitivity to evaluate readiness for change in this population. In particular, the wording for the choices indicating the stages of action and maintenance was such that participants would be unable to move from one stage to the next within the duration of this study (Appendix F). The assessment of readiness for change still applies to future adherence research as previous studies suggested that self-reported adherence may be a better measure of overall health-related behaviors than of medication adherence alone (LaFleur, Nelson, Sauer, & Nebeker, 2011). Evaluating readiness for change can help the clinician view the client's behavior more holistically. This can support best practice for shaping appropriate interventions to facilitate positive behavior change related to adherence that then may also influence other lifestyle changes that are particularly necessary for healthy management of HTN and T2DM. Arafat et al. (2019) found that a two-item stages of change measure significantly predicted adherence as measured by the self-report, eight-item Morisky Medication Adherence Scale. Future research should consider the use of the two-item scale for the duration of the study and how an individual's readiness for change influences adherence as measured by an objective, non-self-report measure.

No significant influence of demographics was found once Type I error corrections were completed for the demographics of age, gender, ethnicity, assistance at home, number of medications, and number of comorbidities (Table 1 and 2). This corroborates a large randomized control trial ($N = 28,967$) by Whittle et al. (2016), which looked at demographic factors across multiple studies and found they had only a small effect on adherence. This finding is also substantiated by a previous meta-analysis (DiMatteo, 2004) that concluded participant demographics have little impact on medication adherence.

Study Limitations

While the randomization of participants created analogous groups for analysis, potentially confounding factors that influence MAP and A1c were not evaluated or controlled. Confounding variables of diet, exercise, health literacy, medication beliefs, and others may have influenced outcomes in either direction (Náfrádi, Nakamoto, & Schulz, 2017). Another factor that was not tracked but may have influenced adherence is whether the participant could consistently afford his or her medications (Sontakke et al., 2015). Missed doses for financial reasons would, at a minimum, affect the ARMS-7 report and the pill count data.

A ceiling effect could potentially influence the results. It was determined to include participants that scored up to and including the highest score on the ARMS-7, but their inclusion allowed those with high self-report of adherence into the study. Although it was later determined that most were not as adherent as they reported, those with truly high adherence had very limited room to improve. These individuals demonstrated little to no change in the outcome variables. Related to this, the researchers were unable to determine from this data set whether the ARMS-7 was measuring adherence as it was intended, or whether it was more accurately measuring the participant's self-awareness of his or her adherence. Further studies should be designed to

evaluate whether self-report measures are most accurately measuring actual adherence or the level of awareness of adherence.

The total sample size was also a limiting factor. The recruitment efforts took nearly twice as long as anticipated and staffing resources prevented an extension of the study. The minimum number of participants were recruited, although with a subsequent attrition of three participants.

Implications for Clinical Practice

These results are consistent with previous research that occupational therapists offer interventions that can increase medication adherence (Schwartz & Smith, 2016; Sanders & Van Oss, 2013). This study also demonstrated that it is feasible for an occupational therapist to provide this intervention in a primary care setting. Recent qualitative research has identified behavior change techniques for improving medication adherence in primary care that fit well within the occupational therapist's scope of practice (e.g., memory, attention, and decision processes; environmental contexts and resources; and social influences) (Patton et al., 2018). While there are clear benefits to an occupational therapist addressing this area in an outpatient or home health setting, the primary care setting provides particular benefits for individuals with limited access to healthcare, as it reduces demands on the client to make a follow-up appointment and travel for additional services (Gorina, Limonero, & Álvarez, 2019). Recent research by Khayyat et al. (2019) also identified an association between quality of life and medication adherence specifically in client populations with HTN and diabetes in the primary care setting. While the occupational therapist's role in primary care is in its early stages of evolution, it is clear that the occupational therapist is well equipped to work with the pharmacy and provider team to improve medication management and adherence.

Conclusion

This study expands the research related to medication management interventions delivered by an occupational therapist, specifically a manualized approach with the IMedS. It supports the conclusion that an occupational therapist can positively influence adherence, with an emphasis on the use of motivational interviewing to coach a client through the analysis of his or her roles and routines and how medication management strategies can be better integrated into meaningful activities. Future research should include the implementation of the IMedS with a larger sample size and over a longer time period to identify possible differences between groups, further examine the impact of the occupational therapy process on behavioral versus biological factors, and an exploration of the use of an adapted stages of change measure.

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Table 1

Demographic Characteristics of Participants in the Study (N = 29)

Variable	Experimental		Control		Total	
	N	Percent	*N*	Percent	*N*	Percent
Gender						
Male	7	41.2%	8	66.7%	15	51.7%
Female	10	58.8%	4	33.3%	14	48.3%
Race						
Caucasian/Non-Hispanic	12	70.6%	10	83.3%	22	75.9%
Hispanic	3	17.6%	1	8.3%	4	13.8%
African American	1	5.9%	0	0%	1	3.4%
Asian	1	5.9%	1	8.3%	2	6.9%
Assistance at home						
Yes	6	35.3%	9	75.0%	15	51.7%
No	11	64.7%	3	25.0%	14	48.3%

Table 2

Demographic Statistics for Variables (N = 29)

Variable	Experimental			Control		
	M	*SD*	Range	*M*	*SD*	Range
Age (years)	52	11.57	30-72	51	7.97	33-65
Number of medications	8.2	3.75	2-15	6.8	5.11	1-15
Comorbidities	3.4	1.37	1-6	2.8	1.29	1-5
Total number of visits	7.1	1.98	3-11	2.8	.577	2-4

Table 3

Descriptive Statistics for MAP (N = 25)

Variable	Experimental (n = 15)		Control (n = 10)	
	M	*SD*	*M*	*SD*
MAP-Initial	98.78	9.89	105.57	9.85
MAP-Midpoint	91.87	28.24	103.73	6.85
MAP-Final	90.62	26.96	88.6	31.78

Table 4

Stages of Change Descriptive Statistics (N = 23)

Variable Measurement	Experimental				Control			
	M	*Mdn*	*SD*	*SE*	*M*	*Mdn*	*SD*	*SE*
SOC - Initial	4.4	4.0	.63	.16	4.13	4.0	.64	.23
SOC - Midpoint	4.3	4.0	.82	.21	4.13	4.0	.35	.13
SOC - Final	4.5	5	.64	.17	4.13	4.0	.35	.13

Note. SOC = Stages of Change

Table 5

Demographic Correlation Results

Variable	ARMS Change Score (Analysis)	Pill Count Change Score (Analysis)	MAP Change Score (Analysis)
Age	$r = .17$, $p = .443$ (Pearson Correlation)	$r_s = .08$, $p = .710$ (Spearman rho)	$r_s = .12$, $p = .555$ (Spearman rho)
Gender	$r = .38$, $p = .078$ (Point biserial correlation)	$r = .07$, $p = .747$ (Point biserial correlation)	$r = -.06$, $p = .774$ (Point biserial correlation)
Ethnicity	X2 (3, $N = 22$) = .66, $p = .882$ (Kruskal-Wallis)	X2 (3, $N = 24$) = 4.98, $p = .173$ (Kruskal-Wallis)	X2 (3, $N = 26$) = 3.2, $p = .362$ (Kruskal-Wallis)
Assist at home	$r = .23$, $p = .302$ (Point biserial correlation)	$r = -.13$, $p = .549$ (Point biserial correlation)	$r = -.07$, $p = .727$ (Point biserial correlation)
Number of comorbidities	$r = .38$, $p = .084$ (Pearson Correlation)	$r = .25$, $p = .239$ (Pearson Correlation)	$r_s = .30$, $p = .139$ (Spearman rho)
Number of medications	$r = .49$, $p = .019$ (Pearson Correlation)	$r = .28$, $p = .183$ (Pearson Correlation)	$r_s = .15$, $p = .480$ (Spearman rho)

CACI Score	r_s = .16, p = .487 (Spearman rho)	r_s = -.22, p = .313 (Spearman rho)	r_s = .26, p = .198 (Spearman rho)

Note. CACI = Charlson age-comorbidity index

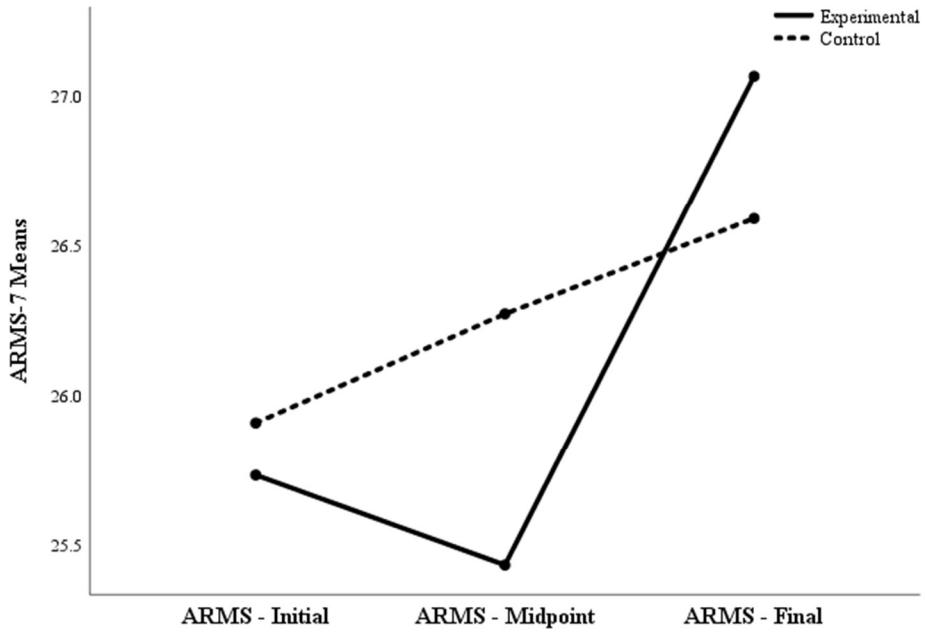


Figure 1. ARMS-7 Line Chart. This figure represents mean ARMS-7 scores by group over time. ($p = .004$)

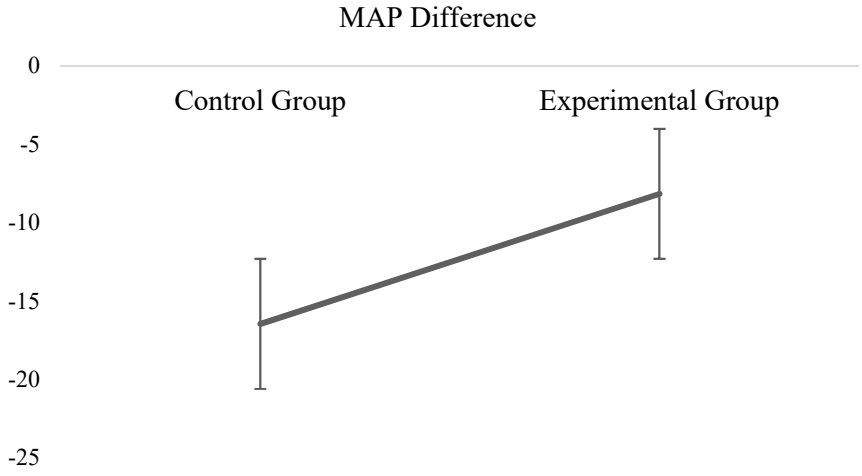


Figure 2. MAP difference between groups. This figure represents the MAP mean difference scores between groups. (p = .259)

Appendix A

ADHERENCE TO REFILLS AND MEDICATIONS SCALE (ARMS)

I will now ask you how often you actually miss taking your medicines. There are no right or wrong answers. For each question, please answer "none of the time," "some of the time," "most of the time," or "all of the time."

1. How often do you forget to take your medicine? 1 2 3 4

2. How often do you decide not to take your medicine? 1 2 3 4

3. How often do you forget to get prescriptions filled? 1 2 3 4

4. How often do you run out of medicine? 1 2 3 4

5. How often do you skip a dose of your medicine before you go to the doctor? 1 2 3 4

6. How often do you miss taking your medicine when you feel better? 1 2 3 4

7. How often do you miss taking your medicine when you feel sick? 1 2 3 4

8. How often do you miss taking your medicine when you are careless? 1 2 3 4

9. How often do you change the dose of your medicines to suit your needs (like when you take more or less pills than you're supposed to)? 1 2 3 4

10. How often do you forget to take your medicine when you are supposed to take it more than once a day? 1 2 3 4

11. How often do you put off refilling your medicines because they cost too much money? 1 2 3 4

12. How often do you plan ahead and refill your medicines before they run out? 1 2 3 4

Scoring: Item 12 should be reverse coded. Then add up the points. Scoring may be completed with either higher or lower scores indicating better adherence. Scores can be treated as a continuous measure or dichotomized. The ARMS-7 consists of the 7 items highlighted above in blue.

Appendix B

JORDAN VALLEY
COMMUNITY HEALTH CENTER

Clinical Pharmacist Hypertension Protocol

Policy Statement:

Jordan Valley Community Health Center (JVCHC) has established procedures for follow-up blood pressure monitoring appointments and titration of blood pressure medications by a pharmacist.

Procedures:

1. Follow-up Blood Pressure Check
   - When a client's blood pressure is elevated on two different readings, the primary care provider (PCP) shall have the client return to clinic within 2-4 weeks for a pharmacy visit for a blood pressure check.
     - If the pharmacist is unavailable at an ideal time for the client, he/ she may be scheduled for a blood pressure check with the Tampa Nurse.
   - The pharmacist will document the prescription order for medication therapy services in the electronic medical record (EMR) per Appendix A.
2. Pharmacist will educate client on pathophysiology of hypertension and importance of medication adherence
3. Pharmacist will assess medication adherence (i.e. utilizing standard assessment of ARMS-7)
4. Pharmacist will obtain diet, exercise, and social history and set self-management goals as needed
5. Pharmacist will ensure appropriate labs have been obtained (e.g., SCr, K^+)
6. Pharmacist will verify client's medication allergies and current medication list at each visit
7. Pharmacist will check client's blood pressure manually
   - If first reading is above goal, the blood pressure will be repeated 5 minutes later before any clinical discussions are made
   - Blood pressure goals set by the PCP will be followed
   - If the PCP does not specify a client-specific goal, the following goals will be used:

<150/90 mmHg	<140/90 mmHg	<130/80 mmHg
≥60 years of age and no other conditions on this table (JNC8)	<60 years of age and no other conditions on this table (JNC8)	CKD with albuminuria ≥30mg/day (KDIGO)
≥80 years of age with CAD (AHA/ACC/ASH)	<80 years of age with CAD (AHA/ACC/ASH)	Kidney transplant (KDIGO)
	DM (ADA, JNC8)	
	CKD with albuminuria <30mg/day (KDIGO)	
	Stroke or TIA (AHA/ASA)	

8. If the client's blood pressure is >180/110 on two separate readings with no associated symptoms (e.g., headache, nosebleeds, chest pain, shortness of breath), the PCP or an available provider will be notified immediately for consultation.
9. If the client's blood pressure is >180/110 with associated symptoms (e.g., headache, nosebleeds, chest pain, shortness of breath), the PCP or an available provider will be notified and the emergency medical system (i.e., call 911) will be activated.
10. If the client's blood pressure is at goal during follow up appointment:
    - No medication changes will be made
    - Client shall have blood pressure rechecked within 6 months of last PCP visit
    - Nurse or pharmacist may refill meds per medication refill protocol
    - Pharmacist will task PCP with appointment documentation
11. If client's blood pressure is not at goal during follow up appointment:
    - Pharmacist will assess client's adherence
        - May contact client's pharmacy as needed
    - Pharmacist will use clinical judgment to adjust medications per Appendix B, C, and D
        - In general, blood pressure medications may be doubled in strength when blood pressure is above goal (e.g., lisinopril 10 to 20mg, HCTZ 12.5 to 25mg, losartan 25 to 50mg, amlodipine 5 to 10mg, metoprolol succ 50 to 100mg).
        - If the blood pressure is >20/10 over goal, consider increasing/ initiating two medications.
    - Client will be scheduled for another blood pressure check within 2-4 weeks
    - Pharmacist will task PCP with appointment documentation
12. During subsequent blood pressure checks, the pharmacist will follow the above procedures.
13. If the client's blood pressure is not at goal after several appointments with no identifiable causes:
    - Consider resistant HTN
    - In-depth consult with PCP to determine appropriate add-on therapy based on client-specific factors
14. Pharmacist will consult with PCP if the client is on more than three (3) blood pressure lowering medications to assess for secondary causes of hypertension
15. If a client no shows to their pharmacist appointment:
    - If the client no shows or cancels a pharmacy appointment, the pharmacist will attempt to reach client via telephone to reschedule the appointment.
    - In the event the pharmacist is unable to contact the client after three (3) attempts and a mailed letter, the PCP will be notified.

Appendix A. Pharmacy EMR Template: Prescription Order for Blood Pressure Medication Therapy Services

I. The pharmacist will document the prescription order as the first chief of complaint of client's first pharmacy visit as: **MTS Prescription Order**
   a. The MTS prescription order will be renewed and documented in the EMR on an annual basis as needed per the provider.

II. The format for the MTS Prescription Order will be as follows:

Client's name:
Client's address:
Client's DOB:
Date of prescription order:
Clinical indication: hypertension
Authorizing physician:
Physician's address:

Appendix B. Considerations in selecting blood pressure medications.

Medication Category	Ideal clients	Considerations	Cautioned Use	Contraindicated
Thiazide diuretic*†	HF, stroke, CAD	Electrolyte levels	Gout, renal impairment	Hypersensitivity, anuria
Angiotensin-converting enzyme inhibitor*	HF, post MI, DM, CKD, stroke, CAD	Electrolyte levels	Women of child bearing age, renal artery stenosis	Hypersensitivity, pregnant women
Angiotensin receptor blocker*	HF, post MI, DM, CKD, CAD	Electrolyte levels	Women of child bearing age, renal artery stenosis	Hypersensitivity, pregnant women
Calcium Channel Blocker*† DHP	CAD	Constipation	Edema	Hypersensitivity
Non DHP	Afib, CAD	Syncope	Bradycardia, HF, edema	Hypersensitivity, SSS, AV block, acute MI
Beta Blocker	HF, post MI, CAD, Afib	Abrupt withdrawal	Bradycardia, bronchospasms	Hypersensitivity, SSS, AV block, decompensated HF
Aldosterone antagonist	HF, post MI, CAD	Electrolyte levels, CNS effects	Renal impairment	Hypersensitivity, anuria, Addison's disease
Loop Diuretic	HF, edema	Electrolyte levels, fluid intake, photosensitivity	Gout, renal impairment	Hypersensitivity, anuria
Alpha-1 antagonist	Add-on therapy	Syncope	Angina, elderly	Hypersensitivity
Alpha-2 agonist	Add-on therapy	CNS effects	Bradycardia, elderly	Hypersensitivity

Vasodilator	Add-on therapy	TID-QID dosing	Renal impairment, edema	Hypersensitivity, mitral valve rheumatic heart

*Recommended first-line therapy per JNC8.

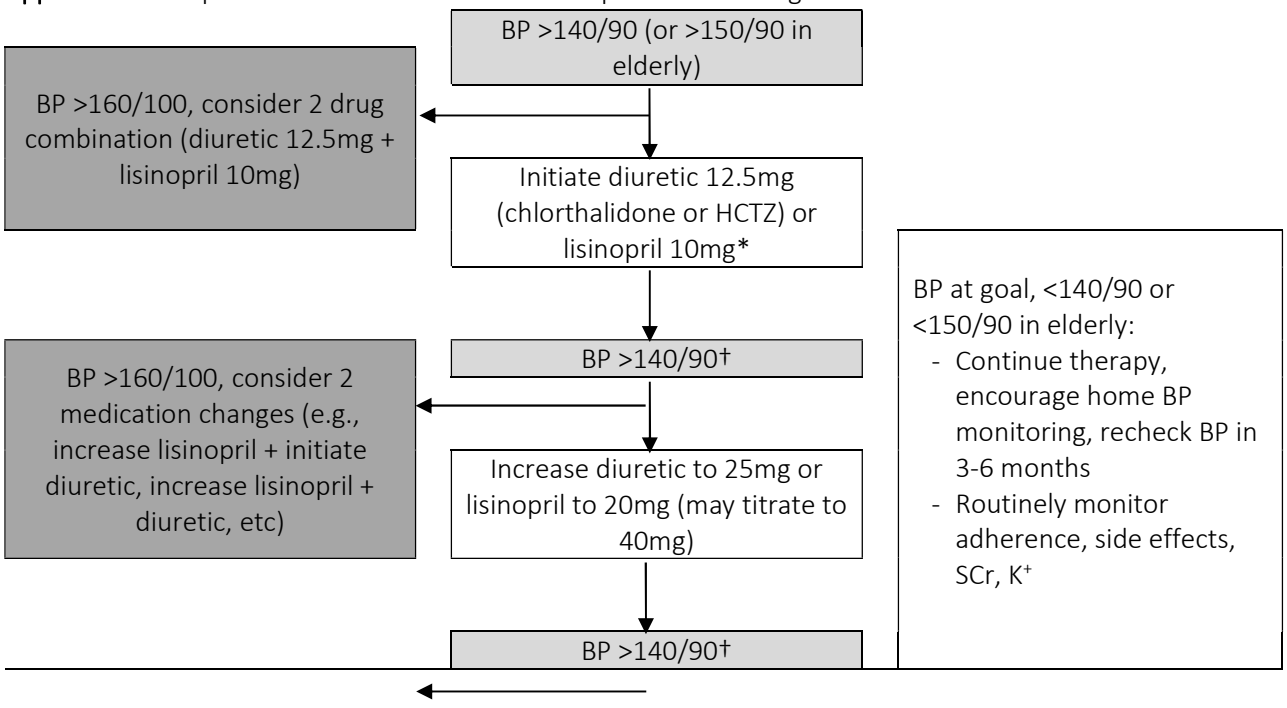
†If no compelling indications, consider a thiazide diuretic or CCB over ACEI or ARB in black clients.

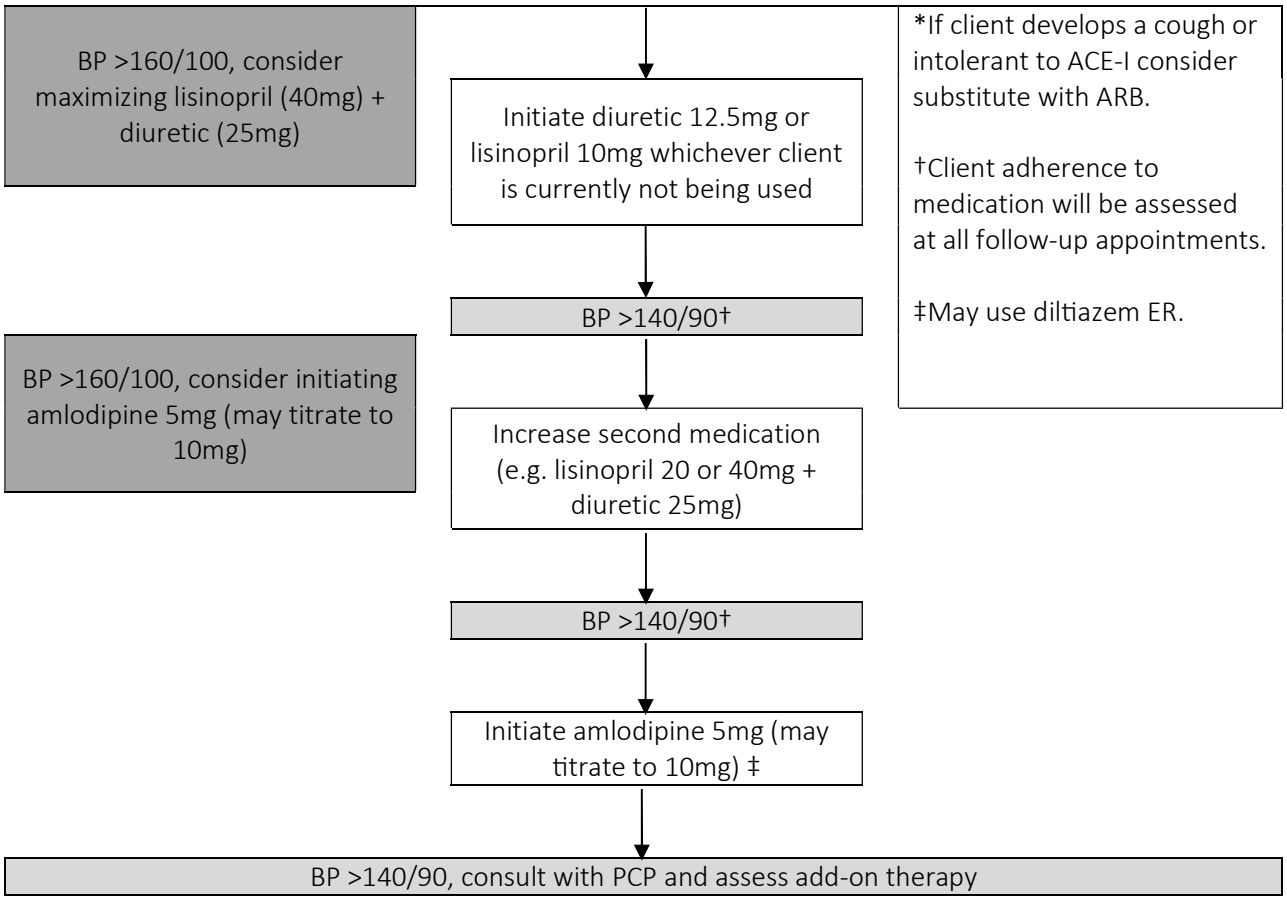
Appendix C. Evidence-based dosing of blood pressure medications.

Antihypertensive Medication	Target Daily Dose, mg
Thiazide-type diuretic	
Chlorthalidone	25
Hydrochlorothiazide	25
Angiotensin-converting enzyme inhibitor	
Lisinopril	40
Enalapril	20 (may be in divided doses)
Angiotensin receptor blocker	
Losartan	100
Valsartan	160-320
Irbestartan	300
Candesartan	12-32
Calcium channel blocker	
Amlodipine	10
Diltiazem ER	360
Beta-Blocker	
Metoprolol	100-200 (divided doses if tartrate)
Atenolol	100

*Adapted from JNC8.

Appendix D. Sample medication titration for blood pressure above goal.




BP >160/100, consider maximizing lisinopril (40mg) + diuretic (25mg)
Initiate diuretic 12.5mg or lisinopril 10mg whichever client is currently not being used
BP >140/90†
BP >160/100, consider initiating amlodipine 5mg (may titrate to 10mg)
Increase second medication (e.g. lisinopril 20 or 40mg + diuretic 25mg)
BP >140/90†
Initiate amlodipine 5mg (may titrate to 10mg) ‡
BP >140/90, consult with PCP and assess add-on therapy
*If client develops a cough or intolerant to ACE-I consider substitute with ARB.
†Client adherence to medication will be assessed at all follow-up appointments.
‡May use diltiazem ER.

Appendix C

JORDAN VALLEY
COMMUNITY HEALTH CENTER

Clinical Pharmacist Diabetes Protocol

Policy Statement:

Jordan Valley Community Health Center (JVCHC) has established procedures for follow-up diabetes monitoring appointments and titration of diabetic medications by a pharmacist.

Procedures:

1. Diabetes Management Follow-up
    - When patient's HbA1c is >9% or the patient is newly diagnosed, the primary care provider (PCP) shall have the patient return to clinic within 4 weeks for a pharmacy visit for diabetes management. A PCP may refer other patients with diabetes at their discretion.
    - A referral to the pharmacist for follow-up will serve as the prescription order for Medication Therapy Services (MTS).
        - The pharmacist will document the prescription order for medication therapy services in the electronic medical record (EMR) per Appendix A.
2. Pharmacist will educate patient on pathophysiology of diabetes and importance of medication adherence.
3. Pharmacist will obtain diet, exercise, and social history and set self-management goals as needed.
    - Patient will be referred to the dietician as needed.
4. Pharmacist will ensure appropriate labs have been obtained (e.g., SCr, HbA1c, UACR)
5. Pharmacist will verify patient's medication allergies and current medication list at each visit.
6. Pharmacist will review diabetes Standards of Care with the patient.
    - Recommended vaccines
        - Annual flu vaccine
        - Hepatitis B vaccine series
        - Pneumococcal vaccine
            - PPSV23 for all patients <65 years old
            - PCV13 followed by PPSV23 for all patients ≥65 years old
    - Regular specialty visits
        - Annual foot exam and daily self foot assessment
        - Annual dilated eye exam
        - Dental exam every 6 months
    - Controlled blood pressure (<140/90)
        - Recommended ACE inhibitor or ARB unless patient is pregnant
    - Regular lipid monitoring and treatment as needed
        - If patient is 40-75 years old, patient should be on a moderate to high intensity statin based on ASCVD risk unless patient is pregnant
        - If patient is <40 or >75 years old, patient's ASCVD risk should be assessed to determine appropriate treatment
        - If patient is not indicated for a statin, fasting lipid panel every 5 years

- Recommended anti-platelet therapy
    - Patient's with a 10-year cardiovascular risk >10% shall take aspirin 81 mg daily unless contraindicated
        - Patients ≥50 years old with one additional risk factor (family history of premature ASCVD, hypertension, smoking, dyslipidemia, albuminuria)

7. Pharmacist will review HbA1c and SMBG readings
    - HbA1c and blood glucose goals set by PCP will be followed.
    - If the PCP does not specify a patient-specific goal, the following ADA goals will be used:

	HbA1C	Fasting/Pre-Prandial Glucose	Post-Prandial Glucose
Nonpregnant adults	<7%	80-130 mg/dL	<180 mg/dL
Pregnant adults	<6.5%	≤90 mg/dL	1 hr ≤130-140 mg/dL 2 hr ≤120 mg/dL
Gestational diabetes		≤95 mg/dL	1 hr ≤140 mg/dL 2 hr ≤120 mg/dL
Adult patients with history of severe hypoglycemia, advanced microvascular or macrovascular complications, or limited life expectancy	<8%	80-150 mg/dL	<200 mg/dL

8. If patient's SMBG readings are at goal during follow-up appointment:
    - No medication changes will be made.
    - Patient shall have HbA1C rechecked in 3 months from last check, may extend to 6 months if last HbA1c was at goal.
    - Nurse or pharmacist may refill medications per medication refill protocol.
    - Patient will follow up with pharmacist and PCP as needed.
    - Pharmacist will task PCP with appointment documentation.
9. If patient's SMBG readings are not at goal during follow-up appointment:
    - Pharmacist will assess patient's adherence.
        - May contact patient's pharmacy as needed
    - Pharmacist will use clinical judgement to adjust medications per Appendix B, C, D, and E.
    - Patients will be scheduled for another diabetes management follow-up within 2-4 weeks.
    - Pharmacist will task PCP with appointment documentation.
10. During subsequent diabetes management appointments, the pharmacist will follow the above procedures.
11. If the patient's HbA1C or blood glucose are still not at goal after several appointments with no identifiable causes:
    - In-depth consult with PCP to determine appropriate add-on therapy based on patient-specific factors.
12. If a patient no shows to their pharmacy appointment:
    - If the patient no shows or cancels a pharmacy appointment, the pharmacist will attempt to reach the patient via telephone to reschedule appointment.
    - In the even the pharmacist is unable to contact the patient after three (3) attempts and a mailed letter, the PCP will be notified.

Appendix A. Pharmacy EMR Template: Prescription Order for Diabetes Medication Therapy Services

I. A referral to the pharmacist for diabetes management follow-up will serve as the prescription order from the provider unless otherwise noted by the provider. The prescription will be valid for 1 year from the date of referral.
II. The pharmacist will document the prescription order as the first chief complaint of patient's first pharmacy visit as: **MTS Prescription Order**.
    a. The MTS prescription order will be renewed and documented in the EMR on an annual basis as needed per the provider.
III. The format for the MTS Prescription Order will be as follows:

    Patient's name:
    Patient's address:
    Patient's DOB:
    Date of prescription order:
    Clinical indication: diabetes
    Authorizing physician:
    Physician's address:

Appendix B. Consideration in selecting diabetic medications

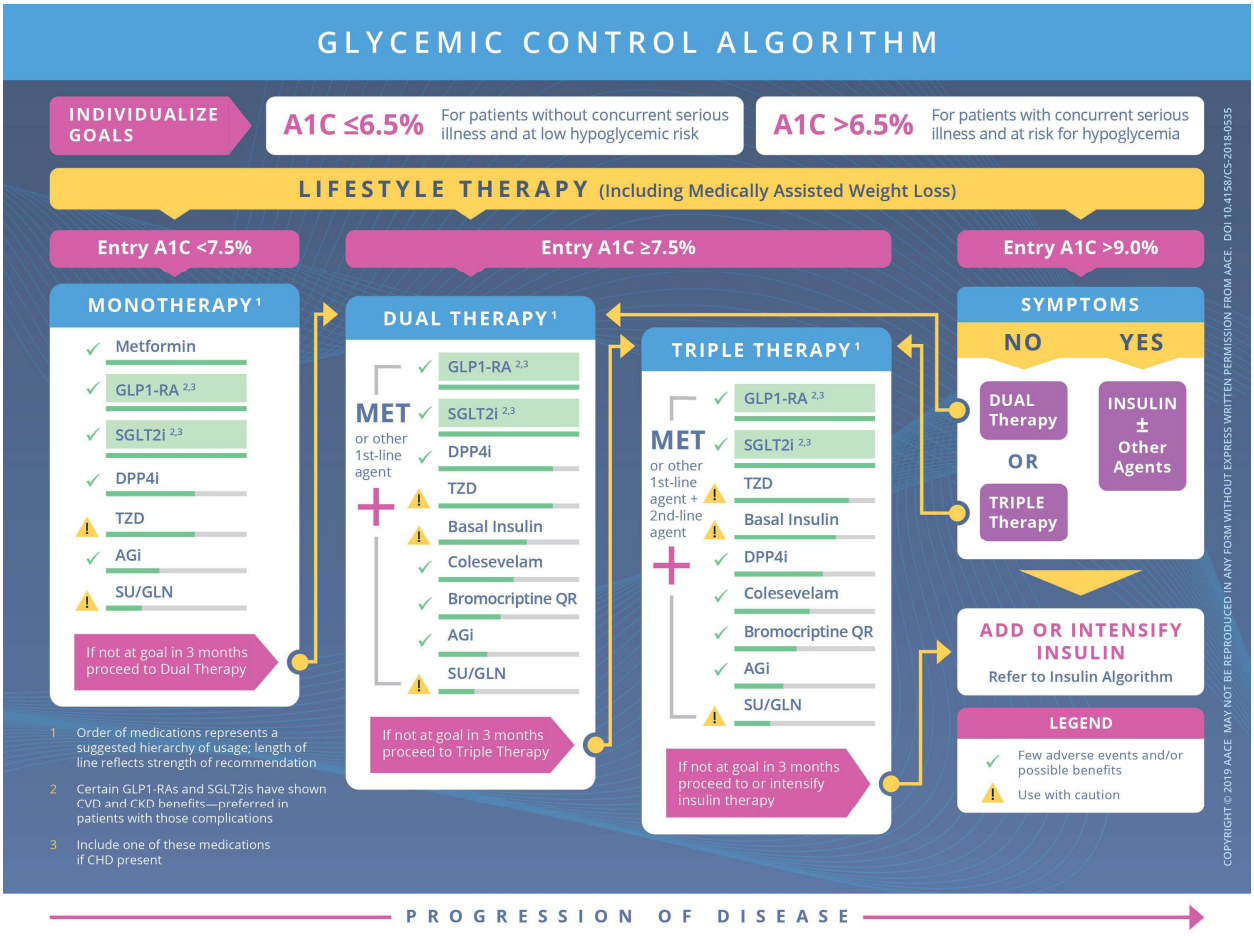
Medication Category	Ideal Patients	Considerations	Cautioned Use	Contraindicated
Biguanide*	All type 2 DM without significant renal impairment	Weight neutral, GI upset, lactic acidosis, B12 deficiency	eGRF 30-45 mL/min, hepatic impairment	Hypersensitivity, eGFR<30 mL/min, contrast media
Sulfonylureas (SU)	Type 2 DM with elevated PPG	Weight gain, hypoglycemia	Renal impairment	Hypersensitivity, severe hepatic impairment
Thiazolidinediones (TZD)	Type 2 DM contraindicated or intolerance to metformin	Weight gain, edema	h/o bladder cancer, fracture risk	Hypersensitivity, HF
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	Type 2 DM with high risk for hypoglycemia	Weight neutral, pancreatitis, joint pain	Renal impairment (except linagliptin)	Hypersensitivity
Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors	Type 2 DM with uncontrolled HTN or overweight	Weight loss, UTI, mycosis, dehydration	Renal impairment, osteoporosis	Hypersensitivity, eGFR<30 mL/min, severe hepatic impairment
Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists	Type 2 DM with high risk for hypoglycemia or overweight	Weight loss, GI upset, injection, pancreatitis	Renal impairment (exenatide)	Hypersensitivity, medullary thyroid carcinoma, multiple endocrine neoplasia syndrome type 2
Insulin	Type 1 & 2 DM	Weight gain, injection, hypoglycemia		Hypersensitivity

*Recommended first-line therapy per ADA.

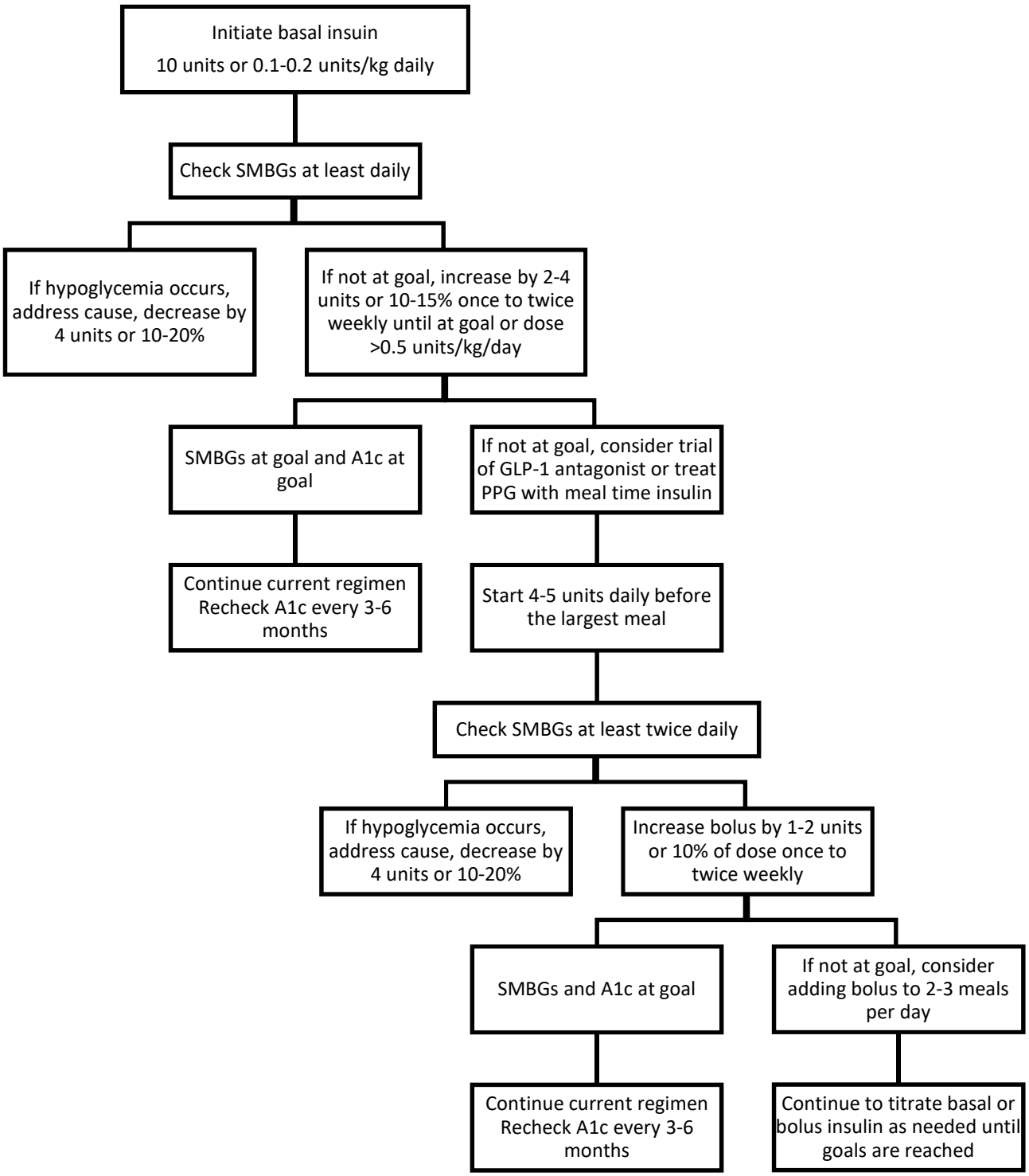
Appendix C. Evidence-based dosing of type 2 diabetes medications.

Antidiabetic Medication	Initial Daily Dose	Max Daily Dose
Biguanide		
Metformin	500 mg	1000 mg BID
Metformin ER	500 mg	2000 mg
Sulfonylurea		
Glimepiride	1-2 mg	8 mg
Glipizide	5 mg	20 mg BID
Glipizide ER	5 mg	20 mg
Glyburide	2.5-5 mg	10 mg BID
Glyburide micronized	1.5-3 mg	12 mg
Thiazolidinedione		
Pioglitazone	15-30 mg	45 mg
Rosiglitazone	4 mg	4 mg BID
DPP-4 Inhibitor		
Linagliptin	5 mg	5 mg
Saxagliptin	2.5-5 mg	2.5-5 mg
Sitagliptin	100 mg	100 mg
Alogliptin	25 mg	25 mg
SGLT2 Inhibitor		
Canagliflozin	100 mg	300 mg
Dapagliflozin	5 mg	10 mg
Empagliflozin	10 mg	25 mg
GLP1 Agonist		
Dulaglutide	0.75 mg weekly	1.5 mg weekly
Exenatide	5 mcg BID	10 mcg BID
Exenatide ER	2 mg weekly	2 mg weekly
Liraglutide	0.6 mg	1.8 mg
Semaglutide	0.5 mg weekly	1.5 mg weekly

Appendix D. Sample medication titration for uncontrolled diabetes.



Appendix E. Sample insulin titration for uncontrolled type 2 diabetes.



Appendix D

Manual Blood Pressure Instructions

1. Place the bottom edge of the deflated blood pressure (BP) cuff 1 inch above the antecubital space with the center of the cuff bladder over the medial surface of the arm.
2. The width of the inflatable bladder of the BP cuff should be 40% of the circumference of the mid-point of the upper arm.
3. Position the arm so that it is relaxed and supported at the level of the heart.
4. In the seated position, legs should be flat on the ground and uncrossed.
5. Use the bell of the stethoscope, rather than the diaphragm (manual BP only), over the brachial artery area with no clothing or dressings touching the device.
6. Eyes should be level with the meniscus of a mercury manometer or centered in front of the gauge of an aneroid when reading pressures (manual BP only).
7. With the stethoscope in place, increase the pressure in the cuff to 30 mm Hg beyond the point where the radial artery pulse is no longer palpable (manual BP only).
8. Decrease the pressure in the BP cuff slowly (rate of 2 to 3 mm Hg/sec) (manual BP only).
9. Systolic BP is the point at which the initial tapping of the Korotkoff sounds are auscultated and diastolic BP is the point when there is a sudden muffling of the Korotkoff sounds (manual BP only).

(Pickering et al., 2005)

Appendix E

Email Correspondence with Permission for use of ARMS-7

ARMS-7.docARMS.DOC
58 KB 28 KB

Traci,
Thanks for your interest in the ARMS. You are welcome to use it in your work, with proper citation. There is no cost for use or more formal licensing process. Attached are the full instrument and a shorter version which I more often use, which correlates highly with the original and saves a little time.
Best,
Sunil

From: Garrison, Traci A [mailto:TraciGarrison@MissouriState.edu]
Sent: Wednesday, January 10, 2018 11:12 AM
To: Kripalani, Sunil
Subject: Use of Adherence to Refills and Medications Scale

Dear Dr. Kripalani,

I hope this finds you having an excellent start to your semester. I am an occupational therapist working on my Doctor of Health Science degree at the University of Indianapolis. I am hoping to complete my doctoral research on whether a client-centered occupational therapy intervention can influence medication adherence in a client population with hypertension. I have read about the ARMS and am contacting you in regards to using it in my research. I will be working directly with a clinical pharmacist. We will be specifically looking at whether an in-home OT assessment and intervention that addresses medication management can improve adherence as compared to the intervention provided by the clinical pharmacist alone. We believe the ARMS is well-suited for this study due to its brevity and ability to provide information about both medication-taking behaviors and barriers to adherence. I would love to speak to you or communicate via e-mail about the proper use of the ARMS in this research. Please contact me by any of the means listed below regarding questions, concerns, and your availability to discuss the ARMS. I greatly appreciate your time.

Kindest regards,

Traci Garrison, MSOT, OTR/L

Appendix F

SINGLE-ITEM STAGE OF CHANGE MEASURE

Directions: People sometimes find it difficult to take their medication as directed by their physician. As directed means consistently taking the amount of medication prescribed by your physician at the time(s) prescribed by your physician. Please find the statement that best describes the way you feel right now about taking your medication as directed.

A. I do not take and right now I am not considering taking my medication as directed,
B. I do not take but right now I am considering taking my medication as directed.
C. I do not take but I am planning to start taking my medication as directed,
D. Right now, I consistently take my medication as directed, however, I have been doing so for less than six months.
E. Right now, I consistently take my medication as directed and I have been doing so at least six months.