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DEVELOPMENT AND TESTING OF AN OCCUPATIONAL THERAPY INTERVENTION TO PROMOTE MEDICATION ADHERENCE

by

Jaclyn Schwartz

A Dissertation Submitted in

Partial Fulfillment of the

Requirements for the Degree of

Doctor of Philosophy in Health Sciences

at

The University of Wisconsin-Milwaukee

May 2015

ABSTRACT

DEVELOPMENT AND TESTING OF AN OCCUPATIONAL THERAPY INTERVENTION TO PROMOTE MEDICATION ADHERENCE by

Jaclyn Schwartz

The University of Wisconsin-Milwaukee, 2015 Under the Supervision of Professor Roger O. Smith

Many persons with chronic health conditions fail to take their medications as prescribed, resulting in declines in health and function. Unfortunately, current interventions for medication nonadherence are not very effective. Medication adherence is a daily activity, which many occupational therapists believe would be responsive to occupational therapy intervention. Unfortunately, few resources support occupational therapists in this role. The purpose of this dissertation is to create the foundational work for occupational therapy medication adherence interventions. In this dissertation, I accomplish five objectives. First, I identify the role of occupational therapy practitioners in the medication adherence field. Second, I create a manualized occupational therapy intervention for medication adherence named the Integrative Medication Self-Management Intervention (or IMedS). Third, I develop a training program to teach the IMedS intervention to entrylevel practitioners. Fourth, I investigate the preliminary effectiveness of this intervention in a small two-group experimental blind pre-post randomized controlled trial. Finally, I explore the feasibility of continued research for the IMedS intervention. Findings from this study support occupational therapy's role in medication adherence intervention and future research in this area.

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I dedicate this project to the memory of David B. Gray, PhD. He taught me what it meant to be an occupational therapist and how to support the rights and lives of persons with disabilities.

Finally, I would like to thank my husband for his support throughout the doctoral process.

Chapter 1 - Introduction

This dissertation is submitted for the degree of Doctor of Philosophy at the University of Wisconsin – Milwaukee. The research described in this dissertation was conducted under the supervision of Professor Roger O. Smith in the Department of Occupational Science and Technology in the College of Health Sciences between August 2012 and May 2015. In this dissertation, I describe my work on the development and testing of an occupational therapy intervention to promote medication adherence for persons with chronic health conditions. I wrote the dissertation using the journal article methodology, so it consists of an introduction, six articles, and a conclusion. Each chapter is designed to stand-alone and has been written to meet the submission requirements for a peer-reviewed journal. In this introduction, I describe the audience for the work, the development of the research question, and the six different (yet related) manuscript chapters.

Target Audience

Occupational therapy practitioners and researchers are the target audience for this work, but this dissertation may be of interest to a variety of professionals within health and human services. Clinicians such as physicians, nurses, physician assistants, psychiatrists, psychologists, social workers, physical therapists, and speech-language pathologists may learn specific techniques for counseling clients on adherence.

Administrators, payors, and policy makers may be interested to learn about the needs around medication adherence in addition to the potential savings of adherence services.

Researchers across health professions can learn about the scientific process of improving and measuring medication adherence. Finally, health care users can reflect upon the their ability to manage medications and improve their own health and functional outcomes.

Developing the Research Question

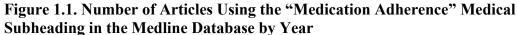
In February 2011, I became a registered and licensed occupational therapist. I plunged into a career at Barnes-Jewish Hospital, a 1,315 bed acute care hospital (Barnes-Jewish Hospital, 2013). Rehabilitation staff worked across hospital units, but my main assignment was on the cardiac medicine and cardiac surgery units. The focus of my position was to facilitate discharge planning. Constantly, I assessed endurance, functional mobility, toilet transfers, and the ability to perform other activities of daily living. One-by-one my clients would all discharge, but over time many would return. Why? Clients failed to take their medications. Their poor adherence resulted in worsening heart disease and frequent hospital readmissions. Eventually, I realized that endurance and toilet transfers were the least of my clients' worries. To truly help my clients' transition home, I needed to focus on medication adherence.

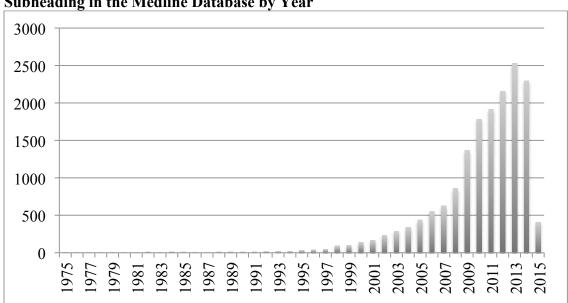
To address the gap between clients' needs and current practice, I looked to the evidence and served on hospital committees to improve the standard of care at my facility. I quickly learned, however, that there was little information available to guide occupational therapists in addressing medication management. While the rehabilitation team was able to improve standard practice at our hospital, I was not satisfied with the scope of change. Frustrated by my lack of impact, I decided to return to school to develop a career in research to better enable occupational therapy practitioners to address the needs of persons with heart disease and other chronic health conditions.

Generating Specific Aims

I wanted to focus my dissertation on a medication management intervention for persons with chronic health conditions. Four points struck me in my initial review of the literature:

1. Medication adherence is well studied (Figure 1.1).





- Medication nonadherence is a public health crisis resulting in declines to the health and function of millions of persons with chronic health conditions (Centers for Disease Control and Prevention, 2013; Krueger, Berger, & Felkey, 2005; Osterberg & Blaschke, 2005).
- 3. Current interventions for medication nonadherence are not very effective (Nieuwlaat et al., 2014).
- Little research supports occupational therapy practitioners in medication adherence evaluation or intervention (Radomski, 2011; Sanders & Van Oss, 2013).

My goal was to enable occupational therapy practitioners with the skills needed to better promote medication adherence. Given the current state of the research, however, I knew I would have to start my investigation with the basics – a phase-one study. Phase-one testing identifies the intervention and then evaluates components for acceptability, feasibility, and safety (Gitlin, 2013). Therefore, in my dissertation I sought to describe the role of the occupational therapy practitioner in promoting medication adherence, develop a new intervention targeted to an occupational therapist's skill set, and then test the intervention. With the guidance of the dissertation committee, I established three specific aims and five research questions to guide my research process (Figure 1.2).

Figure 1.2. Specific Aims

Specific Aim 1: Complete the development of the manual for the Integrative Medication Self-Management Intervention (IMedS).

Specific Aim 2: Understand the feasibility of implementing the IMedS Intervention.

Research Question 1: Who, why, and to what extent are persons with chronic health conditions a) enrolled into the study b) rejected from the study, or c) unable to complete the study?

Research Question 2: Do occupational therapy implementers report high satisfaction and ease of implementation with the intervention? Why or why not?

Research Question 3: To what extent do the occupational therapy implementers deliver the protocols with good fidelity?

Specific Aim 3: Determine if the IMedS intervention is effective.

Research Question 4: Do participants who receive the IMedS intervention demonstrate improvements in health and function?

Research Question 5: How and to what extent do clients feel like they benefit from the intervention? Why or why not?

Setting the Stage

Each chapter of the dissertation answers a series of specific aims and research questions. In this section, I will describe the different chapters of the dissertation and how they come together to meet the specific aims. Figure 1.3 illustrates the relationship between specific aims, research questions, and chapters.

Chapter 1 Specific Aim 1 Introduction Chapter 2 Specific Aim 2 Background Chapter 3 Research Intervention Question 1 Development Chapter 4 Research Student Question 2 Training Research Chapter 5 Question 3 Single-Subject Chapter 6 Specific Aim 3 Qualitative Research Chapter 7 Question 4 Feasibility Research Chapter 8 Question 5 Conclusion

Figure 1.3. Specific Aims Addressed by Dissertation Chapter

Chapter 2: The Importance of Medication Management as a Core Intervention

Chapter 2 is the literature review and background of the dissertation. In this chapter, I define key terms, identify the scope of the problem, and make an evidence-based argument for the role of occupational therapy in promoting medication adherence.

This chapter does not directly address any of the specific aims or research questions, but provides foundational knowledge for the dissertation.

Chapter 3: Development of a Novel Occupational Therapy Intervention for Promoting Medication Adherence

Chapter 3 describes how I developed the Integrative Medication Self-Management (IMedS) intervention. To develop IMedS, I reviewed theory, literature, and current practice among occupational therapists. I then synthesized an intervention manual, leveraging the strongest components of each. Chapter 3 describes the foundation of the intervention and provides a brief discussion of the intervention process. This chapter meets the objectives defined in Specific Aim 1.

Chapter 4: A Win-Win: Benefits to Student Engagement in Intervention Research

After developing the IMedS intervention, I trained a group of students to implement the intervention with research participants. Chapter 4 describes the student research assistant's training process, learning outcomes, and their fidelity and reliability to the study procedures. The data in Chapter 4 meet the objectives defined in Specific Aim 2 and Research Question 2.

Chapter 5: Single-Subject Analysis of an Occupational Therapy Intervention for Medication Nonadherence

Chapter 5 is the first chapter describing the intervention and it's effectiveness.

Research assistants implemented the IMedS intervention with approximately 20 persons with chronic health conditions. Chapter 5 describes the methodology of the two-group experimental random-assignment blinded randomized controlled trial and the results

stemming from the single-subject medication adherence data. The information in Chapter 5 meets the objectives defined in Specific Aim 3 and Research Question 4.

Chapter 6: Developing Real and Meaningful Change in Medication Adherence

Chapter 6 also describes the intervention's effectiveness, but from a qualitative perspective. In this chapter, I explore the participants' perceived changes after intervention and attempt to discover what components of the intervention were most effective. The information in Chapter 6 meets the objectives defined in Specific Aim 3 and Research Question 5.

Chapter 7: Feasibility Analysis of an Occupational Therapy Intervention to Promote Medication Adherence

The purpose of this dissertation was to achieve the phase-one goals of feasibility testing. In Chapter 7, I analyze the feasibility of the intervention, study methodology, and outcomes. I determine if further research is warranted and what changes are needed for future work. The information in Chapter 7 meets the objectives defined in Specific Aim 2, Research Question 1, Research Question 2, and Research Question 4.

Conclusion

At the conclusion of this dissertation, I was able to meet all of the objectives defined in my Specific Aims and Research Questions. I conducted a series of studies measuring the experiences of researchers, occupational therapy practitioners, occupational therapy student research assistants, and persons with chronic health conditions. In the conclusion for the dissertation, I provide an analysis across dissertation

chapters and study populations. Further, I identify my next steps in the study of my personal research trajectory.

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Chapter 2 - The Importance of Medication Management as a Core Intervention

Abstract

Adults and children with chronic health conditions often take medications to manage their health. Unfortunately, about 50% the people in the U.S. do not take their medications as prescribed, resulting in poorer health outcomes, disability, institutionalization, and even death (DiMatteo, Giordani, Lepper, & Croghan, 2002; Sokol, McGuigan, Verbrugge, & Epstein, 2005). Occupational therapy practitioners are positioned to help their clients better take their prescribed medication regimes by addressing medication management. In this article, we review medication nonadherence, discuss current practice, argue for more occupational therapy involvement on the medication team, and discuss strategies to facilitate change.

Keywords: Medication Adherence, Occupational Therapy, Chronic Disease, Practice Patterns

Occupational therapy practitioners enable clients to succeed in everyday life activities. During occupational therapy, clients and therapists work in a partnership to develop the plan of care. Often, the plan of care is based on a client's goals and is supported by the therapist's expertise. As a client's everyday life is filled with hundreds of tasks, the client and therapist must identify the most important life activities to address. In this *Issue Is*, we argue that medication management is one primary self-care activity too often omitted from care plans. Medication management should more frequently be incorporated into practice. Following a brief overview of medication management and current practice, we explain four reasons why medication management is an essential service and provide recommendations to better address medication management in training, practice, and research.

What is Medication Management?

Medication management is a complex daily living activity. To manage one medication, a client must negotiate with the doctor, fill (and refill) the prescription, interpret complicated health information, and take the medication on a daily basis. Considering that most Americans receiving prescriptions manage an average of four medications at a time from two or more prescribing physicians, the complexities of medication adherence can increase tenfold (Stagnitti, 2009; Wilson et al., 2007). The many factors affecting performance are well documented. An inclusive list of factors can be found in Table 2.1. Given the complexity of medication management, it is not surprising that only about half of adults and children take their medications as prescribed (Osterberg & Blaschke, 2005; Vlasnik et al., 2005).

Table 2.1. Factors Found in the Literature to Affect Medication Adherence

| Person | Medication Task | Environment |
|--|---|--|
| Health Literacy¹ Cognition and Memory^{1,2} Anger/ Denial¹ Comorbid conditions^{1,2} Stress¹ Fear of Side Effects 1,2 Body structures and functions¹ Understanding the need for medications¹ Illiteracy 1,2 Personal beliefs about medications² Age² Level of disability² Symptom Severity^{1,2} Rate of disease progression² Motivation² Self Efficacy² | Frequency of medication regimen changes^{1,2} Side Effects ^{1,2} Complexity of managing refills¹ Effectiveness of medication² Treatment duration² Immediacy of symptoms and side effects² | Client Environment Social support 1,2 Socioeconomic status² Cultural beliefs² Access to transportation² Access to medical care² Health Care Environment Number of perscribers¹ Provider knowledge on chronic disease management² Patient-provider relationship² Limited provider incentives for good client performance² Availability of community services² Short provider/client consultation times² |
| | | |

Note. 1 = Vlasnik, Aliotta, & DeLor, 2005, 2= WHO, 2003.

Clients who do not take their medications as prescribed are termed nonadherent. The World Health Organization (WHO) (2003) defines medication adherence as "the extent to which a person's behavior—taking medication ...corresponds with the agreed recommendations from a healthcare provider" (p. 2). Nonadherence can be unintentional or intentional. Unintentional nonadherence means that the client simply forgets or does not understand how to correctly take his or her medications. Intentional nonadherence, however, indicates that the client purposefully does not take his or her medication.

Intentional nonadherence may be due to barriers like negative side effects or the inability

to afford medications. This article addresses nonadherence occurring from both intentional and unintentional causes.

No matter the reason for nonadherence, those who do not take their medications as prescribed often experience negative consequences. Researchers estimate that clients must take about 80% or more of their medication to receive the benefits (Osterberg & Blaschke, 2005). With only a few missed doses, clients are at risk for worse health outcomes, hospitalization, and even death (DiMatteo et al., 2002; Schoen, DiDomenico, Connor, Dischler, & Bauman, 2001). The issue is so prevalent that hospitalizations and emergency room visits due to medication nonadherence alone are estimated to cost \$100 billion yearly (Lewis, 1997). Poor medication adherence hinders health and functioning while also increasing healthcare spending.

Occupational Therapy's Role and Responsibility in Promoting Medication Adherence

Poor medication adherence may have dire consequences, but occupational therapy services have the potential to help clients improve their medication adherence.

Medication management as an occupational therapy intervention can be found in one of the profession's earliest scope of practice, *Uniform Terminology* (American Occupational Therapy Association [AOTA], 1979). Even today, medication management is considered a health management and maintenance instrumental activity of daily living (IADL) and continues to be listed in the third edition of the *Occupational Therapy Practice*Framework (AOTA, 2014).

Core occupational therapy evaluation and intervention skills around self-care, including medication management, are already embedded in foundational training and

practice abilities. Nieuwlaat et al. (2014), in their Cochrane Review, found that education, counseling, training in self-management, assistive technology, behavior change, and group therapy were some of the most widely studied interventions for medication adherence. Occupational therapy practitioners already have the knowledge and skills to implement, not some but all of these approaches. Occupational therapists are well versed in basic anatomy and physiology, chronic health conditions, therapeutic communication, disease management, caregiver training, strategies for behavior change, and other skills needed to counsel clients on improving their medication adherence (Accreditation Council for Occupational Therapy Education, 2013). Occupational therapists have the strong foundational skills necessary to play an influential role on the medications team.

Current Practice in Medication Management

Despite the importance of medication adherence and the potential for occupational therapy intervention, few occupational therapy practitioners seem to be engaged in research and practice in this area. For example, a PubMed search using the terms "medication" or "medications" in the title or abstract of articles published in the *American Journal of Occupational Therapy*, results in found 17 articles. Of those 17 articles, 14 discussed medications as a small component of a larger study on another topic (Andiel & Liu, 1995; Chase, Mann, Wasek, & Arbesman, 2012; Cohen, 1994; Foster, 2014; Kimball, 1986; Kleinman & Stalcup, 1991; Leland, Elliott, O'Malley, & Murphy, 2012; Lowman et al., 1999; MacRae, 1997; Mann, Hurren, & Tomita, 1995; Morris, 1991; Pan & Fisher, 1994; Petersen & Wikoff, 1983; Thibeault & Blackmer, 1987). One article discussed medication management evaluation, while two reported on intervention

strategies (Baum et al., 2008; Sanders & Van Oss, 2013; Yuen, 1993). Even when considering other articles not specific to medication, such as those on self-management, that relate to medication adherence (Arbesman & Mosley, 2012; Pyatak, 2011), there is little literature in academic journals supporting practitioners in the evaluation and intervention of medication management across settings and populations. Congruently, the profession's core textbooks offer limited coverage of medication adherence (Pendleton & Schultz-Krohn, 2013; Radomski & Trombly Latham, 2008). Overall, the occupational therapy professional literature reveals little discussion of medication management.

To further investigate this trend, we recently conducted a national survey on a purposeful group of 70 occupational therapists regarding their use of medication management intervention and evaluation (Schwartz & Smith, 2014). We found that only about a quarter of occupational therapists working in adult physical dysfunction settings consistently evaluate and/or treat for medication management impairments. Persons who do not engage in medication management identified a "lack of knowledge," "lack of interest," lack of resources, and "time constraints" as barriers to addressing this area. There was also a small (but consistent) group of practitioners who responded that they "don't feel this is in [their] scope of practice," that medications are the "nurse's job," or that it is "not an issue" for their clients. Among the surveyed therapists who did address medication management, strategies varied greatly, even among practitioners in similar practice settings. The results of this survey demonstrate little consensus on occupational therapy's role in medication adherence and suggest that occupational therapists may be overlooking this important IADL. While this is just one survey of current practice, even if it is only partially representative of the field, it is troubling. Moreover, triangulation of

data from peer-reviewed manuscripts, professional textbooks, and the practice survey reveals a disconcerting state that most occupational therapists are seemingly not engaged in medication management.

While medication adherence research and practice persists at low levels in occupational therapy, other professions are increasing their coverage of this topic. When we searched the medical subheading term "medication adherence" in the Medline database, we found 15,625 articles, with the number of citations increasing every year. Many of the articles found in this search inform occupational therapy practice in medication adherence. Despite the substantial literature base, occupational therapists do not seem to be reading or integrating these materials into their practice. In the remainder of this paper, we articulate the importance medication management in occupational therapy practice and describe some profession-wide changes needed to support these advancements.

Reasons for Emphasizing Medication Management in Practice

Medication management is like many activities listed in the *Practice Framework* that are addressed infrequently in practice. Four points, however, affirm the current need to increase emphasis: 1) medication management is important to many of the special populations served by occupational therapists, 2) medication nonadherence will continue to grow, 3) occupational therapists can provide distinct value to the medication team, and 4) medication management services are consistent with the profession's emerging roles associated with health care reform.

Relevance of Medication Adherence to Special Populations

Medication management should be emphasized in practice because it is a service with significant demand across occupational therapy clients. In the *Centennial Vision*, the profession has committed to meeting society's needs (AOTA, 2007). The research identifies several populations as critically needing medication adherence interventions, including older adults, persons with mental illness, and children.

Geriatrics. The National Center for Health Statistics (NCHS) (2014) reports that 90% of older adults (>65 years) were on at least one prescription medication with 39.7% using five or more medications (NCHS, 2014). Older adults are not only burdened by polypharmacy, but they are increasingly being asked to manage a complicated set of medications concurrent to changes in vision, cognition, and strength associated with aging (NCHS, 2014).

Mental health. In mental health, about 85% of individuals use prescription medications to manage their condition (Substance Abuse and Mental Health Services Administration, 2012). Nonadherence in persons with mental illness results in further negative consequences including more frequent and intense relapses, increased risk of medication dependence, and rebound effects (Velligan et al., 2009; WHO, 2003).

Pediatrics. Children (and their families) experience more medication nonadherence than one might predict. Twenty-five percent of children and adolescents take medications, half of whom are nonadherent (Mathews, 2010; Boyse, Boujaoude, & Laundy, 2012; NCHS, 2014). Poor medication adherence puts children at risk for worse health outcomes and a decline in functional abilities, affecting performance in the home and school environments (Chacko, Newcorn, Feirsen, & Uderman, 2010).

Expanding Need

Second, medication management should be emphasized in practice because of the expanding need for services. Across age groups, medication use is growing. Not only are more people taking medications, but they are also taking an increasing number of prescriptions. For example, the number of persons on three or more prescription medications has increased from 11.8% in 1988 to 20.8% in 2010 (NCHS, 2014).

Distinct Value

Third, occupational therapists should elevate medication management because of the distinct values they bring to the medication team. Historically, doctors, nurses, and pharmacists are the primary interventionists for medication adherence. These professionals report that they would like to better address adherence but are burdened by limited time with the client, lack of reimbursement for medication adherence services, or little (if any) follow up communication (Ammerman et al., 1993; WHO, 2003). Doctors, nurses, and pharmacists each have a unique and essential role in the medication process, including prescribing, training, monitoring responses, filling prescriptions, and preventing medication interactions. None of these professionals, however, look at the client's ability to manage medications as a daily occupation.

Occupational therapists are uniquely suited to address a person's ability to manage their medications over the course of a lifetime because their diverse expertise complements the needs of medication adherence interventions. Occupational therapists use their knowledge of the dynamic interaction of the person, his or her engagement in occupations, and the context to design client-centered "occupation-based intervention plans that facilitate change or growth in client factors... and skills... needed for

successful participation" in everyday activities (AOTA, 2014, p. S1). Similarly, when Sanders and Van Oss (2013) conducted a task-analysis of medication management behaviors of 149 seniors, they found that habits, routines, the environment, and assistive technology were all important components contributing to a person's ability to manage his or her medications. In their multilevel interventions, occupational therapists use their expertise to prescribe assistive technology, recommend changes to the environment, and suggest changes to routines to improve occupational performance. Occupational therapists have expertise in many of the active ingredients necessary to build effective medication management interventions.

Not only do occupational therapists have the optimal knowledge and skills, they also have the logistical capacity to implement change. Nieuwalaat et al. (2014) reported that the most effective interventions for medication adherence are also characterized by frequent interactions often delivered by allied health professionals that work across diagnoses. Over 100,000 occupational therapy practitioners are employed across relevant settings and already work with the millions of adults and children with various health conditions (AOTA, 2010). Unlike other health care professionals on the medication team, the occupational therapist interacts with the client for several sessions over time, allowing the therapist and client to follow up on intervention strategies. As occupational therapy practitioners are already dedicated to improving occupational performance across daily activities, they can address adherence as a billable activity.

Health Care Reform

Finally, recent changes in health care legislation exacerbate the need for successful medication management interventions. The Affordable Care Act (ACA) aims

to improve the quality and cost of health care by encouraging changes to service delivery (ACA; Pub. L. 111-148). The ACA gives health care providers a monetary incentive to prevent hospital readmissions (Fisher & Friesema, 2013; Roberts & Robinson, 2014). While occupational therapy in primary care is still emerging, Metzler, Hartman, & Lowenthal (2012) envision primary care occupational therapy encompassing wellness, self-management, and patient education approaches — e.g. the keystones of medication management. Roberts and Robinson (2014) further the discussion by stating that occupational therapy interventions, such as self-management and medication management, can directly affect readmissions and are part of the profession's role in readmission prevention.

Recommendations for Change

Occupational therapists have the opportunity and a mandate to help clients better manage their medications. Changes are needed across education, practice, and research to help the profession realize its potential.

Practitioners have identified the lack of knowledge as a barrier to engaging in medication management; therefore, change to pre- and post-professional education is necessary to better prepare occupational therapists to evaluate and treat medication adherence impairments. Medication adherence should be discussed overtly in professional training for occupational therapy students. Practicing therapist require continuing education training to advance their skills in this area. While occupational therapists can apply general occupational therapy skills to treat this performance deficit, practitioners and students would benefit from education on basic medication terminology,

commonly prescribed medications and their side effects, and occupational therapy's scope of practice in this highly interdisciplinary field.

In the area of practice, (after competence is achieved) occupational therapists should begin to evaluate medication management and treat as appropriate. Occupational therapists can complete an eight-question screen to quickly identify clients at risk for medication nonadherence (Morisky, Ang, Krousel-Wood, & Ward, 2008). Aspects of medication management skills can be evaluated using common occupational therapy assessments such as the medication portion of the Executive Function Performance Test, the medication portion of the Cognitive Performance Test, or a myriad of other medication specific assessments found in the literature (Baum et al., 2008; Burns, Mortimer, & Merchak, 1994, Elliott & Marriott, 2009).

In terms of intervention, occupational therapy practitioners can support medication adherence in three ways. Practitioners can influence discharge recommendations by informing the medical team about a client's ability to take medications consistently over time and reporting about the impact of medications on other essentials daily living activities. Also, for clients who are eager to better take their medications, therapists may develop a system of cues, create plans for integrating medication into daily routines, oversee equipment needs, create more supportive environments, and address routines around prescription refills (Sanders & Van Oss, 2013). Lastly, for persons who are not yet ready to change, therapists can educate the client about their medication regimen and empower clients to better discuss their needs with prescribers. Preliminary support for these different approaches can be found in the

182 randomized controlled trials on interventions for medication adherence (Nieuwlaat et al., 2014).

Occupational therapy researchers can work to address the gaps in the literature. Gaps include the poor understanding of the factors affecting medication adherence, the lack of a gold standard evaluation for identifying and developing intervention ideas, and dearth of appropriate study methodology, and the absence of effective interventions (Elliott & Marriott, 2009; Nieuwlaat et al., 2014). Occupational therapy researchers should use their expertise in studying occupational performance to help move the field of medication adherence forward. Occupational therapy researchers should:

- Build off of the work completed by Sanders and Van Oss (2013) to better understand the occupation of managing a complicated medication routine.
- Develop new evaluation tools to better measure medication adherence and to guide interventions.
- Use the distinct value of the profession to conceive novel protocol-driven occupational therapy interventions for medication adherence.
- Create new rigorous research methodologies allowing scientists to study change associated with medication adherence interventions.

Charge to the Profession

The occupational therapy profession has an opportunity to enable millions of Americans to have healthy, productive lives by enhancing medication management performance and subsequent medication adherence. Occupational therapy's occupation-based, multidimensional, client-centered techniques are much-needed innovations in the field of medication adherence. Further, occupational therapists are well positioned

throughout the health care field to make a significant impact. Health care reform enables occupational therapists to effect changes in the area of medication management that demonstrate the value of occupational therapy to our clients, professional peers, and payors.

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Chapter 3 - Development of an Occupational Therapy Intervention to Promote Medication Adherence

Abstract

Medication nonadherence is a significant societal issue affecting the health and function of millions of people in the United States (Osterberg & Blaschke, 2005). Current interventions are complicated and not very effective (Nieuwlaat et al., 2014). Innovations are needed in medication adherence intervention research. The purpose of this study is to describe the development of a novel intervention for medication nonadherence. We used the approach described by Schnyer & Allen (2002) to develop a new manualized intervention based on theory, best evidence, and current practice. Our efforts resulted in the Integrative Medication Self-Management Intervention (IMedS) intervention, or a manualized occupational therapy intervention to support medication adherence in persons with chronic health conditions.

Keywords: Medication Adherence, Occupational Therapy, Research Design

In the *Centennial Vision*, the occupational therapy profession established the goals of becoming an evidence-based science-driven field where professionals work to meet society's needs (American Occupational Therapy Association [AOTA], 2007). To achieve the *Centennial Vision*, however, occupational therapists need new interventions designed to "improve health behaviors, promote healthy lifestyles, prevent disease, reduce symptoms, and promote self-management of chronic diseases and functional disability" (Gitlin, 2013, p.177). The purpose of this study is to describe the evidence-based development of a new occupational therapy self-management intervention to promote medication adherence.

Medication adherence is the extent to which a client's consumption of medications matches a healthcare providers recommendations (World Health Organization, 2003). When clients fail to take their medications as prescribed, they become at risk for poorer health outcomes, institutionalization, disability, and even death (DiMatteo, Giordani, Lepper, & Croghan, 2002; Osterberg & Blaschke, 2005; Schoen, DiDomenico, Connor, Dischler, & Bauman, 2001; Sokol, McGuigan, Verbrugge, & Epstein, 2005). Unfortunately, current interventions for medication adherence are costly, complex, and not very effective (Nieuwlaat et al., 2014). Further, researchers have difficulty determining which intervention aspects are effective due to "persistent methodological weaknesses" throughout the medication adherence research (p. 17). The field of medication adherence needs novel intervention approaches that are tested using rigorous methodologies.

Occupational therapy provides innovative solutions for medication nonadherence.

Occupational therapists are health professionals who improve performance of every day

activities (AOTA, 2014). Given the profession's proclivity for improving basic activities of daily living, occupational therapy may be an effective treatment for medication nonadherence (Doucet, Woodson, & Watford, 2014). There is limited research describing the effectiveness of occupational therapy interventions to promote medication adherence (Sanders & Van Oss, 2013). Occupational therapy may be the novel approach needed by the medication adherence field.

Investigating an occupational therapy intervention to promote medication adherence can be difficult because of practitioner's client-centered approach and diverse set of techniques. Therefore, one of the preliminary research strategies is to "manualize" the treatment. An intervention manual can provide structure to studies, ensure consistent delivery, facilitate training, and allow for replication by researchers and clinicians alike (Bellg et al., 2004; McMurran & Duggan, 2005). Manualization of an intervention creates the foundation for future research (Blanche, Fogelberg, Diaz, Carlson, & Clark, 2011). Therefore, we seek not only to develop a new intervention, but to manualize it as well.

In this paper, we discuss the science-driven development of a manualized occupational therapy intervention to promote medication adherence named the Integrative Medication Self-Management intervention or IMedS. Based off of the intervention development methods presented by Schnyer & Allen (2002) we sought to develop an intervention manual by accomplishing four objectives:

- 1) Identify the theoretical basis
- 2) Evaluate current intervention research
- 3) Survey occupational therapists to describe current practice
- 4) Interview occupational therapists to define techniques and processes

Schneyer & Allen (2002) also recommend identifying and defining techniques. We have elected to use the *Occupational Therapy Practice Framework* to achieve this objective (AOTA, 2014). In this article, we will begin by describing how we achieved each objective through their respective Purpose, Methods, and Results section. Then we will discuss how each component has contributed to the IMedS intervention.

Objective 1: Theory

Purpose

First, we sought to develop the theoretical basis of the intervention.

Interventionists use theory to identify the active ingredients and the mechanisms of change in a proposed intervention. Experts in the field make two critiques of the current literature in regard to theory (Nieuwlaat et al., 2014; Richardson et al., 2014). First, many medication adherence interventions are not theory based. Second, the interventions that are theory-based may be using incomplete theories that do not adequately address the complicated nature of adherence. The experts suggest that the lack of theory may be one of the leading causes of ineffective medication adherence interventions. By developing a sound theoretical basis, we hope to identify the active ingredients and mechanisms of change for successful intervention for medication nonadherence.

Methods

We sought to identify a group of theories that represented health behavior change, occupational therapy, and assistive technology, as all three of these components are fundamental to an occupational therapy intervention promoting medication adherence.

Therefore, we used two of the most common health behavior models (Richardson et al.,

2014), two common occupational therapy models (Lee, 2010), and the predominant assistive technology model (Lenker & Paquet, 2003). From each model, we identified key variables and mechanisms of change and then synthesized variables and mechanisms across theories to create the foundation of the IMedS intervention.

Results

We identified five models that influenced the development of the intervention. In this section, we will briefly describe each model.

- 1. Health Belief Model. The Health Belief Model (HBM) explains why people choose to engage in a health action, such as taking medication. The HBM is one of the most common theories used in medication adherence and self-management research (Richardson et al., 2014). The HBM states that when a client is making a health decision, he weighs the costs and the benefits. Specifically, clients consider their perceived susceptibility to the condition (likeliness of becoming sick or disabled), severity of the condition, benefits of the health action, barriers to the health action (e.g. cost, side-effects, etc.), and self-efficacy (person's own ability to make change) (Champion & Skinner, 2008). After the client weighs the costs and the benefits they decide whether or not to engage in a health behavior. Overall, this model emphasizes education and self-efficacy.
- 2. Transtheortical Model. The Transtheoretical Model (TM) is another common theory used in medication adherence and self-management research (Richardson et al., 2014). The TM model states that behavior change is "a process that unfolds over time" and that behavior change interventions should account for a client's readiness for change (Prochaska, Redding, & Evers, 2008, p. 100). The main idea of this theory is client-

centeredness, or that for an intervention to work it must be tailored to the client's individualized needs and address his or her readiness for change.

- 3. The Model of Human Occupation. The Model of Human Occupation (MOHO) is one of the most commonly used models in occupational therapy practice (Lee, Taylor, Kielhofner, & Fisher, 2008). MOHO is an open systems model in which a person's daily occupations (i.e. taking medication) are driven by volition (the actions the client chooses to do), habituation (a client's habits and roles), and performance skills (Kielhofner, 1995). MOHO is represented as a feedback loop, indicating that current actions are based on previous experiences. This occupational therapy model suggests that performance of everyday activities can be improved by creating goals, giving feedback, and promoting adaptive routines.
- 4. Person-Environment-Occupation Model. The Person-Environment-Occupation (PEO) is another commonly used model by occupational therapists. The PEO model states that occupational performance (i.e. a person's ability to manage their medications) is the result of the dynamic interaction of the person skills, complexities of the task, and the supports or barriers present in the environment (Law et al., 1996). The main idea of this model is that occupational therapy practitioners can change the environment, the task, and the person (at the same time) to improve performance in everyday activities.
- **5. Human Activity Assistive Technology.** The Human Activity Assistive Technology (HAAT) Model is a common assistive technology model (Lenker & Paquet, 2003). The HAAT model that works to understand how assistive technology can improve the lives of people with disabilities (Cook & Polgar, 2008). The model asks users to

consider the person's skills, the activity (i.e. medication management), and the environment when prescribing assistive technology. Most importantly, the HAAT model identifies the importance of assistive technology in the performance of daily activities and provides practitioners with a framework for identifying and prescribing the best devices.

Objective 2: Current Literature

Purpose

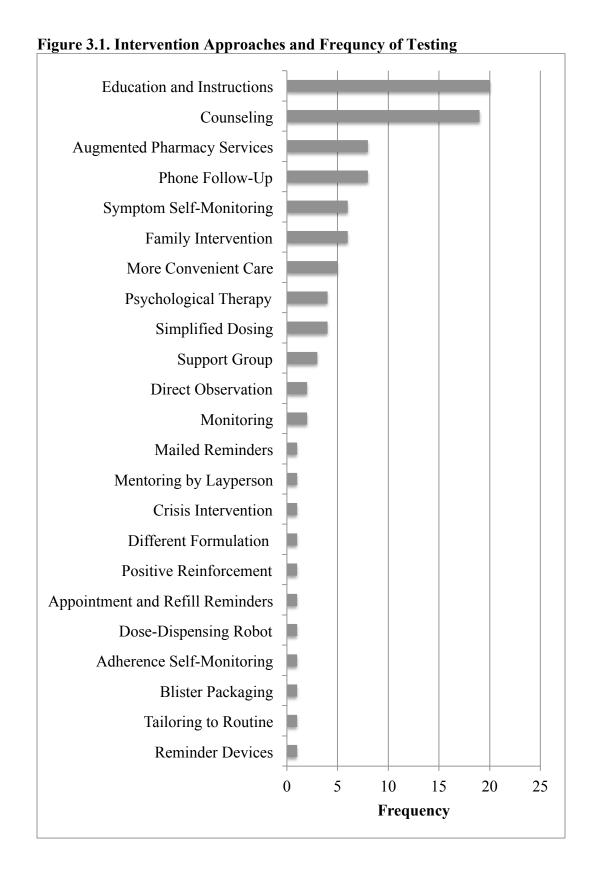
In developing the IMedS intervention we wanted to incorporate the most effective approaches from the literature. In this section, we will briefly discuss the types of interventions that have been studied in the literature and identify the most effective approaches that warrant future use.

Methods

We analyzed the 2008 Cochrane Review *Interventions for Enhancing Medication Adherence* by Haynes et al. (2008). We identified the different types of intervention approaches, frequency of testing, and effectiveness of approaches.

Results

Twenty-three different types of interventions were found in the 78 RCTs identified by Haynes et al. (2008). Interventions ranged from common interventions like education about medications or counseling about health conditions to less common approaches like crisis intervention. Eleven intervention approaches demonstrated significant effects: 1) more convenient care, 2) information, 3) reminders, 4) self-monitoring, 5) reinforcement, 6) counseling, 7) family therapy, 8) psychological therapy,



9) crisis intervention, 10) telephone follow-up, and 11) supportive care. The full list of 23 intervention approaches and frequency of testing can be seen in Figure 3.1.

Objective 3: Practice Survey

Purpose

After reviewing the theory and the research, we surveyed practitioners to better understand occupational therapy interventions for medication nonadherence. The practice survey serves two purposes. First, it allows clinicians to augment the findings from the research and theory sections (Schnyer & Allen, 2002). Clinicians can reveal different types of information such as dose, frequency, care setting, techniques, etc. Second, findings from the practice survey can improve external validity of the intervention. By better identifying practitioners needs, we can build an intervention designed for daily use in the clinic.

Methods

Recruitment. We sought to understand the experiences of a purposeful sample of occupational therapists through an online survey. To participate in this survey, individuals were required to be occupational therapists actively working in an adult physical rehabilitation setting. We sent invitations to participate to key populations through fieldwork list serves, posts on occupational therapy related social media (OT Connections and Facebook), and flyers at the 2014 AOTA Annual Conference and Exposition.

Instrumentation. The practice survey investigated clinician's demographics, medication adherence evaluation techniques, medication adherence intervention

techniques, and frequency of services. Researchers conducted the computer-assisted survey on the Qualtrics platform version 61,401 (Qualtrics, 2014). The survey ranged from 11-19 items depending on the clinician's level of engagement and took about 10 minutes to complete.

Participants began with four demographic questions. They were asked to identify their state of employment, years of experience, area of practice, and types of clients treated. Demographic questions allowed clients to select (all that apply) from a list of responses, with answer options based off recent professional surveys (AOTA, 2010a).

Next, participants described how frequently they provided medication adherence services using a five-point Likert-like scale (1=never, 2=rarely, 3=sometimes, 4=often, and 5=always). Persons engaging in medication adherence services were asked seven additional questions about the types of interventions and assessments used in practice from a checklist of commonly used evaluations (Elliott & Marriott, 2010; Farris & Phillips, 2008) and interventions (AOTA, 2014; Sanders & Van Oss, 2013) derived from the literature. Participants were asked to identify if their assessment was formal, informal, or standardized. Participants using formal assessments were asked to identify the name of the assessment from a list. In terms of intervention, participants were asked to identify what type of interventions they used based off of options from the *Occupational Therapy Practice Framework*.

Data analysis. We used descriptive statistics to define participant's demographics, frequency of services, and intervention and evaluation techniques. Data analyses were completed using IBM SPSS Statistics for Macintosh Version 21.

Results

Participants. Sixty-eight occupational therapists from across the United States and two international occupational therapists completed the web survey. Participants were mostly from the Midwest (n=44, 64%), but also represented the Northeast (n=5, 7%), Southeast (n=11, 16%), Southwest (n=4, 6%), and West (n=5, 7%). The therapists had on average 14 years of experience and reported employment across adult physical rehabilitation settings. Forty percent of participants worked in more than one setting. Within each setting, participants worked in acute care (n=31, 44%), inpatient rehabilitation (n=27, 39%), outpatient rehabilitation (n=21, 30%), and skilled nursing/sub-acute (n=14, 20%), long-term care (n=6, 9%), and home health (n=6, 7%). The participants' clientele spanned a wide range of diagnoses, including stroke and other neurological, orthopedic, cardiac, dementia, amputation, general medicine, trauma, general surgery, spinal cord injury, and oncology conditions.

Frequency of medication adherence services. Most surveyed therapists (93%) evaluate medication management, but only 35% do so regularly (i.e., often or always). Similarly, most surveyed therapists (93%) engaged in medication management interventions, but only 21% did so regularly (i.e. often or always).

Nature of evaluations. Occupational therapists used a myriad of approaches to evaluate medication management abilities. Participants were asked if they used a standardized tool, a non-standardized tool, or no tool. Thirty-percent of respondents (n=21) did not use any tool. Most participants (n=30, 43%) used a non-standardized assessment, such as activity observation or an assessment developed by their facility. Few therapists (n=12, 17%) used a standardized assessment. Assessments used in the field

included the Hopkins Medical Schedule (n=4) (Carlson, Fried, Xue, Tekwe, & Brandt, 2005), the medication portion of the Cognitive Performance Test (n=2) (Burns, Mortimer, & Merchak, 1994), the Standardized Medication Tasks (n=1) (Isaac & Tamblyn, 1993), and the Medication Management Tasks (n=1) (Beckman, Parker, & Thorslund, 2005). Participants also reported using generic assessments such as pain scales, the Montreal Cognitive Assessment (Nasreddine et al., 2005), or the Allen Cognitive Levels (Velligan et al., 1998) and applying the information to medication management.

Nature of interventions. Participants were asked to select intervention approaches (from the *Occupational Therapy Practice Framework*) that they employ when treating medication management (AOTA, 2014). Participants used a combination of occupation and activity (n=47, 67%), preparatory tasks (excluding assistive technology and environment modifications) (n=43, 61%), education (n=37, 53%), caregiver training (n=36, 51%), assistive technology (n= 25, 36%), and environmental modifications (n=8, 11%). Figure 3.2 illustrates that most therapists used a combination of approaches and that intervention use varied by practice setting.

Objective 4: Practice Interviews

Purpose

The purpose of the practice interviews was to bring together theory, evidence, and practice with clinical reasoning. In the interview, practitioners were asked to describe not

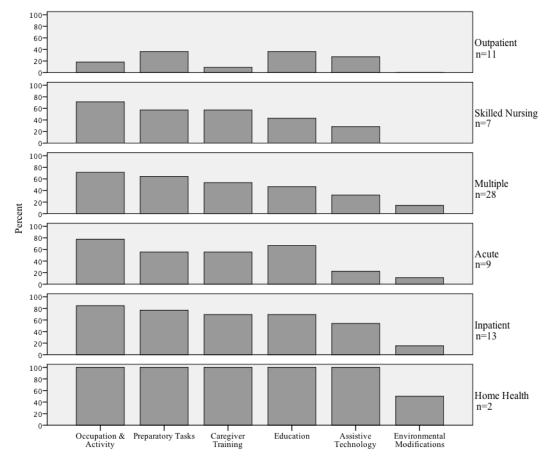


Figure 3.2. Occupational Therapy Intervention Approach By Practice Setting

only the content of a session, but also their clinical reasoning. From the practice interview, we sought to identify specific intervention and evaluation activities in addition to the clinical reasoning processes behind them.

Methods

Recruitment. We interviewed a diverse sample of occupational therapists about their medication management intervention and evaluation practices. The first author recruited participants at the 2014 AOTA Conference & Exposition. Only occupational therapists working in adult physical rehabilitation settings were eligible to participate in the interview. To identify participants, the primary author "staffed" a conference hall

lounge area and invited practitioners to participate in brief one-on-one interviews. Interested individuals were screened and (if appropriate) interviewed immediately.

Participants. Eight occupational therapists participated in the interview. Participants worked in the Northeast (n=4, 50%) (the conference location), Midwest (n=2, 25%), Southeast (n=1, 13%), and West (n=1, 13%). Interview participants had an average of 11 years practice experience, and worked across the continuum of care. The therapists worked in acute care (n=2, 25%), inpatient rehabilitation (n=2, 25%), outpatient rehabilitation (n=2, 25%), skilled nursing (n=1, 13%), and home health (n=1, 13%).

Instrumentation. The interview was 10 questions in length and required about 10 minutes to complete. The demographics section was four questions long and inquired about the therapists work location, years of experience, work setting, and patient population. Interview participants were also asked about the frequency and content of medication management services. All questions were open ended. The interviewer followed-up with probing questions such as "how did you pick that intervention approach?" or "how do you decide which of your clients needs to work on medication management?"

Data analysis. The first author recorded and transcribed all interactions. She used a mixed-methods approach to data analysis. Respondents' answers to the demographics questions, frequency of evaluation, frequency of intervention, type of evaluation, and type of intervention were tabulated and described with descriptive statistics. The first author used grounded theory to describe intervention and evaluation content (Corbin & Strauss, 2008). Participant's descriptions of practice were transcribed and then coded to

their essence. Codes were cleaned and themes emerged across participants. Dedoose 5.2.1 was used to facilitate the coding and analysis of the data (SocioCultural Research Consultants, 2015).

Results

Generally, the interview results correlated with those of the survey data in terms of practice environment, frequency of practice, and content of practice. The interview participants, however, were better able to describe their activities and their clinical reasoning.

Nature of evaluation. Most of the interviewed occupational therapists reported using either no assessment or an informal assessment of medication management. A few participants reported that they simply ask if the client is completing their own medication management and if he or she is having any difficulties. Several occupational therapists said that they either use the client's own medications or a simulated set of medications and engage in a simulated medication task. During the task, the therapist reported analyzing the task to identify possible intervention opportunities. Some participants cited standardized assessments such as the Functional Independence Measure (Keith, Granger, Hamilton, & Sherwin, 1987), the Newest Vital Sign (a health literacy assessment) (Weiss et al., 2005), a pain rating, or a functional vision screen (reading a newspaper) and using that information to deduce medication management abilities. Two interview participants (25%) reported using a standardized assessment for medication management one used the Executive Function Performance Test and the other used the Cognitive Performance Test (Baum et al., 2008; Burns et al., 1994). While the evaluation of medication management is characterized by wide variability, almost all of the interview participants verbalized the importance of understanding a client's occupational profile, medication routines, and seeing the client handle materials for task analysis.

Nature of intervention. Interview participants addressed medication nonadherence using most of the intervention approaches listed in the *Practice Framework* (AOTA, 2014). Table 3.1 lists intervention activities verbalized by the therapists.

Interview participants indicated that their interventions were multidimensional and client-centered. When asked about their clinical reasoning, the interview participants reported that they used information from the occupational profile, task analysis, trial and error, and clinical know-how to select and integrate different intervention approaches. For example, this is how one inpatient rehabilitation therapist described her medication management interventions:

"It really just depends on where the problem is, like if... they have a lot of medication, I may give them a pillbox. If it is forgetting to take their meds, we'll use some kind of alarm system or look at their routine, such as pair it with a meal or something that they always remember to do. Environmental cues, like, some of my guys will have their meds set up, but they put them in a drawer... so [we] put it out in the open where they are going see it. There are different apps... that helps them keep track and set reminders for refills....We will talk about having like a list or card of 'this is what I take' so they can give it to providers.

Intervention Logistics. We also interviewed the occupational therapists about the logistics of their evaluation and interventions. Some therapists worked in facilities with a short length of stay (2-3 days) (i.e. acute care), while other therapists had weeks to complete their intervention. Interventions were also described as short as 20 minutes but

Table 3.1. Intervention Activities Verbalized in Interview by Type of Approach

| | ivities verbanzed in interview by Type of Approach |
|-------------------------|--|
| Intervention Approach | Intervention Activities |
| Occupation and Activity | Pillbox sorting activity with simulated medications or the client's medication |
| | Worksheets requiring clients to read a medication |
| | label and answer questions |
| Preparatory Tasks | Therapeutic exercise to increase hand strength and dexterity |
| Tropulatory Tusks | Education on |
| | Client's health condition |
| | Importance of good medication adherence |
| | Risks associated with nonadherence |
| | Client's medication regimen |
| | • General health literacy (e.g. how to read a |
| | medication label) |
| Education | Polypharmacy and it's risks and symptoms |
| | Prescription of |
| | Pillboxes of various shapes and sizes |
| | • Alarms |
| | Smartphone Apps to function as reminders, pill |
| | identifiers, request refills, and to attain information |
| | about medications |
| | Magnifying glasses |
| | Braille or other tactile cues |
| Assistive Technology | Large print medication labels |
| | Moving medication to a more visible location |
| | Move medications to locations associated with a |
| | routine (e.g. by a toothbrush) |
| Change to the | • Lighting interventions to increase light and decrease |
| Environment | glare (e.g. moving lamps) |
| | Encouraged clients to discuss their medication |
| | concerns with their physicians and pharmacists. |
| A dynagayy | Developed medication lists to share with different dectors |
| Advocacy | doctors. |
| Caragiyar Training | Compensating for client if he or she is unable to appropriate tooks. |
| Caregiver Training | complete tasks. |
| Group Interventions | No therapists described group interventions. |

as long as 60 minutes. Most of the interview participants (n=7, 88%) were clinic based, meaning they had to rely on the client and his or her family to bring in materials as needed and to ensure strategies transition to the home environment.

Discussion

The purpose of this project was to develop a new occupational therapy intervention for medication nonadherence. We reviewed theory, best-evidence, and current practice to identify the important variables and mechanisms for change. Findings from the theory, research, and practice objectives shaped the development of the IMedS intervention (Figure 3.3).

Objective 1: Theory

By reviewing theory we were able to identify the important variables in medication nonadherence and the best strategy for change. We reviewed five models as part of the intervention development process: the HBM (Champion & Skinner, 2008), TM (Prochaska et al., 2008), MOHO (Kielhofner, 1995), PEO (Law et al., 1996), and HAAT (Cook & Polgar, 2008).

Because of the HBM, IMedS evaluates the client's knowledge regarding their medication purpose, medication side effects, knowledge of their health condition, self-efficacy around medical tasks, and perceived health status. It is anticipated that when a client better understands the risks of nonadherence, benefits of adherence, or has increased self-efficacy, the client will be more likely to engage in the health behavior of taking medication.

The TM encouraged the IMedS intervention to evaluate clients' readiness for change. Then the intervention is tailored to meet a client's needs. By "meeting the client where they're at," we anticipate that clients will demonstrate better outcomes.

MOHO identifies the important variables of volition, feedback, and habits. The IMedS intervention provides feedback on past medication adherence behavior, asks

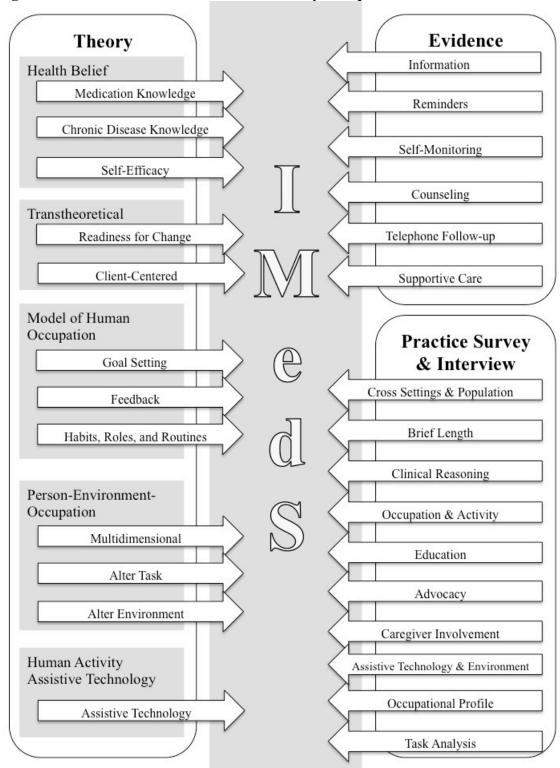


Figure 3.3 IMedS Intervention Construction by Component

clients to set goals (volition), and works to create more adaptive habits. We anticipate that these changes will help improve a client's daily medication taking behaviors.

The PEO model inspired the IMedS intervention to move beyond the person-level interventions to also consider modifying the medication task and the environment. We predict by taking a multidimensional approach, decreasing the task demands, and improving the receptivity of the environment IMedS can improve performance in medication adherence.

Despite the many interventions that incorporate assistive technology, current medication adherence models do not address the prescription of assistive technology. Therefore, we used the HAAT model from the field of assistive technology. Because of this model, the IMedS interventionist prescribes individualized assistive technologies tailored to the client's needs. It is anticipated that client-centered assistive technologies can improve performance in medication activities.

These five theories represent a diverse body of knowledge. Some theories (i.e. HBM & TM) are used regularly in the medication adherence literature. Other theories derive from the field of occupational therapy (i.e. PEO & MOHO) or assistive technology (i.e. HAAT), and they bring new concepts to this intervention. Because of the strong theoretical foundation and the new theories to this practice area, we anticipate that the IMedS intervention will be more effective than current interventions in the literature.

Objective 2: Current Literature

We also based the IMedS intervention on best evidence. Unfortunately, current interventions for medication nonadherence are complex and not very effective (Haynes et al., 2008; Nieuwlaat et al., 2014). Haynes et al. (2008), however, were able to find eleven

types of interventions associated with some improvement in adherence, health, or function. Unfortunately, occupational therapy practitioners cannot implement all of the effective interventions (e.g. psychological therapy). Therefore, the IMedS intervention leverages six of the intervention approaches found to be effective: 1) information 2) reminders 3) self-monitoring 4) counseling 5) telephone follow-up and 6) supportive care. Because the IMeds intervention leverages approaches that have been previously tested with positive results, we anticipate that the IMeds will also be effective.

Objective 3: Practice Survey

The purpose of the practice survey was to identify clinicians' experiences around medication adherence evaluation and intervention. From this objective, IMedS gains external validity and is strengthened by the expertise of 70 practitioners. The practice survey influenced the IMedS intervention in three ways.

First, the IMedS intervention leverages many of the intervention approaches noted by respondents. Specifically, IMeds uses occupation and activity, education, advocacy, caregiver involvement, assistive technology, and environmental modifications.

Second, we noted that practitioners used multiple treatment approaches in their intervention. Therefore, the IMedS intervention encourages interventionist to use more than one approach.

Third, we found that the IMedS intervention needed to be flexible for use across practice setting and population. Almost all respondents (93%) reported engaging in medication adherence evaluation and intervention, but the practitioners were very heterogeneous – working in different settings with various patient populations. We also

noted that practice patterns changed by setting. Therefore, the intervention must have the flexibility to work across people, places, and practitioners.

Finally, in the practice survey we hoped to identify a set of assessments used consistently across practice. Unfortunately, practitioners were inconsistent in their use of medication management assessments. Some practitioners used a standardized evaluation (17%), while others used a non-standardized evaluation (43%), and some used no tool at all (30%). Even among those who did used a standardized tool, few practitioners used the same standardized tool.

Because of the practice survey, the IMeds intervention was designed to use a multidimensional combination of traditional occupational therapy approaches optimized for flexibility across practice setting and populations. We anticipate that the IMedS intervention will be effective and have good external validity because it is founded in the experiences of 70 clinicians.

Objective 4: Practice Interview

The purpose of the practice interviews was to help explain the "how?" and the "why?" of occupational therapy intervention for medication nonadherence. Interviews of eight occupational therapists on their medication management evaluation and intervention practices influenced the IMedS intervention in three ways.

First, the practitioner interviews identified some specific evaluation practices. Similarly to the practice survey, interview participants were divided about the best strategue for evaluation and were unable to suggest specific tools. The interviewed therapists, however, all verbalized the importance of seeing clients interact with medication materials (i.e. task analysis) and understanding the client's daily process

around medication tasks (i.e. occupational profile). Given these two types of information, the therapist could create the client-centered intervention. Therefore, the IMedS intervention evaluation relies heavily on a task analysis and an occupational profile interview around medication routines.

Second, the interviewed occupational therapists also indicated the necessity for clinical reasoning. The participants identified that their client's have a variety of health conditions, are on any number of different medications, and face distinct barriers to adherence. There are infinite permutations and combinations of client situations, and the practitioners rely heavily on their clinical reasoning to build client centered interventions. Therefore, the IMedS intervention creates a framework that supports practitioner's expert clinical reasoning skills. During the IMedS process, interventionists thoroughly evaluate a client to identify his or her strengths and weaknesses around medication adherence using a set of specified evaluations. Then the IMedS allows the clinician to think through the different intervention approaches suggested by theory, evidence, and practice. In the end, the therapist is guided by her clinical reasoning to selects the best intervention approaches.

Lastly, IMedS leverages some specific intervention ideas from the therapists.

During the interviews, the practitioners were able to describe specific techniques they use during intervention. All of the specific intervention ideas are described in Table 3.1.

Based off of this information, the IMedS training includes modules where interventionists are exposed to different intervention activities such as using apps, recommending pillboxes, etc. We have also developed client-handouts to help interventionist use some of the different ideas. For example, several therapists mentioned smart phone apps by

name that they recommend to clients. Therefore, the IMedS manual has a client handout describing the different apps, the functionality, and cost to share with participants.

The participant interviews helped us to bring all of the components of the intervention together and to identify how the intervention works. Because of the participant interviews, the IMedS intervention uses task analysis and an occupational profile for evaluation, leverages the interventionist's clinical reasoning skills, and shares intervention ideas.

Limitations

This article describes a series of four projects resulting in the development of the IMedS intervention. The practice survey and practice interview are limited by their small non-random sample and use of internally developed measurement tools.

While the sample was not random, we succeeded in identifying a diverse group of practitioners that has many characteristics similar to the population of occupational therapists. For example, in the survey, several respondents reported working in a hospital and few in home health, which is consistent with current practice rates (AOTA, 2010b). The sample provided the perspectives of new graduates and experienced clinicians, persons from diverse geographic locations, and from practitioners stationed across the continuum of care. While not random, the participants were able to report on a diversity of experiences needed for the intervention development process.

Also, while the survey and interview only identified the experiences of 78 practitioners, the findings were powered in depth of the study and multiple sources. For example, the HBM suggests that knowledge is important. The evidence indicates that information-based interventions can be effective. Many occupational therapists reported

using education as an intervention approach. The triangulation between theory, research, and practice often resulted in similar conclusions. This suggests that the important variables and mechanisms of change for medication adherence interventions have been identified.

Finally, all of the instrumentation for this study had to be developed internally because of the specific nature of our research questions. We based our instrumentation on common resources in the field. For example the demographics questions and answer options were based off of a recent workforce survey in occupational therapy (AOTA, 2010b). Evaluation and intervention items were based off of the *Occupational Therapy Practice Framework* and recent literature reviews of instruments and approaches. Therefore, while the instrumentation for this study was novel, the content had been vetted in the peer review literature.

Conclusion

Medication nonadherence is a large issue affecting the health and function of millions of persons with chronic health conditions. Unfortunately, few resources are available to help occupational therapy practitioners provide medication management or medication adherence services to their clients. In this article, we described how we used theory, the evidence, and the practice of 78 occupational therapists to manualize the IMedS intervention. Because of the intervention's evidence based foundation, we anticipate that IMedS will be an effective method to help people better manage their medications. Additionally, IMedS serves as one of the few examples of a manualized occupational therapy intervention. Because of the rigorous development process, this intervention can now be used in future research to study the effectiveness of occupational

therapy interventions promoting medication adherence. The documentation of intervention development brings advances to the field of occupational therapy and medication adherence and serves as an example for future research.

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Chapter 4 - A Win-Win: Benefits to Student Engagement in Intervention Research

Abstract

Entry-level occupational therapy students are required by accreditation standards to understand, critique, and design research. However, it is unclear how embedded students should be in real research projects. **Objective:** We sought to understand the benefits of student immersion in research on student learning and quality research. **Method:**Researchers trained six occupational therapy students to implement a manualized intervention with real research subjects. Outcomes were documented using surveys, interviews, video analysis of research activities, a practical exam, and student documentation. **Results:** Students successfully implemented the study protocols with good reliability (intraclass correlation coefficient=.89) and fidelity (99%). Additionally, students reported improvements in comfort with client interactions, confidence with practice skills, self-efficacy in research, and clinical reasoning. **Conclusion:** Student participation in hands-on research supports researchers in attaining their research goals while providing valuable learning experiences to students. Key resources are needed, however, for successful follow-through.

Keywords: Occupational therapy, Education, Behavioral Research, Health
Occupation Student

Research is essential to the profession of occupational therapy. Research develops consumer confidence, justifies the continued support of occupational therapy services from administrators and policy makers, and creates the foundation for clinical practice (Kielhofner, 2006). Research is not only emphasized in occupational therapy education, but it is also as an essential function of the professorate. Potentially, students are an immeasurable resource to the occupational therapy profession. It unclear how student-researcher teams can best be leveraged to develop the high quality intervention research and successful learning experiences. In this article, we look at the process of engaging occupational therapy students in high quality intervention research and examine the benefits to students and researchers.

As a core part of occupational therapy education, research is identified in *The Philosophy of Occupational Therapy Education* (American Occupational Therapy Association [AOTA], 2007b), *Blueprint for Entry-Level Education* (AOTA, 2010), and *Specialized Knowledge and skills of Occupational Therapy Educators of the Future* (AOTA, 2009). Specifically, the Accreditation Council for Occupational Therapy Education (ACOTE) (2013) states that at a minimum, occupational therapy students must learn to understand, critique, and design research. While the importance of research and the content of the learning objectives are clear, educational institutions use several different approaches to expose their students to research. For example, theses, research projects, group projects, service projects, capstone courses, or coursework related to research are just a few ways that institutions meet the research requirements. Unfortunately, limited literature informs instructors which methods are the most beneficial for student success.

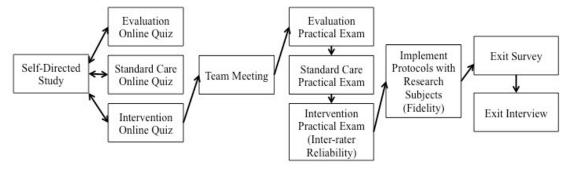
Maintaining a line of scholarly inquiry is increasingly a condition of employment for occupational therapy faculty. Faculty members are asked to provide evidence of success in research, such as peer-reviewed manuscripts, research presentations, and grant funding to attain tenure. As productivity requirements increase, faculty members are struggling to balance their duties across teaching, research, and service (McGrail, Rickard, & Jones, 2006; Milem, Berger, & Dey, 2000). Further, grant funding is shrinking as research is becoming more costly to conduct (Szabo, 2014). Intervention research requires significant funding, in part, because of the need for "skilled personnel intervening in both treatment and control groups...Thus, balancing costs with funding levels and necessary design elements is an ongoing challenge" (Gitlin, 2013, p.181). By engaging students in research, faculty members have the opportunity to synergize teaching and research while also managing the cost of skilled personnel. Unfortunately, faculty members have little guidance in how to best involve students in high quality intervention research. It is unclear, however, if occupational therapy pre-service training students can implement research at the rigor needed by faculty to support publications and future funding.

As part of a larger occupational therapy intervention study, we were able to examine the benefits of the student-research partnership to both members of the team. Specifically, we sought to answer two questions. First, how do students benefit when they engage in hands-on research? Second, were students able to implement study related protocols with enough rigor and effectiveness to support researchers needs?

Methods

The primary investigator (PI) recruited student volunteers to participate as interventionists and evaluators in a phase-one two-group randomized controlled trial testing a novel occupational therapy intervention for medication nonadherence for adults with a variety of chronic health conditions (Schwartz, 2015; Schwartz & Smith, 2015A; Schwartz & Smith 2015b). Students completed training on research procedures, implemented protocols with research subjects, and gave feedback to the PI about their experiences in the study. Figure 4.1 demonstrates students' experiences over the course of a semester.

Figure 4.1 Research Procedures



Recruitment

The PI recruited students from the occupational therapy program at the University. Currently, the University houses five cohorts of occupational therapy students, including a master's program and a combined bachelor's/ master's program. The Institutional Review Board at the University reviewed and approved this study. At the beginning of the Fall 2014 semester, the PI invited all retuning occupational therapy students (who had completed at least one year of occupational therapy coursework) to participate as a research assistant (RA) in return for one-credit of independent study,

valuable learning experiences, and the opportunity to engage in related conference presentations and publications. Interested students met with the PI face-to-face to discuss the nature of the study, identify the time commitments, and to review and sign the informed consent paperwork.

Participants

Six occupational therapy students across three cohorts enrolled in the independent study and engaged as a RA for the Fall 2014 semester. The students were 100% female and an average of 23 years of age. The PI recruited two students from the master's program and four students from the combined bachelor's/master's program.

The students all had completed coursework necessary to their success as research assistants in this particular study. In fact, five of the six students had completed most of their coursework and began level II fieldwork the following semester. In terms of specific courses, all students had completed two semesters of *Evidence*, where they learned research methods, measurement, and the scientific process. The students also completed *Foundations of Professional Practice in Occupational Therapy* and *Adult Physical Rehabilitation I*, which provide a basis for the evaluation and treatment of adults with chronic conditions. All students received training on the group process (including motivational interviewing), and five students completed *Occupational Therapy in Psychosocial Practice*. Both psychosocial courses contributed to student's abilities to engage in discussion of health behaviors and behavior change, which were widely used skills in the research study.

The PI was a doctoral student at the University completing her dissertation research on the larger intervention study. She was an occupational therapist with several

years of clinical experience across settings working with adults and children with chronic health conditions. She had supervised 12 fieldwork students in the clinic, taught occupational therapy coursework, and received advanced training and mentorship in teaching and learning in higher education. The PI benefited from her diverse skillset to help mentor the students through a rewarding research experience.

Research Manual

The PI created a comprehensive manual to facilitate students learning of the complex intervention and evaluation protocols (Schwartz, 2015; Schwartz & Smith, 2015a; Medication Management Research Project, 2014). The manual described the background and need for research, administration and interpretation of the 13-part assessment battery, administration of the treatment intervention, and administration of the standard care intervention. The intervention was highly skilled incorporating techniques such as motivational interviewing, tailoring, and using clinical reasoning to select the best intervention approaches (from a list). RAs were responsible for implementing a combination of treatment interventions, standard care interventions, and follow-up evaluations, making it necessary for the student RAs to learn protocols thoroughly to avoid contamination between groups

Because it was anticipated that the RAs would include students spread across cohorts with little availability to meet face-to-face as a group, the materials were developed for students to be completed via self-directed study. The manual leveraged images, videos, and checklists for all study procedures. The manual also included information about research study logistics, such as managing the audio video equipment

in addition to strategies for skilled intervention. Appendix A shows the table of contents for the research manual and Appendix B shows the checklists of study procedures.

Self Directed Study and Online Learning Quizzes

Student RAs learned the research materials and protocols through self-directed study. The student RAs were given two months to master the materials and were allowed to engage at their own speed. Once students felt that they had learned the materials, they were asked to demonstrate comprehension through a series of competency-based online quizzes. The PI developed three quizzes on the research manual, 1) evaluation (19 questions), 2) treatment intervention (20 questions), and 3) standard care intervention (10 questions). Students took the quizzes before and after reviewing the manual to quantify learning. The student RAs were required to score a minimum of 90% on all three quizzes prior to moving on to the next step in the training process. Students could re-take quizzes until they received a passing score.

Team Meeting

Once all students completed self-directed study, the PI held one team meeting.

The team reviewed questions that arose during self-directed study, analyzed case studies, and discussed logistics such as scheduling and managing resources. The PI presented the RAs with case studies including portions of an assessment battery from simulated clients. RAs were asked to interpret the assessment and identify appropriate intervention strategies through group discussion. The goal of the team meeting was to increase the consistency between team members.

Practical Exam

After the team meeting, the student RAs were required to demonstrate competence in a practical exam with the PI. Each student RA implemented an evaluation session, a standard care session, and an occupational therapy treatment session with a simulated client. Prior to the practical, the student RAs received the documentation they would typically have received before seeing a research subject. For example, for the simulated occupational therapy treatment intervention, the student RAs received the baseline-evaluation data of the simulated research subject. The PI role-played the simulated research subject for all student RAs answering similar questions consistently across students.

Inter-Rater Reliability

During the practical, the PI evaluated RAs on their fidelity to the research protocols and the reliability of their intervention recommendations. Fidelity to the protocol was measured as percent adherence to a checklist matching the selected research protocol (Appendix B). For reliability, the intervention protocol suggests six different types of intervention strategies to help research subjects improve their medications regiments (1) education, 2) advocacy, 3) changes to routine, 4) changes to the environment, 5) prescription of assistive technology, and 6) strategies for consistent and timely refills). The RAs were instructed to use their clinical reasoning to decide which of the six intervention approaches were appropriate for a specific client. RAs could use as few as one or as many as six intervention approaches. At the conclusion of the simulated treatment intervention session, the student documented which intervention approaches she used. These dichotomous data (approaches used vs. not used) were entered in to

SPSS for Mac Version 21 for the identification of the intraclass correlation coefficient (ICC) to depict the reliability of intervention recommendations between raters.

Coaching

At the conclusion of the practical, the PI conducted coaching with the RAs.

During the practical, the PI assessed the RAs in five domains: 1) confidence, 2) demeanor, 3) appropriateness of intervention recommendations, 4) motivational interviewing skills, and 5) appropriateness of prompts (during evaluation). At the end of the practical, the PI coached student on strengths, areas for improvement, fidelity to the protocol, and any missed protocol items. The PI and each student RA then engaged in role-playing to practice feedback. After successfully completing the practical, the RA was allowed to begin engaging with real research subjects as part of the research study. Once the RAs transitioned to working with real research subject, the PI did not provide any further coaching or guidance specific to identifying research subject barriers, intervention ideas, etc. The PI was able, however, to answer questions about the protocol or the process.

Fidelity with Research Subjects

After the training was completed, the RAs were ready to engage research subjects. Each RA was responsible for her own research participants. The PI, however, was always readily available during direct interactions with research subjects. Each student RA saw an average of three intervention research subjects (standard care or occupational therapy) and three follow-up evaluation research subjects. Interactions between the research subjects and student RAs occurred in a campus-based laboratory space and were video recorded. The PI monitored the recordings throughout the study for fidelity to the

protocol using the same checklists used in the practical exam. If a student's fidelity fell below 90%, the research study protocol mandated that student engage in training until she could again administer the protocol with good fidelity.

Research Subject Experiences

When the RAs administered the follow-up evaluation protocol with research subjects, they also administered an exit interview. During the exit interview, the RAs asked the research subjects about their experiences in the study and self-perceived improvements. The study describing the research subjects experiences and outcomes is discussed elsewhere (Schwartz, 2015; Schwartz & Smith 2015b). In this article, however, we will briefly describe the research subject's outcomes and comments around their experiences with the RAs as another outcomes perspective.

Exit Interview and Survey

After the student RAs completed all interactions with the research subjects, they participated in an exit survey and exit interview. The PI entered all grades for the independent study credit prior to exit activities to ensure the students that the feedback would not affect their grade or standing with the faculty. The survey was administered via computer such that RAs could answer anonymously. The 47-item survey asked about the students' thoughts and experiences around the training and inquired about the students' perceived learning outcomes. Students were presented with a statement about the training or learning outcomes and were asked to rate their agreement with the statement using a 5-point Likert scale. Survey responses were assessed with descriptive statistics using SPSS for Mac Version 21.

The students also engaged in a face-to-face exit interview with the PI. The students were asked about their likes and dislikes about the training, likes and dislikes about the intervention, and perceived learning benefits. Interviews were transcribed and analyzed using grounded theory with NVivio for Mac Version 10.1.2.

Results

Student Outcomes

In both the surveys and the interviews, students reported that their participation as a RA was a valuable experience. In the anonymous survey, students reported gains in knowledge of medication adherence, comfort in working with real clients, confidence with occupational therapy skills, understanding of the research process, occupational therapy intervention skills, knowledge of chronic disease management, self-efficacy as a researcher, and clinical reasoning (Table 4.1).

Table 4.1 Student Surveyed Learning Outcomes

| The state of the s | | |
|--|------|-------|
| Because of my experiences as a research assistant, I improved my | M | (SD) |
| Knowledge about medication adherence | 4.67 | (.52) |
| Comfort engaging with clients | 4.33 | (.82) |
| Confidence in my occupational therapy skills | 4.33 | (.52) |
| Understanding of the research process | 4.33 | (.52) |
| Occupational therapy intervention skills | 4.20 | (.84) |
| Knowledge about chronic disease management | 4.17 | (.98) |
| Self-efficacy as a researcher | 4.17 | (.75) |
| Clinical reasoning | 4.00 | (.63) |

Note. N=6. Items were answered on a 5-point Likert agreement scale with 5= Strongly agree, 4=Agree, 3= Neither agree or disagree, 2= Disagree, 1=Strongly Disagree.

The student interviews triangulated well with the survey results. Many of the student RAs felt "more comfortable with client interactions and talking to people." The students also reported that they benefited from the opportunity to deliver assessments,

engage in motivational interviewing, and even practice basic skills such as reviewing a chart. Overall, the students reported that they like practicing the skills learned in coursework with real clients as it felt "more real world than class."

The student RAs also discussed learning around research. Similarly, the students liked engaging in the research study because it helped "apply things [they] already knew." For example, one student reported, "you talk about that [blinding] in stats and stuff, and you're like okay sure, but it makes a lot more sense actually seeing it." Similarly, another student reported being better able to understand the difference between baseline and intervention and feeling more knowledgeable about managing research subject privacy. All of the students reported a positive experience, and would recommend engaging in hands-on research to a classmate.

Research Outcomes

Quizzes. The students successfully learned all research protocols. The student's scores on three quizzes indicated comprehension of research materials. For the evaluation quiz, the students required an average of 1.3 attempts to pass. Their score increased from 56% to 100% after self-directed study. For the intervention quiz, the students required an average of 1.2 attempts to pass. Their average score increased from 53% to 98% after self-directed study. Finally, for the standard care intervention all of the students completed the quiz successfully after only one attempt, and they increased their scores from an average of 65% to 97% after self-directed study.

Practical Exam. The PI tested for synthesis and application of learning through the practical exam. The practical lasted one-hour. All student RAs passed the practical with 100% fidelity to the protocol (with the aid of checklist). The students demonstrated

strong clinical reasoning and professional behaviors, but required some minor coaching around confidence and motivational interviewing strategies. During the practical, the student RAs demonstrated strong reliability of intervention recommendations between RAs evidenced by an ICC of .89.

Fidelity. The students implemented the treatment protocol with 97% fidelity, the standard care protocol with 100% fidelity, and the follow-up evaluation protocol with 100% fidelity with real research subjects. With a checklist of the protocol on their clipboard, the students were abele to maintain high fidelity across session type.

Research Subject Experiences. Not only were the student able to implement the protocol, but also they were able to do it successfully. A majority of research subjects (55%) in the occupational therapy treatment group self-reported improvements in their medication management compared to few research subjects (30%) in the standard care group (Schwartz, 2015; Schwartz & Smith 2015b). Further, in the exit interview several research subjects in both the treatment and standard care groups noted the highly skilled research staff (Schwartz, 2015; Schwartz & Smith 2015b). The RAs were noted in seven of 19 interviews for being "knowledgeable," "respectful," "caring," etc. Several research subjects felt strongly about the research assistants. For example, one research subject praised, "I would say that every single one of the team were professional, friendly, seemed to be truly interested in helping." The student RAs were able to implement the protocol with good accuracy and success.

Practical and Logistical Advantages

Finally, the PI also benefited from the strong motivation that students brought to the project. Five students required overload permissions from the University to take the additional independent study credit. The students also spent a significant amount of time learning the materials and preparing to see their assigned research subjects. The student RAs engaged in self-directed study for an average of 87 minutes to learn the evaluation materials, 93 minutes to learn the intervention materials, and 36 minutes to learn the standard care materials for a total of 3.6 hours of self-directed study. Further, to prepare for research subjects (particularly those receiving the treatment intervention), the RAs would commonly arrive 30-minutes to one-hour early to review the chart and prepare the materials. Because the student RAs successful engagement and dedication to the research study, the PI was able to better leverage the \$2,000 budget to complete a twenty-subject, phase-one, six-week, randomized controlled trial.

Discussion

The purpose of this study was to understand if we could successfully involve occupational therapy students in high quality research. As part of a larger occupational therapy intervention study utilizing occupational therapy students as research assistants, we investigated the outcomes to both students and the research.

Student Outcomes

To be successful, future occupational therapists must learn how to understand, critique, and design research in addition to mastering many other practice related skills. This study demonstrated that by engaging students in a hands-on intervention research study, students gain valuable skills. Not only do the student develop expertise in a specific content area (such as medication adherence and chronic disease management like in this study), but also the students gain comfort with client interactions, confidence with practice skills, self-efficacy in research, and clinical reasoning. Student's experiences did

not compete with other curriculum, but instead was able to complement previous coursework by bringing complex ideas to life. While this study did not compare across types of instruction, it does demonstrate the benefits of hands-on research experiences and suggests that classroom-based research instruction methods may leave students missing out on many of the perks reported by students in this study.

Research Outcomes

The student's engagement not only benefited the students, but it also furthered the research. This study indicates that with the appropriate supports, senior occupational therapy students can learn research protocols (evidenced by an 41 percentage point increase in pre-post learning quizzes) and they can implement intervention reliably (ICC = .89) and with good fidelity (99%). There are many reasons why a phase-one research study may not demonstrate positive results, but the fact that most research subjects found the intervention to be effective is another testament to the students skills. Further, the many of the research subjects reported quality and enjoyable interactions with the students. The protocols implemented by the students were not easy. The intervention required students to use clinical reasoning to select the best approaches, tailor the intervention to the client, and engage in clinical skills like motivational interviewing at the same time. The RAs had to switch seamlessly between protocols. In the end, the research benefited from the student's tremendous motivation and excitement, and the PI was able to implement a larger more thorough study than would otherwise be possible.

Limitations

This study indicates positive outcomes when student participate in research; however, several factors limit the widespread use of this methodology. Foremost, this

study describes the experiences of six occupational therapy students, one occupational therapy researcher, and one University. The PI spent many hours of preparation, training, staging, and running this research project. This degree of intensive workload may not be easily assigned on my campuses or in programs without the resources allowed for this study. Therefore, this approach may not be readily generalized to other occupational therapy students at other occupational therapy programs. The information, however, gleaned throughout the study may be used to inform occupational therapy educators and researchers, who may then add their experiences to the occupational therapy education literature.

The PI developed all of the evaluation tools used in this study. All tools were pilot tested internally and improved for clarity prior to use with the students. The tools, however, lacked formal psychometric testing. This may have contributed to error in the measurement. Fortunately, the study is powered through having several data points for each research assistant and by using a variety of measures invoking both qualitative and quantitative techniques. The results across instruments, time points, and perspectives indicate similar results, demonstrating foundational validity.

This study, however, does define and articulates several unique and replicable features that made it successful. First, the RAs were a sample of students who volunteered, indicating a selection bias of students who were motivated and excited about the topic. Second, the evaluation, intervention, and standard care scenarios were thoroughly manualized, which is an uncommon aspect of occupational therapy research (Blanche, Fogelberg, Diaz, Carlson, & Clark, 2011). The manuals were targeted specifically for students and entry-level practitioners and provided example prompts,

images, and videos of experts implementing different techniques. Third, the PI designed specific features to create a receptive atmosphere to support the students. For example, the PI provided several checklists, included many reminders (in the form of post-it notes, emails, etc.), and helped with the logistical burden of data management. While these safeguards enabled the students to be successful, it required additional time and attention from the PI that would not be required with a professional research staff. Finally, the PI had a unique skill set around occupational therapy research, practice, teaching, and fieldwork education. These competencies helped the PI to integrate teaching, research, and practice while also developing rapport to successfully mentor students. The process was effective, but leveraged motivated senior students, a skilled PI, and a highly manualized process.

Implications for Practice

Several lessons from this research can be gleaned to inform occupational therapy education and research:

- Student participation in hands-on research seemingly has unique benefits such as
 increases in confidence, clinical reasoning, and self-efficacy. Educators should
 incorporate hands-on components into their occupational therapy research
 curriculum.
- More research is needed to become the evidence-based science-driven profession envisioned by the occupational therapy leadership (AOTA, 2007a). Provided with the right supports, occupational therapy students can reliably and successfully implement skilled research approaches. Researchers should better leverage their student partnerships to meet societal and professional research needs.

- Manualizing research interventions has many well known benefits (Blanche et al., 2011). In this study, a manualized intervention enabled occupational therapy students to successfully implement complicated approaches, further supporting the use and need of manualized interventions in occupational therapy.
- Incorporating students into research can be an intimidating process, and there is little guidance for researchers. This study indicates that the methodology of selfdirected study of an electronic research manual, learning quizzes, team discussion, and an individual practical can effectively train students to implement complex research approaches, thus providing a framework for other studentresearcher training.

Conclusion

Standards continue to rise for occupational therapy faculty and students alike.

Research is one of the main components contributing to the rising the bar. Students are not only required to understand research, but now as future practitioners in a complex medical society, they are expected to critique, design, and participate in investigations. Students, therefore, need academic experiences that support their ability to fully participate in research.

Similarly, faculty are being expected to spend an increasing amount of time engaging in both research and teaching (Milem et al., 2000). Time is a finite resource. Faculty members need to learn how to work smarter.

Students and researchers are natural partners, and as this study demonstrates, they can have a symbiotic relationship. This study identified and delineated specific design strategies for successfully administrating a phase-one pilot study using entry-level

occupational therapy students. With training and supports, the occupational therapy students were able to successfully implement skilled and complicated research protocols. This experience provided a natural learning environment for the student with a myriad of educational benefits, while helping the investigator to achieve her research and teaching goals. When students and researchers collaborate, it can truly be a win-win situation.

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Chapter 5 - Single-Subject Analysis of an Intervention to Promote Medication Adherence

Abstract

Many persons with chronic health conditions fail to take their medications as prescribed, resulting in declines in health and function. We wanted to determine if occupational therapy intervention can help people with chronic health conditions improve their adherence to medications. Using single-subject analyses, we evaluated the medication adherence of 11 participants before and after intervention over approximately six weeks. We used a multiple baseline approach. Some participants received an occupational therapy intervention, and others received a standard of care educational session. The occupational therapy intervention was found to decrease performance variability and increase medication adherence rates in some persons with chronic conditions. Findings identify that an occupational therapy intervention can improve medication nonadherence in persons with chronic health conditions.

Keywords: Medication Adherence, Occupational Therapy, Chronic Disease, Intervention Studies

Over 133 million Americans live with one or more chronic condition and require medications to manage their health (Barber, Parsons, Clifford, Darracott, & Horne, 2004; Stafford et al., 2003). Unfortunately, about half of persons with chronic health conditions do not take their medications as prescribed, and are said to be nonadherent (Bodenheimer, Chen, & Bennett, 2009; Osterberg & Blaschke, 2005). When people become nonadherent to their medications, they often experience poorer health outcomes, disability, hospitalizations, and even death (Osterberg & Blaschke, 2005; Sokol, McGuigan, Verbrugge, & Epstein, 2005).

Medication nonadherence is a complex issue with a lack of good solutions (Vlasnik, Aliotta, & DeLor, 2005; World Health Organization, 2003). Medication nonadherence affects people across health conditions, age, race, and socioeconomic conditions. Further, nonadherence may be caused by any number of factors in infinite combinations. For example, medication nonadherence is known to be affected by health literacy, cognitive function, disability, personal beliefs, medication regimen complexity, medication side effects, access to transportation, client/health care provider relationship, and availability of community services just to name a few factors. The complexity of medication adherence has largely stumped researchers, leaving the systematic literature reviewers, Nieuwlaat et al. (2014), to conclude that "current methods of improving medication adherence for chronic health problems are mostly complex and not very effective" (p. 2). New interventions are needed to help people with chronic health conditions better take their medications as prescribed.

Currently, the literature reveals little discussion of occupational therapy in medication adherence interventions (Radomski, 2011; Sanders & Van Oss, 2013).

Occupational therapy practitioners have a role in helping people to better manage their medications (Schwartz, 2015, Chapter 2; American Occupational Therapy Association [AOTA], 2014; Sanders & Van Oss, 2013). Despite the opportunities for occupational therapy practitioners, limited intervention research supports occupational therapy practitioners in this area. Occupational therapy has been shown to improve performance in other daily activities (Doucet, Woodson, & Watford, 2014). Therefore, we hypothesized that occupational therapy may be an effective and novel intervention for medication nonadherence.

Purpose

Given the limited research in the area of occupational therapy and medication adherence, we began our investigation with a feasibility study. Feasibility studies are small budget-constrained investigations that are the first study in a line of research. They investigate if research ideas are worth pursuing (in larger more costly investigations) (Gitlin, 2013). Feasibility studies test many components of the research design and the intervention. One important factor in feasibility testing, however, is limited effectiveness (Bowen et al., 2009). Limited effectiveness testing investigates if the intervention demonstrates enough promise to warrant future study.

This article is one of a series of studies investigating the feasibility of an occupational therapy intervention to promote medication adherence. Details of other components of the feasibility study have been published elsewhere (Schwartz, 2015, Chapter 6 & 7). The purpose of this article, however, is to understand the effectiveness of the occupational therapy intervention in a limited way. Specifically, we had two research questions. First, we wanted to understand it if is possible for occupational therapy to

improve medication adherence in persons with chronic health conditions. Second, we wanted to identify the characteristics of the people who benefited from the intervention to inform further work in this area.

Methods

To understand the feasibility of an occupational therapy intervention for medication nonadherence, we implemented a small two-group, experimental, random-assignment, blinded, randomized controlled trial (RCT). Through the small RCT, we were able to explore the methodology and identify problems in the design of the research. Unfortunately, within and between group designs have limited utility for exploring the effectiveness of an intervention on a small convenience sample of participants, as findings cannot be generalized to the population. Therefore, we used single-subject design methodology to explore the limited effectiveness of the intervention. Our research questions seek to understand effectiveness of the intervention within a person, making single-subject research a natural fit.

Research Design

The research design for this study represents the intertwined nature of the RCT and single-subject methodologies. We used a series of naturally occurring, inter-subject, multiple baseline, AB single-subject designs to understand the effects of the intervention over two phase changes. Single-subject components of this study were designed to meet the standards described by Kratochwill et al. (2010) and Portney & Watkins (2008).

The use of an AB design, however, does not control for possible concurrent covariate effects. Furthermore, the obvious nature of the intervention package introduces potential biases of the participant and the researcher, because both would be aware when

the participant was receiving the intervention. Fortunately, because this study was part of a larger RCT, several design features also served to decreased bias. Given the two group experimental nature of the RCT, participants were adaptively randomized to receive the occupational therapy intervention or the standard of care. Participants and evaluators were blinded to the participant's intervention assignment. This research design procedure is depicted in Figure 5.1.

Perfect Adherers Removed from Analysis n=3Standard Care Follow-up Intervention Evaluation Baseline n=10 n=7Phone Screen Randomization Evaluation n=34 IMedS Follow-up n=21 Evaluation Intervention n=10 n=4 Withdrew from Perfect Adherers Screened Out Study Removed from n = 11Analysis n=1n=5Withdrew from Withdrew from Study Study n=2 n=1

Figure 5.1. Research Process and Enrollment

Participant Selection

We sought to recruit a diverse group of persons with chronic health conditions and medication nonadherence. There were six inclusion criteria for this study.

Participants must: 1) be 18 years or age or older, 2) have a chronic health condition (diagnosed by a physician), 3) live in the community, 4) independently manage their medications, 5) have poor adherence to medications evidenced by a score of six or less on the Morisky Medication Adherence Scale (MMAS) (Morisky, Ang, Krousel-Wood, & Ward, 2008), and 6) report using a medication regimen of five or more pills a day. The

medication regimen may include prescriptions and off-the-shelf medications recommended by a health care professional. The pills per day requirement helped to meet the needs of single-subject design and identify individuals on complicated medication regimens. Persons with significant cognitive impairment (indicated by a score of 10 or more on the Short Blessed Test) and persons unable to travel to the University for research related activities were excluded from the study (Katzman et al., 1983). Also, persons who did not take their medications for financial reasons were excluded from the study, because it was anticipated that occupational therapy intervention could not overcome this type of barrier.

Study Staff

Research assistants conducted the study-related procedures. Senior occupational therapy students were trained to deliver all sessions using a manual and series of protocols. Each research assistant completed a six-hour training and demonstrated competence through a series of written and practical-based exams prior to implementing the interventions with the research participant (Schwartz, 2015, Chapter 4). All research assistants demonstrated good fidelity to the study protocols and good reliability with fellow research assistants in terms of intervention recommendations (Schwartz, 2015, Chapter 4).

Instrumentation

Six instruments were used in this study. The tools served to collect demographic information, guide the intervention, and measure outcomes.

Demographics. Participants were given a demographics survey. They were asked to identify their race, sex, health insurance status, employment status, relationship status, and medical diagnoses.

Guiding intervention. Four assessments helped the research team create clientcentered evaluations. First, the Pillbox Test served as a task analysis of the medication routine and was used to understand if the client possessed the underlying body structures and function needed to manage medications (Zartman, Hilsabeck, Guarnaccia, & Houtz, 2013). Second, the Medication Knowledge Assessment (MKA) (a semi-structured interview) identified how well a participant knew his or her medication regimen (American Society on Aging & American Society of Consultant Pharmacists Foundation, 2006). The MKA also helped researchers collect the participant's prescribed medication and dosing schedule. Third, the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) collected participant descriptions of what type of assistive technology devices they used to manage their medications and how satisfied they were with their device (e.g. pillboxes). This tool also facilitated the prescription of new assistive technology (as needed) in the intervention phase of the study. Finally, an occupational profile interview documented the participant's medication routines and home environment.

Measuring Outcomes. This study uses one outcome measure, a medication adherence calendar. The calendar is a self-report measure where the client identifies how many medications he or she took each day. This tool provides the single-subject data for this study.

Intervention

As part of a RCT, participants were randomized to receive one of two possible interventions. Some persons were randomized to the occupational therapy treatment, while others received an educational standard care intervention.

Integrative Medication Self-Management Intervention (IMedS), was designed to help people better take their medications as prescribed. An occupational therapist developed the IMedS intervention grounded on theory, current practice, and best evidence (Schwartz, 2015, Chapter 3).

A key design feature of the IMedS intervention is that it uses a highly structured process to ensure that each person has a complete and similar experience. The protocol prompts the therapist to select and tailor specific intervention tasks using clinical reasoning ultimately creating a personalized intervention package. During the IMedS intervention, the client and interventionist completed six steps: 1) identify the client's current medications adherence, 2) discuss readiness for change 3) set a medication adherence goal, 4) generate strategies to help the client reach their goal, 5) review plan, 6) trial plan and update as needed. To further increase effectiveness, interventionist used skilled communication approaches throughout the intervention including motivational interviewing, the teach-back method, and therapeutic use of self.

Standard care intervention. The standard care intervention was designed to contrast the occupational therapy intervention and simulate the standard of care. Similarly to the intervention participants, interventionist told the standard care participants that taking medications as prescribed is important. However, instead of having a conversation

about medications the interventionist and participant had an educational session based on the pamphlet *Managing Your Medicines: Our Guide to Effective Medication Management* by the American Heart Association (AHA) and the American Stoke Association (ASA) (2013). While the AHA and ASA developed the pamphlet, it provides general information appropriate across diagnosis groups. During the standard care procedures, the interventionist was allowed to engage in active listening and discussion of the materials found in the pamphlet. The interventionist was prohibited from providing client-centered recommendations or using skilled therapeutic communication approaches. The pamphlet had many of the same intervention strategies recommended in the IMedS intervention, but the delivery of the information lacked the skilled approached used in the treatment intervention.

Procedures

The research participants had four interactions with the research team: a phone screen, baseline evaluation session, intervention, and follow-up evaluation. The research team paid participants \$20 in gift cards to Walgreens at the conclusion of each face-to-face interaction, for a total of \$60 for persons completing the study.

Recruitment and phone screen. Individuals were recruited through paper and electronic flyers posted throughout the community and on electronic list serves for groups serving people with chronic health conditions. Interested individuals called the research team to participate in a phone screen. Potential participants were asked a series of questions pertaining to the inclusion and exclusion criteria and were screened with the Short Blessed Test and MMAS. Persons who passed the phone screen were invited to schedule a baseline evaluation appointment.

Baseline data collection. During the baseline data collection session, the participant reviewed and signed the informed consent, completed the series of evaluations, and learned how to complete the medication calendar. The session took approximately one hour and occurred either at the participant's home or in a shared lab space at the University. At the end of the baseline data collection, the RA instructed the participant on keeping a medication calendar. The participant was instructed to record the number of pills that he or she actually took each day on the calendar. Participants were instructed not to record PRN or "as needed" medications. Researchers instructed the participant to record medication changes recommended by a health care professional in the margins of the calendar. Participants began recording the number of pills consumed each day at the baseline evaluation, and they continued for the duration of the study. Because baseline data collection occurred prior to randomization, both the evaluating RA and the participant were blind to condition at baseline.

Randomization. After the baseline evaluation, research participants were adaptively randomized to receive the intervention or standard care condition. Using the protocol described by Smoak & Lin (2001), the randomization process accounted for the participants age, gender, and extent of medication nonadherence (i.e. the score on the MMAS).

Intervention. The intervention was scheduled two weeks after the baseline evaluation. All interventions occurred in a shared lab space at the University. As randomized, study participants received either the occupational therapy intervention or the standard of care educational session. Both the treatment and standard care conditions lasted approximately 30 minutes.

The research participants were blinded to their assignment to the stanard care or the treatment conditions. When the participants were enrolled in the study, they were told that they would receive either an education-based session or a strategy-based session to help them better take their medications. The participants were not told which was the experimental treatment. The interventionist, however, was unable to be blinded.

Follow-up data collection. Participants were scheduled for follow up one month after intervention. Participants met with a new RA who was blinded to their treatment condition. Participants returned to the University for the hour-long follow-up. During the visit, the participant turned in their medication calendar and engaged in an exit interview. The qualitative results from the exit interview are described elsewhere, but the quantitative procedures and results follow (Schwartz, 2015, Chapter 6).

Data Analysis

At the conclusion of the study, the researcher collected the medication diary and calculated percent adherence for each study day. Percent adherence describes the ratio of the number of pills actually consumed to number of pills prescribed to be consumed each day. A score of 100% indicated that the client took all of his or her prescribed pills for that day. Scores above 100% indicate that the client took more pills than prescribed, and scores less than 100% indicate that the client took fewer pills than prescribed. The medication calendar provided the researchers with the participant's daily medication adherence over the course of the baseline and intervention phases. The participant's daily percent adherence was the dependent variable used for the single-subject analyses.

Single-subject data were analyzed visually and by using Simulation Modeling

Analysis. Researchers visually analyzed the single-subject data using the methods

described by Kratochwill et al. (2010) and Portney & Watkins (2008) for changes in level, slope, variability, immediacy of the effect, overlap, and consistency of data patterns across similar phases. While visual analysis is informative, it is also associated with poor reliability and an increase in the Type I error rate. Therefore, we also used Simulation Modeling Analysis (SMA) determine the statistical significance of changes to slope and level (Borckardt et al., 2008). SMA accounts for the autocorrelation of time series data and uses bootstrapping methodologies to determine the true probability of identifying changes of the magnitude noted in the data. The SMA procedure was completed using the freely available software, SMA 9.9.28 for Mac (Clincal Research Solutions, N.D.)

Results

Participants

Thirty-four individuals were screened for the study. Twenty-three were admitted to the study, while 11 were rejected because they failed to meet the inclusion criteria.

Two people withdrew from the study prior to the baseline evaluation.

Twenty-one participants received the baseline evaluation and were instructed to keep a medication calendar. After the baseline evaluation, two participants dropped-out of the study. Eight participants had perfect medication adherence for all six-weeks of the study. These perfect adherers were removed from the single-subject analyses because they did not demonstrate occupational performance deficits in medication management.

Eleven participants with true medication nonadherence completed the study.

Seven participants had been assigned to the standard care condition and four participants to the IMedS condition. Eight male participants had been recruited into the study, two dropped out and six demonstrated perfect medication adherence, resulting in a sample of

100% women for the single-subject portion of the study. The participants had a diverse age range of 23 to 79 years, but on average participants were older with a mean age of 53 years (Standard Deviation [SD]=20). Participants were mostly white and lived alone. All of the participants had health insurance. On average, participants had four chronic health conditions (SD=2) and took 10 medications a day (SD=4). Persons in the treatment group were diagnosed with a variety of health conditions including osteoporosis, arthritis, heart disease, anxiety, depression, human immunodeficiency virus, and diabetes. Persons in the standard care group also demonstrated a variety of health conditions including arthritis, heart disease, anxiety, depression, asthma, diabetes, chronic obstructive pulmonary disease, attention deficit disorder, and post-cancer related conditions. Table 5.1 identifies participant demographics by group.

The study lasted approximately six weeks and included a baseline and intervention phase. For the standard care group, the baseline phase lasted an average of 15 days (SD = 10) and the intervention lasted an average of 29 days (SD = 9). For the intervention group, the baseline phase lasted an average of 17 days (SD = 7) and the intervention lasted an average of 26 days (SD = 9).

Standard Care Effectiveness

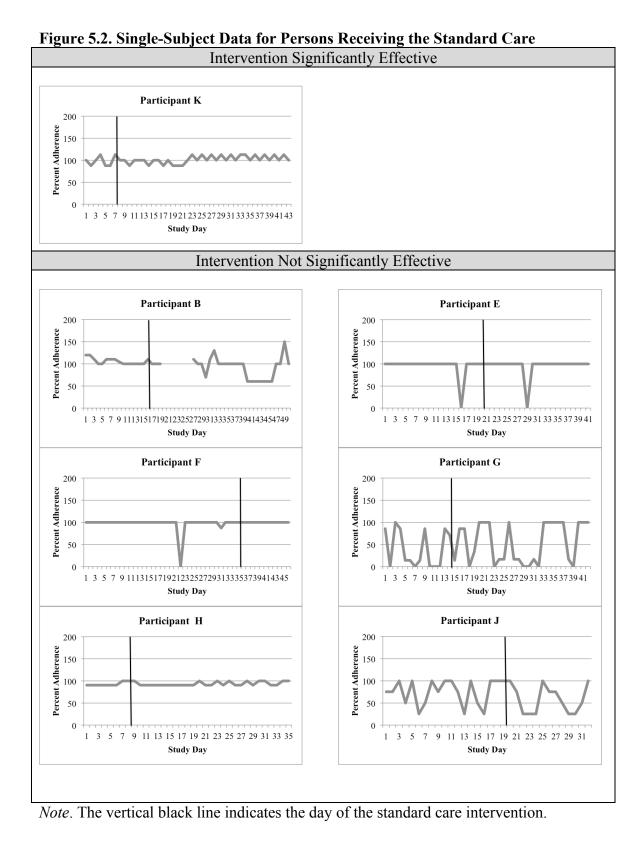
Seven participants received the pamphlet based education session for medication adherence. Figure 5.2 demonstrates the single-subject data for each person in the standard care group. Most (n=6, 86%) were not able to significantly improve their medication adherence. SMA revealed that Participant K had a significant change in slope ($r_{slope} = -0.48$, p=.004) but not level ($r_{level} = 0.13$, p=.48). While Participant K's percent adherence increased, she continued to demonstrate variability in performance. Participant F reported

Table 5.1. Demographics

| | Standard Care | | Treatment | | | |
|----------------------------|---------------|------|-----------|------|------|---------|
| | M | (SD) | Range | M | (SD) | Range |
| Age (years) | 51 | 23 | 23 - 79 | 45 | 15 | 44 - 73 |
| Number of Daily | | | | | | |
| Medications | 9 | 4 | 5 - 17 | 11 | 4 | 7 - 15 |
| Number of Prescribers | 3 | 1 | 1 - 4 | 3 | 2 | 1 - 6 |
| Morisky Medication | | | | | | |
| Adherence Survey | 4.43 | 1.72 | 1 - 6 | 4.00 | 0.82 | 3 - 5 |
| Short Blessed Test | 1.71 | 2.43 | 0 - 6 | 1 | 1.15 | 0 - 2 |
| | n | (%) | | n | (%) | |
| Sex | | | | | | |
| Female | 7 | 100 | | 4 | 100 | |
| Race | | | | | | |
| White | 7 | 100 | | 3 | 75 | |
| Relationship Status | | | | | | |
| Single/ Divorced/ Widowed | 5 | 71 | | 3 | 75 | |
| Married/ In a Relationship | 2 | 29 | | 1 | 25 | |
| Employment Status | | | | | | |
| Employed | 1 | 14 | | 1 | 25 | |
| Unemployed | 1 | 14 | | 0 | 0 | |
| Student | 2 | 29 | | 0 | 0 | |
| Retired | 2 | 29 | | 1 | 25 | |
| Disabled | 1 | 14 | | 2 | 50 | |

Note. MMAS =Morisky Medication Adherence Survey. Mean=M. Standard Deviation = SD.

two lapses in medication adherence at baseline and had no lapses in the intervention phase. The change, however, was too small to be statistically significant. The remaining five participants demonstrated no improvements in level, trend, and variability after receiving the educational session. Participants E, G, and J's adherence patterns persisted in to the intervention phase, while Participants B and H seemed to have worse medication adherence after the educational session.



Treatment Effectiveness

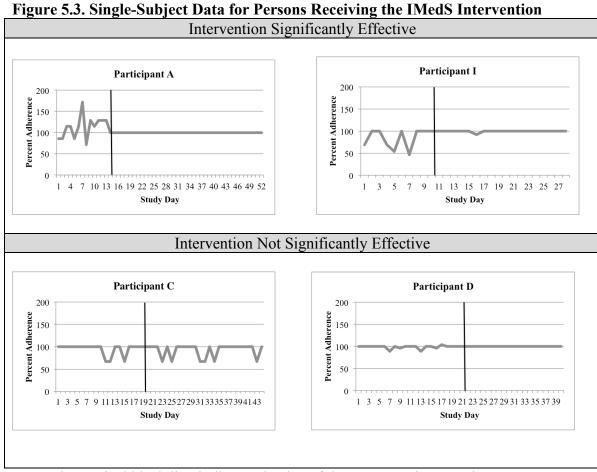
Four participants received the IMedS intervention. Figure 5.3 demonstrates the single-subject data for each person in the standard care group. Half of the participants (n=2) significantly improved their medication adherence at follow-up and maintained improvements for approximately four weeks. SMA revealed that Participant A had a significant change in slope ($r_{slope} = 0.29$, p=.05) and level ($r_{level} = -0.40$, p=.01). Participant I had a significant change in level ($r_{level} = 0.52$, p=.01) alone. Visual analysis of participants A and I indicate that IMedS intervention decreased both under and over dosing of medication (decreasing variability) and was able to stabilize medication adherence at an optimal level. Participant E's adherence data suggests improvements in trend and level and decreases in variability, but changes did not meet the threshold for statistical significance. Data for participants A, D, and I indicate that the intervention begins to work immediately and that effects persisted for the observed period (about four weeks). Participant C's nonadherence persisted at the same frequency and extent even after intervention indicating that the intervention was not effective for her.

Discussion

The purpose of this small feasibility study is two fold. First, we wanted to determine if the IMedS intervention is worthy of further research. Second, we wanted to identify the characteristics of those who benefited from the intervention to inform future research. We accomplished both objectives.

Intervention Outcomes

Most persons (n=3, 75%) in the occupational therapy group seemed to benefit from the intervention. Occupational therapy significantly improved the medication



Note. The vertical black line indicates the day of the treatment intervention.

adherence of two participants, and one participant demonstrated improvement (but the extent of change failed to meet statistical significance). Participants in the standard care group demonstrated far fewer changes. Most participants either continued their pattern of nonadherence (n=3, 43%) or had worse adherence at after at follow-up (n=2, 29%). Two participants (29%) did demonstrate positive change after the educational session, but only one participant experienced enough change to reach statistical significance. Together, the results indicate that medication adherence can be responsive to occupational therapy intervention, and that occupational therapy positively affected a higher percentage of participants than standard care.

The occupational therapy intervention also demonstrated large effect sizes. For example, Participant A's medication adherence at baseline ranged from 71% to 129%. After intervention, her adherence stabilized at 100% for the length of the intervention phase. Similar results were found for Participant I. Conversely, in the standard care group Participant K's adherence only improved by about 10% and she continued to demonstrate large performance variability into intervention phase. These findings suggest that occupational therapy intervention may have a larger effect size and may produce more consistent results than standard care. This is one of the first findings that support's occupational therapy as an effective intervention for medication nonadherence and supports future research on occupational therapy interventions to promote medication adherence.

Who Benefits?

The other objective from this study is to determine what type of participants benefit from the IMedS intervention. Participants A, D, and I were very different. Their health conditions included arthritis, anxiety, depression, diabetes, human immunodeficiency virus, osteoporosis, and a thyroid disorder. They had a range of eight to 15 daily medications. Participants A, D, and I had a variety of life experiences as well. Their ages ranged from 44 – 70. Of the three participants, one was single, one married, and one widowed. Similarly, one was a high school graduate, one had an associate's degree, and one had a bachelor's degree. The diversity between the participants' experiences indicates that the intervention may potentially work across populations and settings. More research is needed to better identify what populations benefit the most from occupational therapy intervention.

Limitations

The purpose of this study was to understand the limited effectiveness of an occupational therapy intervention for medication nonadherence. While this objective has been accomplished, the data do not yet support generalization of these techniques to the clinic. This article describes the experiences of a non-random sample of 11 people with chronic health conditions. Recruitment resulted in a biased sample of mostly while, female, older adult sample. Future research is needed to determine effectiveness of the intervention on a larger and more representative sample.

Another limitation is the number of persons who withdrew or were found to be ineligible for the study. Despite recruiting 23 individuals, only 11 were appropriate for the single-subject portion of this study. Eight persons screened into the study and were later found to have perfect medication adherence. Thus, these eight individuals were not appropriate for a study on medication nonadherence. Two issues likely caused the recruitment of perfect adherers. First the MMAS, or the screen for medication nonadherence, is highly sensitive (93%) but not very specific (53%), resulting in several false positives (Morisky et al., 2008). Another issue was that participants were asked to record their adherence daily on a calendar. While the intent of the self-monitoring was for data collection, it also served as an intervention. Some perfect adherers reported that they did have issues with medication adherence prior to the study. But, they indicated that writing down their daily medication consumption helped them to remember to take their medications resulting in perfect adherence throughout the study. Future research should better identify research participants.

Despite the limitations, the study methodology included several measures to ensure reliability and validity. The standard care condition was tested over seven phase changes, and the treatment condition was tested over four phase changes. The immediacy of the change experienced by occupational therapy participants, the lack of change in the standard care group, and the consistency of data patterns across people within groups indicate that differences in medication adherence rates were due to the intervention as opposed to some unobserved phenomenon. Further, the blinding of the research participants, the randomization of persons to treatment conditions, and the presence of a standard care group served to improve the internal validity of the study. Together, these aspects of the methodology help to increase the likelihood that future studies will yield similar results.

Implications for Occupational Therapy Practice

The purpose of this feasibility study was to determine if it is possible for occupational therapy to be a solution for medication nonadherence. Not only did the study achieve this objective, but it also provides a foundation for future research in this area. Specifically, we have identified three implications for occupational therapy practice.

- These finding support the research of Sanders & Van Oss (2013) and Schwartz (2015, Chapter 2) in indicating that occupational therapy practitioners can play a role on the medication adherence team. Occupational therapy has the potential improve medication adherence in persons with chronic health conditions.
- All participants in this study lived in the community and were independent in their activities of daily living. As such, it is anticipated that these participants would not typically be referred to or enrolled in occupational therapy services.

The baseline data for many participants, however, demonstrated significant impairments in medication management. The fact that the research participants would not qualify for occupational therapy services while demonstrating significant occupational performance deficits indicates a disconnect between service provision and need. Occupational therapists should consider performance across all daily living activities when making admission and discharge decisions for occupational therapy services.

 The IMedS approach is a manualized occupational therapy intervention. This pilot study reinforces the findings of Blanche, Fogelberg, Diaz, Carlson, & Clark (2011) and supports the effectiveness of manualized occupational therapy interventions.

Conclusion

While occupational therapy practitioners are widely considered experts in occupational performance, the profession has been absent from the research around the occupation of medication management. Based on the profession's expertise, researchers anticipated that occupational therapy could improve medication nonadherence, but little research supported therapists in this role. In this feasibility study, we tested the relationship between occupational therapy intervention and the medication adherence rates of persons with chronic health conditions. Using multiple baseline single-subject design with inter-subject replications, we provide the foundational data to show that occupational therapy can improve medication adherence, and that it is likely more effective than standard care. Medication management is a critical life skill for persons with a chronic health conditions, and occupational therapy practitioners have a role on the

medication team. Further research is needed to define and prepare occupational therapy interventions for medication nonadherence for use in the clinic.

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Chapter 6 - Developing Real and Meaningful Change in Medication Management

Abstract

Objective: In this feasibility study, we determine if occupational therapy can improve medication management in adults with chronic conditions and identify the most effective components of the occupational therapy intervention. Method: Nineteen participants in a two-group, blinded, randomized study described their intervention experiences.

Participants received either an occupational therapy or standard care intervention.

Researchers used a mixed-methods approach to measure the participants' changes in performance and behavior after intervention and to quantify the most effective intervention components. Results: Occupational therapy participants reported greater improvements in performance and implemented twice as many medication management strategies. Participants indicated that the developments of strategies in combination with a caring therapeutic relationship are the active ingredients of the intervention.

Conclusion: Occupational therapy can be a unique and effective intervention for medication nonadherence.

Keywords: Medication Adherence, Occupational Therapy, Chronic Disease, Intervention Studies

Over 66 million persons in the United States with chronic health conditions do not take their medications as prescribed, and they are said to be nonadherent (Centers for Disease Control and Prevention, 2014; Dunear-Jacob et al., 2000; World Health Organization, 2003). Medication adherence is a foundation of chronic disease management. Thus, persons with poor adherence often experience larger declines in health and function (compared to their adherent peers) (Osterberg & Blaschke, 2005; Zullig, Peterson, & Bosworth, 2013). Unfortunately, interventions to help people better manage their medicines are very complicated and not very effective (Nieuwlaat et al., 2014). In this study, we explore a new intervention for medication nonadherence.

Historically, physicians both prescribed and ensured adherence to medications. In current practice, however, many doctors do not have the time or expertise to counsel clients in medication adherence (Ammerman et al., 1993; Meichenbaum & Turk, 1987; World Health Organization, 2003). Researchers are increasingly testing interventions implemented by allied health professionals, as they offer better generalizability to real world situations (Nieuwlaat et al., 2014). Allied health professionals have led complex interventions with promising results. Unfortunately, due to the complexity of the intervention and limitations in the research methodology, it is unclear which aspects of allied health interventions caused the effects. Is the intervention effective because of specific approaches, the professional, or the setting? Allied health professionals need to better identify their unique contributions to complex interventions (Richardson et al., 2014).

In this study, we seek to evaluate the effectiveness of one allied health profession's approach to medication nonadherence – occupational therapy. Occupational

therapy practitioners are highly skilled interventionists that offer many advantages to the medication adherence team. Little research, however, explores the effectiveness of this profession and it's intervention approaches on medication nonadherence (Radomski, 2011; Sanders & Van Oss, 2013; Schwartz, 2015, Chapter 2).

Due to the lack of research in occupational therapy and medication adherence, we began our investigation of occupational therapy interventions for medication nonadherence with a feasibility study. Feasibility studies are the first in a line of research. They serve to identify any issues with the intervention or study methodology and justify the need for further investigation (Gitlin, 2013). While feasibility studies evaluate many components of the study, one important factor is limited effectiveness (Bowen et al., 2009). Limited effectiveness testing asks "is the intervention effective enough to warrant further research?"

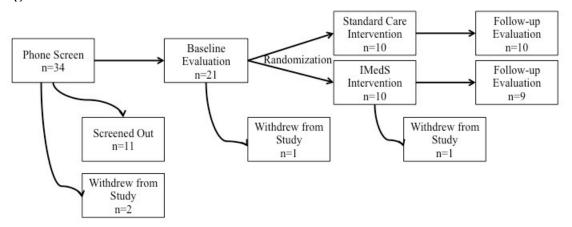
This article is part of a series of studies investigating the feasibility of an occupational therapy intervention to promote medication adherence. Details of other components of the feasibility study have been published elsewhere (Schwartz, 2015, Chapter 5 & 7). The purpose of this article, however, is to understand the experiences of the participants in the study. Specifically, we had two research objectives. First, we wanted to understand the effects of the intervention on the participants. Did participants believe that they benefited from the intervention? Second, we wanted to identify the aspects of the intervention that were most effective. Identifying effective intervention components not only informs future investigations, but also helps to describe the distinct value of occupational therapists on a medication adherence team.

Methods

Research Design

We used a small two-group experimental blinded randomized controlled trial (RCT) to understand the feasibility of an occupational therapy intervention to promote medication adherence. All of the participants received an intervention designed to improve medication adherence. Half of participants engaged in an occupational therapy strategy-based session. The other half of participants received a pamphlet-based educational session designed to simulate standard care. At the end of the study, participants were asked to reflect on their experiences in the study during an exit interview. This study focuses on the participant's experiences (derived from the exit interview). The research procedures can be seen in Figure 6.1. A detailed description of the methods can be found in other articles (Schwartz, 2015, Chapter 5 & 7). We will briefly review the study and describe components unique to the qualitative research questions.

Figure 6.1. Research Process and Enrollment



Participant Selection

We sought to recruit a diverse group of community-dwelling adults with chronic health conditions on a complex medication regimen that demonstrated poor medication adherence. Participants who were unable to travel to the University and those with significant cognitive impairment were excluded from the study.

Study Staff

Senior occupational therapy students were trained as research assistants for this study. The research assistants engaged in rigorous training and testing prior to working with research participants. All research assistants demonstrated good fidelity to the study protocols and good reliability with fellow research assistants in terms of intervention recommendations (Schwartz, 2015, Chapter 4).

Instrumentation

Data for this study derived from two tools. First, participants filled out a demographics questionnaire. The participant indicated his or her health condition(s), age, race, sex, health insurance status, relationship status, and employment status.

At the conclusion of the study, all participants completed a brief semi-structured exit interview. Research assistants used the same semi-structured interview with both the standard care and occupational therapy intervention participants. During the interview, the participants described the success of the intervention in three ways. Researcher asked participants to 1) describe if their ability to take medications has improved, declined, or stayed the same, 2) identify if they had implemented any new strategies for medication management, and 3) indicate if they thought that similar medication adherence services should be offered in their doctor's office. To understand the effective components of the

intervention, researchers asked participants to describe the intervention components they found most helpful. The question route was standardized, but the research assistants were indicated to ask probing questions as needed.

For the duration of the study, all participants self-monitored their daily adherence rate on a calendar. The results of the adherence calendar are discussed elsewhere (Schwartz, 2015, Chapter 5), but some participants discuss their experiences around self-monitoring their adherence rates.

Intervention

As part of a RCT, participants were randomized to receive one of two possible interventions. Half of persons were randomized to the occupational therapy treatment, while the other half received an educational standard care intervention.

Treatment intervention. The treatment intervention was a manualized occupational therapy intervention named <u>Integrative Medication Self-Management</u>
Intervention (IMedS). An occupational therapist developed the IMedS intervention grounded on theory, current practice, and best evidence with the goal of helping persons with chronic health conditions better take their medications (Schwartz, 2015, Chapter 3).

Briefly, the IMedS intervention asks the client and interventionist complete six steps: 1) identify the client's current medications adherence, 2) discuss readiness for change 3) set a medication adherence goal, 4) generate strategies to help the client reach their goal, 5) review plan, 6) trial plan and update as needed. To further increase effectiveness, interventionist use skilled communication approaches throughout the intervention including motivational interviewing, the teach-back method, and therapeutic use of self.

Standard care intervention. The standard care intervention was a pamphlet based educational session. During the intervention, the participant and interventionist reviewed the pamphlet, *Managing Your Medicines: Our Guide to Effective Medication Management* by the American Heart Association (AHA) and the American Stoke Association (ASA), and engaged in active listening (2013). The interventionist was prohibited from providing client-centered recommendations or using skilled therapeutic communication approaches. The pamphlet had many of the same intervention strategies recommended in the IMedS intervention, but the delivery of the information lacked the skilled approached used in the treatment intervention.

Procedures

The research participants had four interactions with the research team: a phone screen, baseline evaluation session, intervention, and follow-up evaluation. The research team paid participants \$20 in gift cards to Walgreens at the conclusion of each face-to-face interaction, for a total of \$60 for persons completing the study.

Recruitment and phone screen. Individuals were recruited through paper and electronic flyers in the community. Interested individuals called the research team to participate in a phone screen based on the inclusion and exclusion criteria. Persons who passed the phone screen were invited to schedule a baseline evaluation appointment.

Baseline data collection. During the baseline data collection session, the participant reviewed and signed the informed consent and completed the baseline evaluation packet of assessments. The session took approximately one hour and occurred either at the participant's home or in a shared lab space at the University.

Randomization. After the baseline evaluation, research participants were adaptively randomized to receive the intervention or standard care condition based on age, gender, and extent of medication nonadherence.

Intervention. The intervention was scheduled two weeks after the baseline evaluation. All interventions occurred in a shared lab space at the University. As randomized, study participants received either the occupational therapy intervention or the standard of care educational session. Both conditions lasted approximately 30 minutes. The participants were blinded to their group assignment, but the research assistants could not be blinded.

Follow-up data collection. Participants were scheduled for follow up one month after intervention. During the hour-long session the participant completed surveys and engaged in an exit interview. The research assistant administering the follow-up and the participant were blinded to the participant's assignment.

Data Analysis

Researchers used a mixed methods approach to analyze the data. Researchers used descriptive statistics to calculate the frequency of perceived improvement, the number of strategies implemented, and the frequency of strategies implemented.

Researchers used the grounded theory methodology described by Corbin & Strauss (2008). The first author of this study, who is an experienced researcher with advanced training in qualitative research procedures, analyzed all transcripts. Using Dedoose 5.2.1, the researcher, identified the general essence of comments through open coding. Then she clarified the relationships between concepts using in axial coding. Throughout the process, the researcher developed memos discussing the relationships

between the data to distill the themes between participant's experiences. From the memo's, themes emerged. This process helped the researchers to identify similarities and differences in experiences within and between groups.

Results

Participants

The research team screened 34 potential participants. Eleven individuals were screened out. Four participants withdrew from the study, resulting in 19 research participants who completed the trial. Figure 6.1 demonstrates enrollment across study phases. Ten participants received the standard care and nine participants received the IMedS intervention. Participants tended to be older, female, and white. All participants were covered by health insurance. Only two participants were employed. The remainder of participants were retired, students, or on disability. Participants often had more than one chronic health condition. Participants assigned the standard care group reported conditions including heart disease (n=6), anxiety (n=4), depression (n=3), arthritis (n=2), asthma (n=2), diabetes (n=1), chronic obstructive pulmonary disease (n=1), and stroke (n=1). Participants assigned to the occupational therapy group reported conditions like arthritis (n=6), diabetes (n=5), depression (n=4) heart disease (n=3), asthma (n=2), anxiety (n=1), human immunodeficiency virus (n=1), osteoporosis (n=1), and stroke (n=1). Demographics by group can be seen in Table 6.1.

Objective 1: Intervention Effectiveness

The success of the intervention was determined foremost by asking the participants if their ability to take and manage their medications has improved, stayed the

Table 6.1. Demographics

| Tuble oil Demographics | Standard Care | | Occupational Therapy | |
|---|---------------|------|----------------------|------|
| | M | (SD) | M | (SD) |
| Age | 56 | 21 | 61 | 11 |
| Number of Daily | | | | |
| Medications | 9 | 3 | 11 | 3 |
| Prescribers | 3 | 1 | 3 | 2 |
| Chronic Health Conditions Morisky Medication | 4 | 3 | 3 | 1 |
| Adherence Survey | 3.70 | 1.70 | 4.22 | 0.67 |
| Short Blessed Test | 2.00 | 2.00 | 0.89 | 1.05 |
| | n | (%) | n | (%) |
| Sex | | | | |
| Female | 7 | 70 | 6 | 67 |
| Race | | | | |
| White | 10 | 100 | 8 | 89 |
| Relationship Status Single/ Divorced/ | | | | |
| Widowed | 7 | 70 | 4 | 44 |
| Married/ In a Relationship | 3 | 30 | 5 | 56 |
| Employment Status | | | | |
| Employed | 1 | 10 | 1 | 11 |
| Unemployed | 1 | 10 | 1 | 11 |
| Student | 2 | 20 | 0 | 0 |
| Retired | 5 | 50 | 4 | 45 |
| Disabled | 1 | 10 | 3 | 33 |

same, or become worse. Fifty-five percent of occupational therapy participants (n=5) indicated that their ability to manage their medications had improved, but only 30% of standard care participants (n=3) felt their performance had improved. The remaining participants indicated that they had stayed the same. No participants reported declines.

Occupational therapy participants also used stronger language to describe their intervention experiences. For example, one standard care participant described that her medication adherence "probably improved" likely because of the "brochure, which was really helpful." Occupational therapy participants used stronger adjectives, revealed

deeper emotions, and often spoke longer. For example, one occupational therapy participant said that her medication adherence had improve because:

I kind of had swayed from taking care of myself the way that I need to in order to stay healthy for myself and for the people that I love. I have a tendency at times to sway off and over take care of other people and not take care of myself, which I almost died doing that a couple of years ago, so you guys brought the alarm back to me to help me, and I really appreciate that. You're going to make me cry. This is a present. Thank you.

Researchers also monitored success by counting the number of reported behavior changes after intervention. During the exit interview, researchers asked participants to describe what new strategies (if any) they use at home to better manage their medications. Sixty-six percent of persons in the occupational therapy group and 40% of persons in the in the standard care group implemented new strategies. On average, occupational therapy participants implemented 2 (*SD*=1) new strategies while standard care participants only implemented one new strategy (*SD*=.84). Persons in the occupational therapy group were able to identify eight different types of strategies that they implemented at home. Persons in the standard care group only identified four types of strategies. Table 6.2 indicates the different types of strategies implemented by participants.

The last indicator of success was if the participant would recommend the services to others. Specifically, the participant was asked if medication management services (like those received during the study) should be a part of regular care at their physician's

Table 6.2. Frequency of New Strategy Implementation by Group

| Strategy | Standard Care | Occupational Therapy |
|---|------------------|-------------------------|
| | n | n |
| Use a New Pillbox | 2 | 2 |
| Set an Alarm | 0 | 3 |
| Change Medication Storage Location | 0 | 3 |
| Talk to Pharmacist | 0 | 2 |
| Self-Monitor with Calendar | 1 | 1 |
| Talk to Physician | 0 | 1 |
| Develop Medication List | 0 | 1 |
| Use a Smartphone App | 0 | 1 |
| Maintain Separation Between Old and New Pills | 1 | 0 |
| Review medication documentation | 1 | 0 |

office. All participants in the occupational therapy group and 90% of participants in the standard care group indicated that additional services would be beneficial.

Participants often went on to give further information about need for medication adherence services that is valuable for future practice and research. Many participants indicated that services may not be appropriate for everyone, but thought that services may be particularly helpful to older adults, persons on a number of medications, persons on new medications, or persons with a record of poor adherence. The one participant who would not recommend services indicated "the doctor-patient relationship is special and so far I'm satisfied with the interaction between most of my doctors." However, several participants noted a more acute need for services. For example, when asked if services should be offered in clinics, a different participant responded "Yes that would be great because they never ask if you are taking your pills on time, or where you keep them, or what's going on with your medication. They never ask that. My doctors don't." Most participants see a need for additional medication adherence services in traditional practice settings and would recommend the intervention they received to other people.

Objective 2: Effective Intervention Components

Standard care. Persons in the standard care group identified six different aspects of their intervention that they found to be effective: awareness, being listened to, information, caring, feedback, and validation. Most participants reported being more aware of medications. For example, one reported that the process "just makes you more cognizant of your medication and when you're taking that medication." Participants also reported that they enjoyed being "able to tell stories and being able to talk about... experiences." Further, participants liked interactions with the caring staff saying that the research assistants were "nice, respectful, and interested." All persons in the standard care group received the pamphlet, but only three persons commented about the "helpful information." As part of the study, all participants recorded their daily adherence to medications. Two participants felt that feedback they received by recording their adherence was helpful. Finally, one person described feeling validated as the process "reinforced a lot of what I was doing."

Three individuals reported that they did not find any aspects of the intervention helpful. For example, the participants said, "I don't feel like there was any kind of intervention" or "I didn't hear anything I didn't know already." Table 6.3 indicates the intervention components noted by the participants.

Occupational therapy intervention. Persons who received the IMedS intervention described five constructive intervention components: strategies, caring staff, awareness, feedback, and validation. Most participants described how the research assistant helped them to "develop solutions to the problems." Participants then went on to describe the different strategies they had discovered such as alarms, different types of

pillboxes, etc. Intervention participants also noted the caring staff, but often to a larger extent than the standard care participants. For example, one participant described:

I think the personal conversation was always helpful. It takes it from the institutional level – and let's not smile, and let's not be in the moment, let's just get the job done and move on – that's not me. It's a quality of life issue, it is, it's called caring. It's beyond the project. It takes so little to do that, and it's so important. Similarly to the standard care participants, the occupational therapy participants also believed that the intervention helped them to become more aware of their medication routine, to better self-monitor their adherence, and to feel validated about their current

Table 6.3. Effective Intervention Components Verbalized by Participants

therapy participants.

routines. Table 6.3 also shows intervention components noted by the occupational

| Intervention Component | Standard Care | Occupational Therapy |
|--|------------------|-------------------------|
| | n | n |
| Strategies for medication management | 0 | 6 |
| Caring staff | 2 | 5 |
| Awareness to the importance of medication management | 8 | 4 |
| Feedback about medication adherence | 2 | 2 |
| Validation regarding current management strategies | 1 | 2 |
| Being listened to | 3 | 0 |
| Information about medication management | 3 | 0 |
| No effective intervention components | 3 | 0 |

Discussion

In this study, we explored the effects of a medication adherence intervention on the experiences of 19 persons with chronic health conditions and medication nonadherence. During the study, half of the participants (n=10) received a pamphlet-based educational session designed to simulate standard care. The other half of

participants (n=9) received a manualized occupational therapy intervention called IMedS. Researchers had two objectives 1) to understand the effects of an occupational therapy intervention in persons with medication nonadherence, 2) to identify the active intervention ingredients of the intervention that the participants find effective. Researchers used mixed methods to compared participant experiences between groups to elucidate the extent and content of differences.

Intervention Effectiveness

The occupational therapy group demonstrated greater improvements across all measures of intervention effectiveness. Occupational therapy participants were more likely to perceive improvements in performance and implement new medication management strategies at home. On average, occupational therapy participants implemented twice as many strategies as persons in the standard care group, and the strategies represented a greater variety of approaches. Occupational therapy participants also reported stronger more meaningful changes. Occupational therapy intervention demonstrated improvements in both participant performance and behavior indicating better outcomes than standard care.

Researchers also investigated the participants perceived value of the intervention.

Researchers asked participants if they thought their doctor should offer similar medication adherence services in their office. Ninety-five percent of all participants agreed that additional services would be beneficial. Several participants indicated a more extensive need, indicating that their health care providers do not ask about medication adherence or review strategies for medication management. Participants across groups

identified that medication adherence is an important topic worthy of more attention, and that both the intervention and standard care conditions helped to fill this gap.

Active Ingredients

Researchers sought to identify the active and unique ingredients of the occupational therapy intervention. During the exit interview, participants described what intervention components they found to be most helpful. Researchers discovered that participants described seven different types of intervention components. Within both groups, participants identified that awareness to medication management, feedback from self-monitoring, and validation about their current routines helped them to better manage their medications.

The biggest difference between groups was the role of strategies vs information. In the standard care group, three participants described the helpful the information in the pamphlet. Occupational therapy participants did not comment on information, but rather described the strategies that they developed with the research assistant. Because the role of information versus strategies is one of the largest differences between the groups, we believe that strategies may be one factor driving the increased effectiveness of the occupational therapy intervention. The occupational therapy participants greater gains indicate that helping people to develop their own ideas is likely a more effective approach than giving clients the information directly.

The second largest difference in experiences between groups was the concept of caring. Participants in both groups described the research assistant as being a helpful component of the intervention, but participants described the staff to different extents.

Two people in the standard care group identified the staff, but used terms like

"knowledgeable," "respectful," and "nice." Over half of the participants in the occupational therapy group mentioned the research assistant as an active ingredient. When occupational therapy participants talked about the research assistant they used stronger language such as "truly interested in helping." Occupational therapy participants often described a specific situation where they perceived a research assistant to go above and beyond expectations. Why did the occupational therapy participants group feel like they received better care? We attribute the difference to the skilled therapeutic communication techniques. In occupational therapy sessions, research assistants used motivational interviewing, therapeutic use of self, etc., which resulted in a client-driven experience w. We believe that participant's noted the question asking and client-centeredness and perceived research assistants to be more interested and involved in their care.

Finally, three participants in the standard care group were unable to identify any active intervention ingredients, stating that they did not perceive any type of intervention or that they did not learn any new information. Standard care participants perceived lack of intervention further indicates that the standard of care is not very effective.

Limitations

This study describes the experiences of a non-random sample of 19 individuals with chronic health conditions. Therefore, the results cannot be easily generalized to other individuals or settings. Further, the sample demonstrated disparities in terms of race, sex, and insurance status as participants tended to be mostly white, female, and insured.

Despite the sampling biases, the participants provide a good series of case studies for pilot work in this area. Most participants had mutiple (mean=4) common chronic conditions such as heart disease, arthritis, diabetes, and stroke. We were also able to include the perspectives of a few individuals with rare conditions. Overall, the participants had complicated health histories, common of many occupational therapy clients. The participants' experiences as persons with multiple physical and mental health conditions are consistent with current figures of chronic disease in the United States and provide a indication of how the intervention will preform across diagnostic categories (Centers for Disease Control and Prevention, 2014).

Participants also demonstrated a good series of case studies across the lifespan. Medication adherence research often focuses on older adults, but the participants in this study enrolled from a variety of life stages. While the average age was 58 years old, participant's ages ranged from 22 to 80. Therefore, the study represents the views of college students, seniors, and people in between.

The other limitation of this study is the risk for bias. The participant and the research assistant conducting the exit interview were blinded to the participant's group assignment. The research assistant delivering the intervention, however, was unable to be blinded introducing a risk of bias. To manage the risk, all the research assistants received the same training, used similar scripted introduction and conclusions, and engaged with a combination of treatment and standard care participants. Further, both interventions were heavily manualized. All research assistant/participant interactions were video recorded and monitored for fidelity. These protections helped to mitigate the risk and ensure that differences were due to the intervention.

Implications for Occupational Therapy Practice

This study is one of the first exploring occupational therapy interventions supporting medication adherence. As such, the findings of this study have implications for occupational therapy practice, chronic disease management, medication management, and general practice concepts.

- Occupational therapy intervention can improve medication management in adults with chronic health conditions.
- Occupational therapy intervention helps clients self-generate a larger and more diverse set of strategies remediate occupational performance deficits.
- Therapeutic communication techniques (e.g. motivational interviewing and therapeutic use of self) can help clients engage in meaningful changes in health behavior.
- Clients may demonstrate better outcomes when they perceived a caring relationship with their health care professionals.
- Clients who self-generated intervention strategies were more likely to implement them at home.

Conclusion

Many persons with chronic health conditions fail to live healthy productive lives because of the consequences of medication nonadherence. Occupational therapy practitioners possess the opportunity to improve client's medication adherence. By developing a caring relationship, using therapeutic communication techniques, and helping clients to self-generate strategies, occupational therapy practitioners can develop real meaningful change in their client's health behaviors.

The medication adherence field combines the expertise of many health care professionals. Are occupational therapy services needed in this well-studied and crowded field? Absolutely. The occupational therapy participants not only demonstrated greater improvements than persons receiving standard care, but also they indicated that the strength of the intervention derived from the profession's expertise in daily occupation. In the end, one participant describes it best. She not only indicates why the intervention worked for her, but she also describes the important role of occupational therapy in medication nonadherence:

Because sometimes you do things sort of automatically, like taking pills – that gets pretty automatic after a while, and you forget there are all kinds of things you might be overlooking because you are so familiar with it. I think the questions I was asked made me think about, wait a second, you could do something different here.

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Chapter 7 - Feasibility Analysis of an Occupational Therapy Intervention
Promoting Medication Adherence

Abstract

Millions of Americans are affected by chronic health conditions and would benefit from occupational therapy chronic disease management services. Unfortunately, there is little literature supporting occupational therapists in this role. The purpose of this study is to evaluate the feasibility of an occupational therapy self-management intervention to promote medication adherence. We conducted a small randomized controlled trial on an on an occupational therapy self-management intervention. In this article, we analyze the acceptability, demand, implementation, practicality, adaptation, integration, expansion, and limited efficacy of the intervention. By reviewing the study against these eight criteria, we determine if the intervention is worthy of further research and identify the changes needed for future studies. This study informs research across the occupational therapy, medication adherence, and chronic disease management fields.

Keywords: Medication Adherence, Occupational Therapy, Research Methodology

Chronic health conditions affect 133 million Americans and are the leading cause of death and disability in the United States (Centers for Disease Control and Prevention, 2014). Given the growing needs of this population, occupational therapy practitioners must be prepared to not only address the disability resulting from chronic disease, but also to offer self-management interventions (Richardson et al., 2014). Unfortunately, there are few supports for occupational therapists in chronic disease management. A recent scoping review by Richardson et al. (2014) found only ten articles describing occupational therapist led self-management interventions (in the Medline, CINAHL, Cochrane, and REHABDATA databases combined). There is an urgent need to increase the number of chronic disease self-management interventions (Grady, 2011).

Gitlin (2013) estimates that a new intervention requires 17 or more years to become practice in the clinic. Unfortunately, the profession does not have that amount of time to develop new research. Given the immense research needs, the time sensitivity, and the limited supply of occupational therapy researchers, the profession must better share information about self-management intervention (and subsequent research methodology) through discussions at professional meetings and in publications.

Purpose

The purpose of this study is to provide a feasibility analysis of a new occupational therapy self-management intervention. In the article, we will critique both the intervention and the research methodology. By sharing our findings, we hope to inform the research of other investigators working in chronic disease self-management, while also improving our own research program to more quickly and fastidiously bring the self-management through the phases of research (and closer to practice).

This article has five components. First, we will begin by discussing the concept of feasibility and identifying our criteria for analysis. Second, we will briefly describe the self-management intervention. Third, we will discuss the feasibility study methodology. Fourth, we will discuss the feasibility data results we were able to collect throughout the study. Finally, we will discuss our findings. Through this process we seek to answer three questions: 1) should this line of research continue? 2) what changes are needed to the intervention? and 3) what changes are needed to the research methodology.

Feasibility

Feasibility studies "determine whether an intervention is appropriate for further testing" (Bowen et al., 2009, p.2). They provide a quick and easy way for researchers to decide if they should continue along a line of research or abandon a research question and try a new idea. Additionally, feasibility studies also help researchers to tweak their intervention and research methodologies with the hopes of improving studies prior to larger more expensive investigations.

Feasibility studies can be very informative for researchers advancing through the phases of research. Bowen et al. (2009) developed criteria for analyzing feasibility studies during research funded by the National Cancer Institute. I will evaluate the feasibility of the medication adherence study using these criteria. Because cancer research is often characterized by a combination of behavioral and medical interventions implemented by a variety of health professionals, I anticipated that these criteria would translate well to an occupational therapy intervention. Bowen et al. (2009) suggest that the success of a feasibility study can be measured on eight criteria:

1. Acceptability – How participants react to the intervention

- 2. Demand Estimated use of an intervention in traditional practice
- Implementation The extent to which an intervention is implemented as planned
- 4. Practicality How well an intervention may be administered with limited resources
- 5. Adaptation Ability of the intervention to be administered with different populations or setting
- Integration The level of fit of the intervention with current practice settings
- 7. Expansion Ability of the intervention to grow
- 8. Limited efficacy Identifies if the intervention can work

Self-Management Intervention

This study investigated the feasibility of the Integrative Medication Self-Management (IMedS) intervention. The purpose of IMedS intervention is to help adults with chronic health conditions better manage their medications. The intervention was designed by an occupational therapist for use by other occupational therapy practitoners across the continuum of care. The intervention is evidence-based as it was developed with a foundation in theory, current practice, and best evidence (Schwartz, 2015, Chapter 3). IMedS has been manualized to enable consistent training and delivery across interventionist

The IMedS process consists of one evaluation session and one intervention. In the evaluation, the interventionist conducts an occupational profile around the client's medication routines. Then the client engages in a simulated medication sorting task.

Finally, the client describes his or her medication regimen describing each medication, dosing instructions, medication purpose, etc.

The interventionist then uses the evaluation information to then conduct the six-step intervention process. During the intervention the client and interventionist 1) identify the client's current medications adherence, 2) discuss readiness for change, 3) set a medication adherence goal, 4) generate strategies to help the client reach their goal, 5) review plan, 6) trial plan and update as needed. Throughout the process, the interventionists use skilled approaches such as tailoring, motivational interviewing, therapeutic use of self, and the teach-back method throughout the intervention. Each client experiences the same process, but the specific discussion points in the intervention are client centered based on the persons wants and needs.

Methodology

Study Design

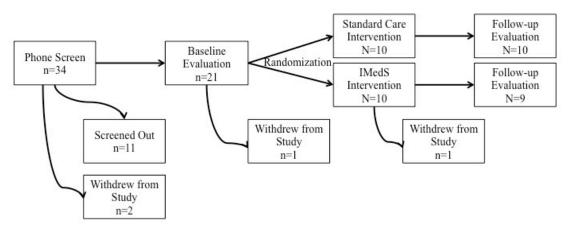
We tested the IMedS intervention in small two-group experimental blind pre-post randomized controlled trial. Half of the participants (n=10) received the IMedS intervention. Half (n=10) received a pamphlet based educational session designed to simulate the standard of care. The study design is depicted in Figure 7.1.

Participants

This feasibility study features two types of participants, persons with chronic health conditions and research assistants.

Persons with chronic health conditions. The research subjects (i.e. participants) for this study were community-dwelling adults with a chronic health conditions and poor

Figure 7.1. Research Procedures



medication adherence who were independently living managing their own medications.

Persons unable to travel to the University and persons with significant cognitive impairment were excluded from the study.

Research assistants. The research assistants (RAs) also provided data for this feasibility study. Senior occupational therapy students were invited to participate as RAs in this study. The RAs engaged in training, testing, and implementing the study procedures (Schwartz, 2014, Chapter 4).

Procedures

Participants had four interactions with the research team: 1) phone screen, 2) baseline evaluation, 3) intervention, and 4) follow-up evaluation. The participants were blinded throughout the experience. The RAs conducting the screen, baseline, and follow-up evaluation were blind to the participant's group assignment. Participants received one \$20 gift card per face-to-face interaction. RAs received independent study credit.

Interested participants called the research team to participate in a phone screen. Eligible participants were scheduled for a baseline evaluation.

The baseline evaluation occurred either at the University or in the participant's home (at the participant's discretion). The evaluation lasted approximately one hour and included the demographics survey, an assessment battery, and an interview regarding medication management practices. Also, the participant was trained on using an adherence calendar. The participant was asked to keep an adherence calendar, where he or she writes down the number pills consumed each day.

Participants were scheduled for intervention two weeks after the baseline. The person received either the standard care or IMedS intervention. Both interventions lasted 30 minutes and occurred in a lab at the University.

Participants were instructed to schedule a follow-up evaluation one month after their intervention. At the follow-up evaluation, participants returned their medication calendar, completed the same battery of assessments (as baseline), and participated in an exit interview.

After all participants had completed the study, the RAs completed an anonymous exit survey with the PI.

Instrumentation Measuring Feasibility

Researchers used a mixed-methods approach to understand the feasibility of the IMedS intervention study. They used four different types of instrumentation, 1) demographics, 2) participant outcomes, 3) RA outcomes, and 4) logistical measures. Table 8.1 indicates the measures used to evaluate the different feasibility criteria.

Demographics. Participants completed a demographics survey identifying their race, sex, health insurance status, employment status, relationship status, and medical diagnoses.

Table 8.1. Eight Feasibility Criteria and Measurement

| Criteria | Measurement |
|----------------|--|
| Implementation | Number of participants completing the study Appropriateness of recruited participants |
| | Dropout rateDemographic equality |
| Acceptability | Participant's perceived helpfulness of the intervention RA's satisfaction with the intervention |
| Demand | Participant's perceived need for services in their doctor's office |
| | • RA's future use of the intervention |
| Practicality | Ability to recruit Cost of implementation Participant's ability to self-monitor adherence Participant's ability to bring materials to evaluation sessions Participant's implementation of the intervention at home |
| Adaptation | Anticipated outcomes with other populations and settings |
| Integration | Perceived fit with general occupational therapy practice patterns |
| Expansion | Fit with current health care cultureAnticipated disruption due to expansion |
| Efficacy | Participant's changes to medication adherence rates Participant's perceived effectiveness RA's perceived effectiveness |

Note. RA= Research Assistant.

Participant Outcomes. Participants indicated their outcomes in two ways. First, they recorded their daily medication adherence on a calendar. Researchers used the calendar to measure how the participant's daily adherence changed after the intervention. Results from the participants medication calendar is discussed elsewhere (Schwartz, 2015, Chapter 5). At the conclusion of the study, participants also engaged in an exit

interview. All participants were asked the same questions regardless of group assignment.

RAs asked the participants the following questions:

- Since you met with us last time, have your started using any new strategies to help you manage your medications?
- Do you think your meetings with the research team were helpful?
- Do you think your ability to take your medications has improved, stayed the same, or declined?
- You had your meeting about medications as part of a research study. Do you
 think your doctor should offer services like these in his office?

Research assistant. At the end of the study, the RAs completed an anonymous 46-question exit survey on the computer. The survey presented statements, and the RAs had to describe their agreement with the statement using a five-point Likert-type scale from strongly disagree to strongly agree. RAs answered questions about the quality of the RA training, the quality of the interventions, and their learning experience. RAs' experiences are further addressed elsewhere (Schwartz, 2015, Chapter 4). For this study, we looked at the RAs responses to the following questions:

- I will use some of these assessment tools in my practice when I work with adults with chronic health conditions.
- I will use some of these intervention techniques in my practice when I work with adults with chronic health conditions.
- I believe that my occupational therapy interventions helped my clients better manage their medications.

- I believe that my standard care interventions helped my clients better manage their medications.
- I am satisfied with the quality of the treatment interventions I administered.

Logistical metrics. The research team also collected logistical metrics around enrollment and participant activities. Researchers tracked the length of the enrollment (in days), the number of persons enrolled, and the number of persons who dropped out. Researchers also measured the number of people who were able to track their daily medication adherence for the length of the study and remembered to bring their medications to the University for the baseline evaluation.

Results

Participants, Implementation, Adaptation

The research team screened 34 potential participants. Eleven individuals were screened out. Nine people (82%) screened out of the study because their medication adherence was too high according to the MMAS. Two people (18%) screened out of the study because their daily medication regimen consisted of less than five medications a day. Four participants withdrew from the study, resulting in 19 research participants who completed the trial. Figure 8.1 demonstrates enrollment across study phases. Table 8.2 describes the demographics of participants who dropped out or who were screened out. Ten participants received the standard care and nine participants received the IMedS intervention. Participants tended to be older, female, and white. All participants were covered by health insurance. Only two participants were employed. The remainder of participants were mostly retired, students, or on disability. Participants often had more than one chronic health condition. Participants assigned the standard care group reported

| Table 8.2. Demographics of Dropped Out and Screened Out Participants | | | | | | | |
|--|-------------|------|--------------|------|--|--|--|
| | Dropped Out | | Screened Out | | | | |
| | M | (SD) | M | (SD) | | | |
| Age | 47 | 28 | 68 | 11 | | | |
| Morisky Medication | | | | | | | |
| Adherence Survey | 4.5 | 1.73 | | | | | |
| | n | % | n | % | | | |
| Sex | | | | | | | |
| Female | 2 | 50 | 5 | 45 | | | |
| Race | | | | | | | |
| White | 4 | 100 | 10 | 91 | | | |

Table 8.2. Demographics of Dropped Out and Screened Out Participants

conditions including heart disease (n=6), anxiety (n=4), depression (n=3), arthritis (n=2), asthma (n=2), diabetes (n=1), chronic obstructive pulmonary disease (n=1), and stroke (n=1). Participants assigned to the occupational therapy group reported conditions including arthritis (n=6), diabetes (n=5), depression (n=4) heart disease (n=3), asthma (n=2), anxiety (n=1), human immunodeficiency virus (n=1), osteoporosis (n=1), and stroke (n=1). Demographics by group can be seen in Table 8.3.

At the end of the study, researchers identified a group of individuals who were not appropriate for this study on medication nonadherence. Despite the use of the MMAS to identify persons with medication nonadherence, eight participants reported perfect adherence to their medications everyday for the duration of the six-week study. Participants tended to be older and male compared to the true nonadherent participants (Table 8.4). Adherent participants had similar health conditions, race, number of medications, and score on the MMAS. By chance, more adherent participants were randomized to receive the occupational therapy intervention.

Table 8.3. Demographics of Participants Completing the Study

| | Standard Care | | Occupational Therapy | |
|----------------------------|---------------|------|----------------------|------|
| | M | (SD) | M | (SD) |
| Age | 56 | 21 | 61 | 11 |
| Number of Daily | | | | |
| Medications | 9 | 3 | 11 | 3 |
| Prescribers | 3 | 1 | 3 | 2 |
| Chronic Health Conditions | 4 | 3 | 3 | 1 |
| Morisky Medication | | | | |
| Adherence Survey | 3.70 | 1.70 | 4.22 | 0.67 |
| Short Blessed Test | 2.00 | 2.00 | 0.89 | 1.05 |
| | n | (%) | n | (%) |
| Sex | | | | |
| Female | 7 | 70 | 6 | 67 |
| Race | | | | |
| White | 10 | 100 | 8 | 89 |
| Relationship Status | | | | |
| Single/ Divorced/ Widowed | 7 | 70 | 4 | 44 |
| Married/ In a Relationship | 3 | 30 | 5 | 56 |
| Employment Status | | | | |
| Employed | 1 | 10 | 1 | 11 |
| Unemployed | 1 | 10 | 1 | 11 |
| Student | 2 | 20 | 0 | 0 |
| Retired | 5 | 50 | 4 | 45 |
| Disabled | 1 | 10 | 3 | 33 |

Acceptability

Both the participants and the research participants reported the intervention to be acceptable. Eight persons in the occupational therapy group (88%) and nine persons in the standard care group (90%) found the medication adherence intervention to be helpful. Similarly, five of the RAs (83%) reported that they were satisfied with the quality of the IMedS intervention.

Table 8.4. Demographics of Adherent Participants

| <u> </u> | M | (SD) |
|------------------------------|------|------|
| Age | 65 | 9 |
| Number of Daily Medications | 11 | 3 |
| Prescribers | 3 | 1 |
| Chronic Health Conditions | 3 | 1 |
| Morisky Medication Adherence | 4.25 | 1.16 |
| Survey | 4.23 | 1.10 |
| Short Blessed Test | 1.5 | 2 |
| | n | (%) |
| Group Assignment | | |
| Occupational Therapy | 5 | 63 |
| Standard Care | 3 | 37 |
| Sex | | |
| Female | 2 | 25 |
| Race | | |
| White | 8 | 100 |
| Relationship Status | | |
| Single/ Divorced/ Widowed | 3 | 38 |
| Married/ In a Relationship | 5 | 62 |
| Employment Status | | |
| Employed | 0 | 0 |
| Unemployed | 1 | 13 |
| Student | 0 | 0 |
| Retired | 6 | 75 |
| Disabled | 1 | 13 |

Demand

Participants perceived a demand for medication adherence services in their doctors' offices. In the occupational therapy group, 100% of participants thought that their doctor should offer occupational therapy medication adherence services. Ninety percent of persons in the standard care group (n=9) thought that their doctor should offer medication adherence educational services in their office.

The RAs believed that they would use the skills learned during the IMedS training in the future. Specifically, all of the RAs reported that they would use the assessment

tools the intervention approaches they learned in their future practice as occupational therapists.

Practicality

Recruitment. The research team easily found participants with chronic health conditions on many medications in the Milwaukee metropolitan area. The research team would have liked to recruit more participants but were limited by the laboratory space, RA availability, and administrative support. The laboratory space could only accommodate one participant at a time. Issues arose when participants arrived late or early for their appointment and the lab space was in use by another participant. The research team also had a limited data collection tools including video cameras, voice recorder, and tripods. Because the RAs were students, they had to schedule participants around their work and school schedule. Finally, while each participant only spent about two to three hours engaging in study activities, there was a high administrative burden for each participant. Every participant required additional time and efforts for scheduling, reminder phone calls, data entry, transcription, file management, etc.

Cost. The main costs for the study were PI time, participant reimbursement, and transcription services. The PI spent \$1,200 on participant reimbursement. The RAs volunteered their time and were reimbursed with one credit hour of independent study. A professional transcribed all interviews for \$230. Finally, the PI completed the study design, preparation, administration, data analysis, and write-up with intermural fellowship funding of \$16,500. Therefore, the total cost of the study was \$17,930.

Participant engagement. Prior to the study, the researchers were concerned that the participants would not fully participate in the study, resulting in lost data or

intervention effectiveness. Therefore, the research team monitored participant's ability to self-monitor adherence, to bring medications to evaluation session, and to implement intervention strategies at home.

All of the participants who completed the study were able to track their daily medication adherence and return their medication calendar to the research team. Some participants did forget, but were able to return the calendar later by mail or fax. Two participants had missing data on their calendar, or days where they just forgot to record their medication adherence.

A few participants had difficulty remembering to bring their medications to the evaluation sessions. At the baseline evaluation, three of 21 participants failed to bring their medications to the session. At the follow-up evaluation, two of 19 participants forgot to bring their medications to the session. The two participants who forgot their medications at follow-up were also two of the people who forgot at baseline.

Finally, researchers looked at the ability of participants to implement strategies at home. The IMedS intervention asks participants to think of new strategies to better manage their medications and then to trial them at home. Five participants (67%) in the IMedS group did implement new strategies at home. Two of the three participants that did not implement any strategies, however, reported perfect medication adherence at baseline on their medication adherence calendar.

Efficacy

Over half of the participants who received the IMedS intervention (n=5, 55%) reported that their ability to manage their medications had improved. Only three people

who received standard care (30%) believed that their ability to manage medications had improved.

For the RAs, five (83%) agreed or strongly agreed that the IMedS intervention improved their clients' medication management abilities. For the standard care, five of the research assistants felt neutral about the effectiveness of the intervention. One research assistant believed that the standard care was ineffective.

Discussion

The purpose of this study was to explore the feasibility of the IMedS intervention study. Specifically, we wanted to determine if the IMedS research line should continue and what changes are needed to support future more rigerous studies. In this section, we will analyze all eight criteria indicated by Bowen et al. (2009) and discuss implications for future studies including changes needed to the intervention and the methodology.

Implementation

Researchers successfully implemented two-group experimental blind pre-post randomized controlled trial on an occupational therapy intervention to promote medication adherence. The research team successfully recruited 23 people with chronic health conditions on five or more medications a day over the course of two months. Nineteen people were able to complete the study, indicating a retention rate of 83%. No large biases were noted in the group of people who were screened out or dropped out. Individuals who were screened out were similar to study participants on all metrics except medication adherence measured by the MMAS. Most people failed the screen because they were too adherent to their medications. Persons who dropped out were evenly distributed between sex and age groups and included people across the spectrum

of adherence. Researchers were able to successfully find participants and keep them in the study.

Researcher found one large implementation issue. Eight participants (42% of those completing the study) demonstrated perfect adherence to their medications on their daily adherence calendar, despite qualifying for a study on medication nonadherence. Adherent participants tended to be older and male. Surprisingly, the average adherence rate for adherent participants on the MMAS was 4.25 (*SD*=1). Any score less than six indicates significant nonadherence.

Unfortunately the poor targeting of participants suggests that changes should be made to both the intervention and the research methodogy. The MMAS did not have the specificity needed to correctly identify the sample. Also, having participants self monitor their adherence resulted in inflated adherence levels. Both the intervention manual and the research procedures would benefit from more stringent criteria regarding identifying the participants that are appropriate for this study.

Acceptability

Persons in the standard care and occupational therapy groups found the intervention to be acceptable. All but two participants found the interventions to be helpful. Most research assistants (83%) were satisfied with the IMedS intervention. All groups were satisfied with the intervention and no participants indicated dissatisfaction. This supports the continuation of IMedS research. No changes are indicated to the manual or research methodology to meet acceptability demands.

Demand

One of the most important aspects is the perceived demand for services. If participants do not think that the intervention topic is important, it does not matter how effective or how satisfying participants find their experiences. Fortunately, the participants and RAs identified a high demand for services. Ninety-five percent of all participants believed that their doctor should offer additional medication adherence services in his or her office. This indicates that all participants, regardless of group, understand the importance of medication adherence and believe that additional services could be beneficial.

Similarly, all of the RAs believe that they will continue to use the evaluation and intervention techniques they learned in the IMedS training, as they transition to practice. This indicates that the RAs also perceive the need for medication adherence services.

Demand for the intervention is a strength of the IMedS intervention and supports continued research. Demand does not indicate changes to the manual or research methodology.

Practicality

Practicality indicates how well an intervention can be delivered with limited resources. In this study, the researchers addressed practicality by measuring issues around recruitment, cost, and participant's ability to fully participate in the intervention.

The research team was easily able to recruit participants with chronic health conditions on several medications. The main restrictions to the size of the study were due to limitations in infrastructure (e.g. cameras and facility space) and administrative support. The size was also limited by the availability of the six student RAs.

The study was completed in a very cost efficient manner. The total cost of the study was \$17,930. Participants were motivated by receiving \$20 in gift cards per visit.

This research study had a high workload for the participants. The research team was concerned about participant's ability to successfully complete all research activities. During the study, participants were asked to track their daily medication adherence on a calendar, bring in their medications to the first and last session, and implement new medication management strategies at home. All of the participants that completed the study turned in their medication calendar, and only two participants had missing data. Two participants were unable to bring in their medications to evaluation sessions, which resulted in lost data. Most of the participants in the IMedS group (67%) did return home to implement new medication adherence strategies. Most of the participants who enrolled in the study were able to manage the home workload. Unfortunatley, a few participants consistently failed to complete requested study activities.

The research team was able to conduct this study on very limited resources, indicating that the cost of IMedS is feasible for future studies. We experienced several practicality issues around the research procedures. The research team struggled around a lack of infrastructure. Future investigations would benefit from additional RAs, administrative support, funding, and time flexibility. These issues are easily ameliorated with additional funding. Issues were also noted with the high workload on participants. Future studies should consider discontinuing participants who consistently fail to complete study related activities at home or changing research methodologies to decrease the participant's workload. No practicality changes are needed to the intervention manual.

Adaptation

Adaptation indicates how well an intervention will translate to other people or settings. Unfortunately, this study sample was very homogenous. Participants were 90% white, 68% female, and tended to be older adults. Future studies may experience different results or barriers when the study procedures are implemented on more diverse individuals.

While the study is weakened due to lack of diversity in sex, age, and race, the study is strengthened by the diversity of health conditions. Persons with many types of health conditions were represented. Most participants had more than one health condition, and saw several doctors to manage their condition. Participants in this study consisted of many "typical" people with chronic health conditions and comorbid conditions. The participants' diversity of health care experiences suggests that the intervention would perform in a similar manner across health populations.

Issues in adaptation suggest changes for the research methodology. Future studies should focus on recruiting a more diverse and representative sample by altering recruitment materials and recruitment strategies. Currently, no changes are indicated to the manual to adapt it to larger or other populations, but researchers should monitor cultural sensitivity of the intervention as it is trialed on more diverse groups. Easy adaptation supports continued IMedS research.

Integration

Integration describes how well the intervention fits within current occupational therapy practice patterns. Medication adherence is a core part of occupational therapy practice (Schwartz, 2015, Chapter 2). Over 90% of occupational therapists engage in

medication adherence evaluation and intervention from time-to-time (Schwartz, 2015, Chapter 2). Therefore, the content of the intervention is consistent with current occupational therapy practice.

Logistically, the intervention is also a good fit for current occupational therapy practice. The IMedS intervention was thoughtfully developed to ensure good external validity. When developing the IMedS intervention, the developer surveyed 70 and interviewed eight occupational therapists about their standard medication management practices (Schwartz, 2015, Chapter 3). The research team then designed the intervention to meet practitioner's needs.

The IMedS process consists of one evaluation and one intervention session.

Therapists across the continuum of care often have two visits or more visits. The intervention is thirty minutes in length and could easily be applied in a short interactions (e.g. acute care) or as part of a longer session (e.g. inpatient rehabilitation). Finally, the IMedS intervention does not use many physical tools, so it is inexpensive and easy to implement.

Finally, helping clients better manage their medications is a billable service. Participants received an occupational therapy evaluation and 30 minutes of occupational therapy intervention. According to the Physician Fee Schedule for the State of Wisconsin (where the study was implemented), occupational therapists could bill one unit of occupational therapy evaluation (for \$57.76) and two units of Self Care/ Home Management Training (for 18.87 x 2 = \$37.74) for this intervention (Wisconsin Department of Health Services, 2015). Because this service is billable, the intervention is consistent with current systems and procedures.

Integration with current practice is a strength of the IMedS intervention and supports further research. Currently, no changes are indicated to the research methodology or manual to integrate the intervention with current practice. Future investigations, however, should trial the intervention in more realistic practice settings and adjust as necessary.

Expansion

While integration focuses on how well the intervention fits within the profession of occupational therapy, expansion questions how well the intervention fits within the health care system. Passed in 2010, the Affordable Care Act (ACA) seeks to improve health and reduce hospitalizations (ACA; Pub. L. 111-148). When occupational therapists provide medication adherence interventions, it is anticipated that they help people to stay healthy and out of the hospital. Therefore, services like IMedS are consistent with the goals of the current health care environment (Fisher & Friesema, 2013; Roberts & Robinson, 2014).

Expansion also investigates how well the intervention can be expanded to serve clients on a larger scale. The IMedS intervention is anticipated to be able to grow with few limitations for three reasons. First, the IMedS training consists of independent study of the manual and online quizzes. Therefore, it would be easy to train more interventionist while maintaining a similar level of quality. Second, because the IMedS intervention was developed based on current practice and designed to ensure good external validity, the intervention should easily transition into current practice. Finally, there are over 100,000 occupational therapy practitioners employed throughout the health care system (American Occupational Therapy Association, 2010). Practitioners are

already in place to implement the intervention. No changes are needed to health systems or policies.

Expansion is a strength of the IMedS intervention and supports further research.

No changes are indicated to the manual or the research methodology to expand the intervention

Efficacy

The last purpose of a feasibility study is to understand more about the effectiveness of the intervention. Was the IMedS intervention effective enough to warrant further study? The research team measured efficacy by investigating changes in participants' perceptions of their medication management abilities and the RAs' perceived effectiveness of the intervention. Most IMedS participants (n=5, 55%) believed that they were better at taking their medications as prescribed. Only 30% (n=3) of standard care participants thought their abilities to take and manage their medications had improved. This indicates that participants perceive the intervention to be more effective than standard care. Most RA's (n=5, 83%) also agreed that the IMedS intervention helped participants better take their medications. Consensus between the participants and the RAs indicated that the intervention was effective at improving medication management and medication adherence for some indivudals. These findings are also supported by data presented in other articles (Schwartz, 2015, 6 & 7).

Limited effectiveness data demonstrates large enough effects to warrant future IMedS research. Currently, no changes are needed to the manual, but the research team should continue to monitor the materials as they are used with persons of more diverse

backgrounds. Also, better identification of appropriate participants may help select individuals who will most benefit from the intervention.

Conclusion

The purpose of this study was to determine the success of a feasibility study on a new occupational therapy intervention for medication nonadherence named IMedS. We used the eight characteristics described by Bowen et al. (2009) to measure the success of the intervention. The IMedS intervention demonstrated good outcomes in acceptability, demand, practicality, integration, expansion, and efficacy. In general, participants liked the intervention and thought that medication adherence was an important topic. IMedS was perceived to improve performance in medication management by both the RA and the participant. Further, the intervention was easy to implement and was consistent with current occupational therapy practice and health care systems. Challenges were noted in implementation and adaptation. Almost half of the participants that completed the study were inappropriate for intervention as they had perfect medication adherence for the length of the study. Also, the sample was biased towards while older adult females. Therefore, it is unclear how the intervention will perform with more representative samples. Overall, the successes of the study outweigh the limitations. Thus, the IMedS intervention would benefit from future research with larger more diverse participants. Based on these findings, researchers can improve the research methodology to enhance outcomes for future investigation.

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Chapter 8 - Conclusion

I commenced the research process as a clinician with a question. I wanted to know how I could better address medication nonadherence in my clients with chronic health conditions. I began on a multiyear journey through the doctoral education and dissertation process with the goal of improving the skills of clinicians and the lives of people with chronic health conditions. In this section, I will briefly describe the research; measure the success of the research against the specific aims; and discuss recommendations for future research, policy, and practice.

Summary

The purpose of this dissertation was to complete a phase-one research study to both identify an occupational therapy intervention that promotes medication adherence and to test the intervnetion's feasibility and effectiveness. I began by exploring the occupational therapy practitioner's role in medication adherence interventions (Schwartz, 2015, Chapter 2). During the literature review, I found occupational therapy practitioners have many opportunities but few resources for medication adherence interventions.

Subsequently, few occupational therapists regularly evaluate and treat their clients for issues around medication adherence (Schwartz, 2015, Chapter 3).

To fill the need for occupational therapy specific resources, I developed a manualized occupational therapy intervention to promote medication adherence called the Intergrative Medication Self-Management Intervention or IMedS (Schwartz, 2015, Chapter 3). IMedS was developed on a basis of theory, current research, and the practice of 78 occupational therapists. Because of the intervention's strong foundation, I anticipated that the it would effectively improve medication nonadherence.

After developing the IMedS manual, I had to train the study staff to engage in research procedures. I recruited and trained six senior occupational therapy students to implement the intervention and follow up evaluation (Schwartz, 2015, Chapter 4). The student research assistants (RAs) completed a series of competency based testing including an online learning quizes and a practical exam. Then the RAs implemented the protocols with real research participants while being monitored for fidelity to the research procedures. The training was a success. The student RAs demonstrated good validity in intervention recommendations (interclass correlation coefficient = .89) and good fidelity to the study protocols (99%). The student RAs also reported self-perceived improvements in their clinical skills.

With the trained student RAs and the manualized intervention, we completed a feasibility study on the IMedS intervention compared to a standard care pamphlet-based educational intervention. The feasibility study was a two-group blinded randomized prepost investigation consisting of three visits: baseline data collection, intervention, and follow-up data collection. The purpose of the feasibility study was to test the procedures and to identify if the intervention could be effective.

First, I wanted to understand the effectiveness of the intervention. Unfortunately, there was limited prior research supporting occupational therapy intervention for medication nonadherence. Therefore, I wanted to determine if occupational therapy could improve medication adherence. During the study, the participants recorded the number of pills consumed daily over a baseline and intervention phase. At the end of the study, 11 participants had data appropriate for single-subject analysis. I used this data to understand the effectiveness of the occupational therapy intervention and the standard care

intervention (Schwartz, 2015, Chapter 5). Two IMedS participants significantly improved their medication adherence, indicating that occupational therapy intervention can improve medication nonadherence.

I also wanted to explore intervention effectiveness from the participant's perspective (Schwartz, 2015, Chapter 6). At the end of the participants' research experiences, they engaged in an exit interview. Using a mixed methods approach, I explored intervention effectiveness by asking participants about their perceptions and investigating their behavior change. I found that persons in the IMedS group reported greater improvements in their own medication management abilities and implemented twice as many new strategies. Further, the participants indicated that the most effective components of the IMeds intervention were the focus on strategies as well as the caring therapeutic relationship. This mixed methods study further indicates that occupational therapy can improve medication nonadherence. This study also suggests that the unique skills of occupational therapists make the IMedS intervention effective.

Finally, I looked across sources to determine the feasibility of the IMedS intervention study (Schwartz, 2015, Chapter 7). I wanted to evaluate the appropriateness of further research and identify any changes needed to the intervention manual or research methodology. I used the eight feasibility study criteria described by Bowen et al. (2009) (acceptability, demand, implementation, practicality, adaptation, integration, expansion, and limited efficacy) to understand the feasibility outcomes. Through this process, I determined that the study was largely a success and warranted future investigations. The process also helped to identify improvements needed in infrastructure, recruitment, and participant identification needed for future investigations.

Findings in Regards to the Specific Aims

Through this six-study series, I have answered all of the specific aims and research questions. In this section, I will speak to each research question and specific aim drawing data across studies.

Specific Aim 1: Complete the development of the manual for the Integrative Medication Self-Management Intervention (IMedS).

Using theory, best evidence, and the practice-patterns of 78 occupational therapists, I successfully created the manualized an occupational therapy intervention to promote medication adherence named IMedS. The IMedS intervention is described in a 50-page electronic manual and includes training on screening, evaluation, and the IMedS intervention process (Schwartz, 2015, Chapter 3). The manual also includes videos, pictures, and case studies. Not only was the manual completed, but also entry-level practitioners were able to learn the materials. Six occupational therapy student research assistants learned all of the protocol in the manual and demonstrated their learning through the online quizzes and practical exam (Schwartz, 2015, Chapter 4).

Specific Aim 2: Understand the feasibility of implementing the IMedS Intervention.

I explored the feasibility of the IMedS intervention by analyzing the acceptability, demand, implementation, practicality, adaptation, integration, expansion, and limited efficacy of this study (Schwartz, 2015, Chapter 7). I found that the IMedS intervention was an enjoyable and effective intervention for medication nonadherence that is anticipated to be in high demand. The intervention is consistent with current health care systems and policies. Thereofore, I anticipate that it would be easy to implement and grow the IMedS intervention. The research team did experience a few challenges related

to implementation and adaptation. Several participants were recruited who were not appropriate. The research team experienced less than optimal capacity, due to limitations in infrastructure and administrative support. Fortunately, the limitations of this study can be easily remedied with better inclusion criteria and additional funding thereby supporting the case for future IMedS research.

Research Question 1: Who, why, and to what extent are persons with chronic health conditions a) enrolled into the study b) rejected from the study, or c) unable to complete the study?

I was able to easily recruit and retain research participants (Schwartz, 2015, Chapter 7). Thirty-four participants were screened for the study. Eleven individuals were screened out, often due to too high adherence levels. Four individuals withdrew from the study, resulting in a dropout rate of 17%. Participants tended to older white females. These biases were consistent with the people who both dropped out and were screened out of the study.

Research Question 2: Do occupational therapy implementers report high satisfaction and ease of implementation with the intervention? Why or why not?

The occupational therapy implementers or RAs did report high satisfaction with the IMedS intervention (Schwartz, 2015, Chapter 7). Five RAs (83%) reported that they were satisfied with the quality of the IMeds intervention. All of the RAs indicated that they would continue using the techniques they learned as they transition to independent practitioners. Further, the RAs found the intervention to be easy to learn and implement given the detailed manual, group discussion, and use of technical videos (Schwartz, 2015, Chapter 4).

Research Question 3: To what extent do the occupational therapy implementers deliver the protocols with good fidelity?

The RAs were able to implement the IMedS intervention, the standard care intervention, and evaluations with good fidelity to the protocols (99%) (Schwartz, 2015, Chapter 4).

Specific Aim 3: Determine if the IMedS intervention is effective.

The IMeds intervention was seemingly effective for some participants in the study. Using the single-subject data, two individuals in the IMedS intervention demonstrated statistically significant improvements in medication adherence (Schwartz, 2015, Chapter 5). Fifty-five percent of persons receiving the IMedS intervention reported self-perceived improvements in their ability to manage their medications, which was far greater than the 30% of persons in the standard care group who believed they improved (Schwartz, 2015, Chapter 6). Finally, all of the RAs who implemented IMedS interventions believed that the intervention helped their participants to better take their medications as prescribed (Schwartz, 2015, Chapter 7). The triangulation between the single-subject data, participant's perceived improvements, and the research assistant's perspectives indicates that the IMeds intervention was effective for several participants. Further, the rate of effectiveness is seemingly greater than that of the standard care group.

Research Question 4: Do participants who receive the treatment demonstrate improvements in health and function?

This intervention study was a brief feasibility trial. On average, the research team conducted the follow-up evaluation four weeks after intervention. No participants reported changes to health or functional abilities. No differences were noted in SF-36

scores (Schwartz, 2015, Chapter 7). It is anticipated, however, that health and function may improve in studies of longer duration.

Research Question 5: How and to what extent do participants feel like they benefit from the intervention? Why or why not?

Eighty-eight percent of persons in the IMeds group found the intervention to be helpful, and several (55%, n=5) also reported improvements in the medication management abilities (Schwartz, 2015, Chapter 6). The participants reported that the IMedS intervention was effective because it helped them to develop new strategies for medication nonadherence (Schwartz, 2015, Chapter 6).

Limitations and Strengths

This study was a small feasibility trial with several limitations. The sample was small in size and biased towards older adult white females. Further, study procedures took place in one simulated clinical setting. Therefore, the results of this study may not be generalizable to other people, populations or settings.

The purpose of this study, however, was quite narrow, and the research team effectively accomplished their goals through six strong research studies. The depth of the materials and the collaboration between resources and perspectives strengthens the findings. Further, researchers used several strategies to control for bias including blinding, random assignment, and the use of a "control" group. These methodological approaches helped to ensure that changes noted during the study were most likely due to the intervention as opposed to some unobserved or unmeasured variable. Finally, while the study was small for a randomized controlled trail, the 19 participants were sufficient for single-subject, qualitative, and feasibility analyses.

Implications for Future Research, Policy, and Practice

This dissertation describes the development and testing of a new inftervention designed to promote medication adherence. This dissertation informs the fields of medication adherence, occupational therapy, medicine, nursing, public health, etc. As such, it has several implications for future activities in research, policy, and practice.

Research

- New tools are needed to study medication adherence (Schwartz, 2015, Chapter 2).
 We mainly measured medication adherence using a daily adherence calendar.
 Unfortunately, some participants forgot to return their calendars or had missing data. Tools are needed that collect data daily and are less of a burden to participants.
- This dissertation supports the use of manualized interventions in occupational therapy research. The manualization of the materials facilitated a thorough consistent and quality training. Further, the manual allowed the PI to monitor fidelity to pre-determined criteria and maintain a high level of quality throughout the intervention. While practitioners commonly associate manualization with a loss of clinical independence (Blanche, Fogelberg, Diaz, Carlson, & Clark, 2011), the RAs reported feeing satisfied with the intervention that they were able to implement. No RA reported feeling stuck or limited in their intervention plans. Further, the participants reflected positively about the client-centeredness of the intervention. The IMedS intervention demonstrates a manualized intervention that respects the client-centered approach and leverages clinical reasoning.

• Nieuwlaat et al. (2014) suggests that the current theories that are being used to explain medication adherence many be insufficient, resulting in interventions with limited effectiveness. The IMedS intervention is based on two occupational therapy models, the Model of Human Occupation (Kielhofner, 1995) and the Person Environment Occupational Model (Law et al., 1996). These models are new to medication adherence. In this dissertation pilot study, however, these new models performed well. These finding support the use of occupational theory in the study of medication nonadherence.

Policy

- Both participants and interventionist identified that medication nonadherence as
 an important issues worthy of increased services. Policy makers and
 administrators should identify strategies to increase the provision of medication
 adherence services.
- The IMedS intervention was implemented at low cost and is a billable service
 when provided by skilled occupational therapists. Medication adherence
 interventions delievered by occupational therapy practitioers may provide cost
 effective solutions to nonadherence.

Practice

- Occupational therapists bring distinct value to the to the medication adherence team. Occupational therapy practitioners should advocate for their role in medication adherence across their positions in the continuum of care.
- Preliminary findings suggest that only about 25% of occupational therapists regularly address client's medication nonadherence. The research, however,

suggest that 50% of occupational therapy clients would benefit from services.

This finding suggests that service provision level may not meet consumer need.

Occupational therapy practitioners and administrators should reflect on their client's needs and adjust medication abderence service provision accordingly.

- Participants reported that the most helpful part of the IMeds intervention was the
 development of strategies. This finding supports the effectiveness of clientidentified strategies in a self-management intervention.
- Participants also reported that they benefited from the therapeutic relationship
 with the interventionist. Occupational therapy practitioners should value their
 relationship with their clients. Further, using skills like motivational interviewing
 and therapeutic use of self seemingly help to develop strong therapeutic relations.
- All of the interventionist in this study were senior occupational therapy students.
 The quantitative and qualitative success of the participants indicates that medication adherence intervention and evaluation are entry-level professional skills.

General Conclusions

Prior to this study, there was little support for occupational therapy's role in medication nonadherence and limited support for occupational therapy intervention (Radomski, 2011; Sanders & Van Oss, 2013). This dissertation provides the foundational work for occupational therapists seeking to engage in medication adherence interventions. In this dissertation, I have identified the role of occupational therapists in medication nonadherence, developed an intervention designed for occupational therapy professionals, and then tested the intervention's feasibility and effectiveness on a small

sample of persons with chronic health conditions. This work demonstrates that the IMedS intervention is deserving of further study and that occupational therapy intervention has the potential to improve medication adherence and medication management.

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Appendix A - IMedS Manual Table of Contents

- 1. Welcome
- 2. Background and importance of medication adherence interventions
- 3. Medication Adherence Study Training Process
- 4. Assessment: Administration and Interpretation
- 5. Treatment Intervention
- 6. Standard of Care Intervention

Appendix B - Protocol Checklists

Treatment Intervention Checklist

- 1. Review chart and fill out the plan of care worksheet.
- 2. Set up the room.
 - a. Make sure chair, table, and recording equipment are in the appropriate positions.
 - b. Make sure video camera is charged with sufficient memory.
 - c. Make sure you have needed educational materials.
- 3. Greet the participant.
 - a. Ensure positive client identification.
- 4. Introduce yourself to the participant.
 - a. State you name and role as an occupational therapy student research assistant.
- 5. Introduce the activity
 - a. Describe the purpose, type, and duration of the intervention
- 6. Remind the participant that the session is being recorded.
- 7. Request the participant's medication adherence diary. Copy it and return it to the participant.
- 8. Discuss the participant's baseline adherence level.
 - a. Review the results of the participant's medication adherence survey and diary.
- 9. Discuss behavior change around medication adherence.
- 10. Direct the client to set a medication adherence goal.
- 11. Using motivational interviewing, collaboratively develop strategies to reach goal.
 - a. Be sure to think about strategies including
 - i. Education
 - ii. Advocacy
 - iii. Changes to routine
 - iv. Changes to the environment
 - v. Prescription of assistive technology
 - vi. Strategies for consistent and timely refills
- 12. Check for questions.
- 13. Use teach-back method to encourage participants to review session and verbalize action items.
- 14. Pay the participants. Ensure a signed receipt.
- 15. Document the session using the SOAP note worksheet.
- 16. Clean up.
 - a. Stop and turn off video camera.
 - b. Return materials to correct storage location.

Standard Care Checklist

- 1. Set up the room.
 - a. Make sure chair, table, and recording equipment are in the appropriate positions.
 - b. Make sure video camera is charged with sufficient memory
- 2. Greet the participant.
 - a. Ensure positive client identification.
- 3. Introduce yourself to the participant.
 - a. State you name and role as an occupational therapy student research assistant.
- 4. Introduce the activity.
 - a. Describe the purpose, type, and duration of the intervention.
- 5. Remind the participant that the session is being recorded.
- 6. Review the *Managing Your Medicines* pamphlet and engage in active listening.
- 7. Request the participant's medication adherence diary. Copy it and return it to the participant.
- 8. Pay the participant. Ensure a signed receipt.
- 9. Document the session using the SOAP note worksheet.
- 10. Clean up.
 - a. Stop and turn off video camera.
- 11. Return materials to correct storage location.

Follow-up Evaluation Checklist

- 1. Set up the room.
 - a. Make sure chair, table, and recording equipment are in the appropriate positions.
 - b. Make sure video camera is charged with sufficient memory.
 - c. Make sure you have pens, gloves, and a pill count container.
- 2. Greet the participant.
 - a. Ensure positive client identification.
- 3. Introduce yourself to the participant.
 - a. State you name and role as an occupational therapy student research assistant.
- 4. Introduce the activity
 - a. Describe the purpose, type, and duration of the intervention
- 5. Remind the participant that the session is being recorded.
- 6. Administer the survey packet and pen.
- 7. Complete the pill count for all available medications.
- 8. Administer the Medication Knowledge Assessment.
- 9. Administer the exit interview.
- 10. Request the participant's medication adherence diary. Copy it and return it to the participant.
- 11. Pay the participants. Ensure a signed receipt.
- 12. Clean up.
 - a. Stop and turn off video camera.
 - b. Return materials to correct storage location.

Appendix C - Equivalent Text Descriptions

Figure 1.1.

Brief Description:

Number of Articles Using the "Medication Adherence" Medical Subheading in the Medline Database by Year

Essential Description:

Table showing the year on the X-axis and the number of publications listing "medication adherence" as a key word on the Y-axis. Usage of the term starts in the late 1990's and continues to increase. There were over 2,500 articles using "medication adherence" as a medical subheading term in 2013.

Figure 1.2

Brief Description:

Box with text identifying the three specific aims and five research questions included in the study.

Essential Description:

Specific Aim 1: Complete the development of the manual for the Integrative Medication Self-Management Intervention (IMedS).

Specific Aim 2: Understand the feasibility of implementing the IMedS Intervention. Research Question 1: Who, why, and to what extent are persons with chronic health conditions a) enrolled into the study b) rejected from the study, or c) unable to complete the study?

Research Question 2: Do occupational therapy implementers report high satisfaction and ease of implementation with the intervention? Why or why not?

Research Question 3: To what extent do the occupational therapy implementers deliver the protocols with good fidelity?

Specific Aim 3: Determine if the IMedS intervention is effective.

Research Question 4: Do participants who receive the treatment demonstrate improvements in health and function?

Research Question 5: How and to what extent do clients feel like they benefit from the intervention? Why or why not?

Figure 1.3

Brief Description:

Diagram describing where information regarding the specific aims and research questions can be found across the chapters of the dissertation.

Essential Description:

Diagram describing where information regarding the specific aims and research questions

can be found across the chapters of the dissertation. This information can be found in the text of chapter one as well.

Figure 3.1

Brief Description:

Medication adherence intervention approaches trialed in the literature and the number of research studies for which each type intervention has been tested.

Essential Description:

Bar chart with twenty-three different types of interventions to improve medication adherence on the Y-axis and the number of research studies for which each type of intervention has been tested on the X-axis. Most intervention approaches have only been tested in about 2-3 studies, and only two intervention approaches (education and counseling) have been tested across 10 or more studies.

Figure 3.2

Brief Description:

Bar chart describing how often occupational therapy practitioners use different occupational therapy intervention approaches to treat impairments in medication management. Bar charts are divided by practice setting.

Essential Description:

Bar charts with occupational therapy intervention approaches on the X-axis and percent of occupational therapy respondents who use that approach in the Y-axis. Bar charts are divided by practice area (acute, home health, outpatient, etc.). Chart illustrates that some practitioners rarely engage in medication management (e.g. outpatient) while others treat for medication management regularly (e.g. home health). Also demonstrates that therapists use a variety of approaches to treat medication adherence.

Figure 3.3

Brief Description:

Graphic depicting the components of the IMedS intervention gleaned from the theory, evidence, and practice.

Essential Description:

Graphic depicting components of the IMedS intervention and weather they derived from the theory, evidence, or practice survey/interview components.

Twelve components of the IMedS intervention derived from theory: medication knowledge, chronic disease knowledge, self-efficacy, readiness for change, client-centeredness, goal setting, feedback, routines, a multidimensional approach, altering the task, altering the environment, and providing assistive technology.

Six components of the IMedS intervention derived from the evidence: information, reminders, self-monitoring, counseling, telephone follow-up, and supportive care.

Ten components of the IMedS intervention derived from surveys and interviews with practitioners: intervention designed to work across settings and populations, brief length, clinical reasoning, occupation/activity, education, advocacy, caregiver involvement, assistive technology/ the environment, occupational profile, and task analysis.

Figure 4.1

Brief Description:

Flow chart of research procedures followed by the research assistants throughout the study.

Essential Description:

When the research assistants participated in the study they engaged in 11 different steps: 1) self-directed study, 2) evaluation quiz, 3) standard care quiz, 4) intervention quiz, 5) team meeting, 6) evaluation practical exam, 7) standard care practical exam, 8) intervention practical exam, 9) implement protocols with research subjects, , 10) exit survey, 11) exit interview.

Figure 5.1.

Brief Description:

Flow chart depicting research procedures experienced by the research participants in the single-subject study.

Essential Description:

Participants in the single-subject research study experienced four steps: 1) phone screen n=34 2) baseline evaluation n=21 3) 30-minute intervention. Ten people received standard care and 10 people received IMedS. 4) Follow-up evaluation n=11. During the study 4 people withdrew, 11 people screened out, and 8 people were removed from analysis due to perfect adherence to their medications.

Figure 5.2.

Brief Description:

Seven line charts demonstrating the results of persons who received the standard care intervention

Essential Description:

Seven line charts with study day on the X-axis and percent adherence on the Y-axis. There is a black line separating the baseline and intervention phases. One line chart is placed in the "intervention significantly effective" section. Six line charts are placed in the "intervention not significantly effective" section.

Figure 5.3.

Brief Description:

Four line charts demonstrating the results of persons who received the IMedS intervention.

Essential Description:

Four line charts with study day on the X-axis and percent adherence on the Y-axis. There is a black line separating the baseline and intervention phases. Two line charts are placed in the "intervention significantly effective" section. Two line charts are placed in the "intervention not significantly effective" section.

Figure 6.1.

Brief Description:

Flow chart depicting research procedures experienced by the research participants in the qualitative study.

Essential Description:

Participants in the qualitative research study experienced four study components: 1) phone screen (n=34) 2) baseline evaluation (n=21) 3) 30-minute intervention (10 people received standard care and 10 people received IMedS) 4) Follow-up evaluation (n=19). During the study 4 people withdrew and 11 people screened out.

Figure 7.1.

Brief Description:

Flow chart depicting research procedures experienced by the research participants in the medication study.

Essential Description:

Participants in the medication research study experienced four study components: 1) phone screen (n=34) 2) baseline evaluation (n=21) 3) 30-minute intervention (10 people received standard care and 10 people received IMedS) 4) Follow-up evaluation (n=19). During the study, four people withdrew and 11 people screened out.

Curriculum Vitae

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Education

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Presentations:

- **Schwartz, J.K.** & Smith, R.O. (2015). *Pilot Study of a Novel Occupational Therapy Medication Management Intervention*. Paper presented at the Fourth Annual Occupational Therapy Summit of Scholars, Los Angeles, CA. Refereed.
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- **Schwartz, J. K.** & Smith, R.O. (2014). A critical review of assistive technology in medication management assessment and intervention. Presentation at the Rehabilitation Engineering and Assistive Technology Society of North America 2014 Conference, Indianapolis, IN. Refereed.
- **Schwartz, J. K.**, & Smith, R. O. (2014). A critical review of evaluation and intervention in medication management. Poster at the Third Annual Occupational Therapy Summit of Scholars, Philadelphia, PA. Refereed.