IMPROVING MEDICATION ADHERENCE IN PATIENTS WITH MULTIPLE CHRONIC CONDITIONS: EVALUATION OF A PILOT INTERVENTION IN A RURAL PRIMARY CARE CLINIC

by

Laura Daniels

December 2014

Director of Dissertation: Lisa Campbell, Ph. D.

Major Department: Department of Psychology

Background: More than 25% of primary care patients are managing multiple chronic conditions (MCC) and 50% of their medications are not taken as prescribed. Self-efficacy is the foundation of many successful medication adherence and chronic disease self-management (CDSM) interventions for specific chronic conditions. Interventions designed within a self-efficacy framework and tailored for the primary care setting could improve health outcomes for patients with MCC. **Primary Aims:** 1) Describe demographic and psychosocial characteristics of patients with MCC, 2) Examine the relationships between number of chronic conditions, primary (medication adherence) and secondary (health literacy, self-efficacy, problem-solving, and QOL) variables, 3) Evaluate the preliminary efficacy of a medication adherence intervention for patients with MCC on improving outcomes. **Methods**: Adult patients presenting for care in the Family Medicine department at a rural Federally Qualified Health Center were recruited to complete a survey on CDSM and participate in the intervention. The intervention involved 4 group sessions and 2 follow-up telephone sessions. Data collection occurred at baseline and post-treatment. **Results**: Pilot study results indicated that MCC was prevalent in 62% of the sample ($N = 53$), patients and providers generally had similar perceptions of CDSM needs, and better medication adherence was among the most frequently endorsed need. The intervention study participants ($N = 20$) were managing on average 5 chronic conditions and 40% had less than adequate health literacy levels. Health literacy and MCC were significantly positively associated ($p = 0.036$). Outcomes analyses indicated that scores significantly improved on measures of Effective Problem-solving ($p = .028$, $d = .67$), Positive Transfer Problem-solving ($p = .010$, $d = .67$), Self-efficacy for managing chronic disease in general ($p = .005$, $d = .66$), and Self-efficacy for engaging in social/recreational activities ($p = .005$, $d = .42$). Self-reported medication adherence improvements fell short of significance. **Conclusions**: Participants reported significant improvements on factors theoretically and empirically linked to adherence and health outcomes. Research with larger samples and longer follow-up is needed in order to evaluate the efficacy of this treatment and mechanisms for change. Collaborating with patients and providers during program development could facilitate acceptability and sustainability of CDSM programs.

IMPROVING MEDICATION ADHERENCE IN PATIENTS WITH MULTIPLE CHRONIC CONDITIONS: EVALUATION OF A PILOT INTERVENTION IN A RURAL PRIMARY CARE CLINIC

A Dissertation

Presented to the Faculty of the Department of Psychology

East Carolina University

In Partial Fulfillment of the Requirements for the Degree

Doctor of Philosophy in Clinical Health Psychology

by

Laura Daniels

December, 2014

IMPROVING MEDICATION ADHERENCE
IN PATIENTS WITH MULTIPLE CHRONIC CONDITIONS:
EVALUATION OF A PILOT INTERVENTION IN A RURAL PRIMARY CARE CLINIC.

by

Laura Daniels

APPROVED BY:

DIRECTOR OF DISSERTATION	Lisa Campbell, Ph. D.
COMMITTEE MEMBER	Lesley Lutes, Ph. D.
COMMITTEE MEMBER	Dennis Russo, Ph. D.
COMMITTEE MEMBER	Darah Wallsten, Psy. D.
COMMITTEE MEMBER	Karl L. Wuensch, Ph. D.
CHAIR, DEPARTMENT OF PSYCHOLOGY	Susan McCammon, Ph. D.
DEAN OF THE GRADUATE SCHOOL	Paul J. Gemperline, Ph. D.

ACKNOWLEDGEMENTS

This significant chapter in my life was only possible with the support from family, friends, and mentors. My family’s unconditional love and trust in me gave me the confidence to maintain my tenacity and spirituality throughout this journey. The frequent affirmations from my friends, our frank discussions, and their sense of humor were critical support for helping me to stay true to myself. I would like to thank my mentors for challenging me in unforeseen ways, believing in me, creating invaluable opportunities where I was able to develop my professional identity, and providing advice for navigating the world of health care and academia. Collectively, these relationships and my experiences have consistently shown that the journey is so much more valuable than the light at the end of the tunnel.

TABLE OF CONTENTS

LIST OF TABLES .... *vii*

LIST OF FIGURES .... *viii*

CHAPTER I: INTRODUCTION 1

CHAPTER II: LITERATURE REVIEW 4

Quality of Life for Patients with MCC 4

Common Adherence Tasks in Treatment for MCC 6

Barriers to Medication Adherence 12

Medication Adherence Interventions for Patients with MCC 19

Self-efficacy as a Framework for Interventions 25

Providing Evidence-based Interventions in FQHCs 40

Study 1 Pilot Survey Study of Chronic Disease Self-Management Needs 42

Study 2: Medication Adherence Intervention Study 43

CHAPTER III: METHODS 45

Study Site 45

Institutional Review Board (IRB) Approval 46

CHAPTER IV: STUDY 1 47

Method 47

Analyses 48

Results 48

Implications for Intervention Priorities 50

CHAPTER V: METHODS OF STUDY 2 53

Method 53

Assessment of Primary and Secondary Outcomes 59

Power 65

CHAPTER VI: RESULTS OF STUDY 2 66

Attrition 66

Baseline Results 69

Post-treatment Outcomes 77

Post-hoc and Exploratory Results 80

CHAPTER VII: DISCUSSION 81

Demographics and Psychosocial Characteristics of Patients with MCC 81

Relationships Between Variables at Baseline 85

Intervention Efficacy on Psychosocial Outcomes 89

Limitations 92

Conclusions and Future Directions 96

REFERENCES 98

APPENDIX A: Institutional Review Board Study Approvals 111

APPENDIX B: Patient and Provider Surveys 114

APPENDIX C: Session-by-Session Outline 119

LIST OF TABLES

1. Commonalities in Treatment for MCC: Medication Adherence 8

2. Chronic Disease Self-management Needs by Patient and Provider.................49

3. Overview of Session Content 56

4. Overview of Study Outcomes by Measures 64

5. Participant Baseline Demographic and Psychosocial Characteristics 69

6. Correlations Between Number of Chronic Conditions and Baseline Measures...72

7. Correlations Between Baseline Measures 76

8. Results of Baseline and Post-treatment Outcome Analyses.............................79

LIST OF FIGURES

1. Intervention Targets for Improving Self-efficacy for Medication Adherence.... 27

2. Flow Chart of Project Procedures 58

3. Flow Diagram of Recruitment and Retention 68

Chapter 1: Introduction

The data consistently indicate that a significant proportion of patients seeking healthcare are increasingly likely to be managing multiple chronic conditions (MCC). Multiple chronic conditions, often referred to as multimorbidity, is commonly defined as the presence of more than two diagnoses of a major chronic condition (e.g. obesity, diabetes, high blood pressure, chronic pain, depression, etc.) (Fortin, Stewart, Poitras, Almirall, & Maddocks, 2012). Boyd and Fortin (2010) reported that one in four patients in primary care is managing MCC, while others have reported that three out of four people aged 65 or older have MCC (Anderson-Rothman & Wagner, 2003; Wolff, Starfield, & Anderson, 2002). In fact, the trend is increasing for patients at younger ages to be managing MCC (Mercer, Smith, Wyke, O’Dowd, & Watt, 2009).

The majority of research efforts have focused on the epidemiology of this clinical phenomenon and its economic burden and impact on the health care system (Smith, Soubhi, Fortin, Hudon, & O'Dowd, 2012). One analysis reported that individuals with MCC accrue, on average, $650 more per month in health care costs than those with less than two chronic conditions (Melek & Norris, 2008). Patients with MCC also have more interaction with the health care system including higher frequency of doctor’s visits, hospital readmissions, and adverse events due to poor medication adherence (Boyd & Fortin, 2010; Starfield, 2011). Moreover, they are more likely to be on disability as their ability to work is significantly compromised and they experience a number of psychosocial stressors (Boyd & Fortin, 2010). In sum, living with MCC is a complex burden affecting patients, families, and the health care system that cuts across individual, community, and system levels. Thus, efforts to address this burden need to be multi-faceted, collaborative, and interdisciplinary.

Federally Qualified Health Centers (FQHCs) are one of the most common settings for treating and controlling symptoms of chronic conditions for many reasons. Primary care clinics, like FQHCs, are the point of care for the majority of patients with MCC (Anderson-Rothman & Wagner, 2003). Research shows that chronic conditions are disproportionately present in ethnic minority groups and among rural and/or low income populations (Shi et al., 2013). According to the Bureau of Primary Health Care (BPHC) of the Health Resources and Services Administration, to be an FQHC, a clinic must meet specific Medicare and Medicaid Program criteria and provide accessible affordable health care to medically underserved individuals. Therefore, FQHCs generally reside in low-resource communities and serve patients who are low income, and/or are members of ethnic or racial minority groups (Taylor, 2004).

One of the recent goals of the BPHC and its partners include reducing health disparities in FQHC populations by improving chronic disease self-management of its patients. Self-management is defined as the day-to-day care of chronic condition(s), which involves many tasks related to medical and health behavior management, role management, and emotional management (Lorig & Holman, 2003). When patients engage in good self-management practices, symptoms are better controlled, quality of life is improved, and the risk of complications is substantially reduced (Anderson-Rothman & Wagner, 2002; Bodenheimer, Lorig, Holman, & Grumbach, 2002).

Pharmaceuticals are the most common medical interventions, and particularly for patients with MCC, the most critical aspect of self-management is adhering to the prescribed medication regimen. Medication adherence is generally defined as the extent to which patients follow their provider's prescribed instructions for taking medications; therefore, the treatment's effectiveness in controlling symptoms and preventing complications depends on patients taking their medications. However, poor medication adherence is a particularly common problem as approximately 50% of medications for chronic conditions are not taken as prescribed (Haynes, Ackloo, Sahota, McDonald, & Yao, 2008; Osterberg & Blaschke, 2005).

Recent reviews on medication adherence interventions research conclude that interventions are minimally to moderately effective at improving long-term adherence and most are impractical for use in primary care settings (Haynes, et al., 2008; Osterberg & Blaschke, 2005; Viswanathan et al., 2012; Williams, Manias, & Walker, 2008). Reviewers of self-management interventions for chronic conditions conclude that programs successful in changing health behaviors are typically grounded in social cognitive theory and should focus on improving health literacy, motivation to learn self-management skills, problem-solving skills, and self-efficacy (Bodenheimer et al., 2002; Nilsen & Olster, 2013; Rothman et al., 2004; von Wagner, Steptoe, Wolf, & Wardle, 2009). However, research on medication adherence and self-management interventions traditionally involves single-disease populations and, with the increasing prevalence of patients with MCC, there is a substantial need for intervention research with this population.

Chapter II: Literature Review

Quality of Life for Patients with MCC

Studies show that multimorbidity is an important independent predictor of adverse outcomes. The burden of multimorbidity is associated with decreases in quality of life and functionality beyond the additive effects of a having a single disease (Gijsen, et al., 2001; Oldridge, Stump, Nothwehr, & Clark, 2001). Thus, the first step to improving health outcomes is to collaborate with patients and develop a more holistic understanding of how multimorbidity affects patient quality of life and functionality.

A nationally representative prospective cohort study (*N* = 17,195) showed that patients with co-morbid diabetes, obesity and heart disease have significantly poorer outcomes (i.e. mobility, health service utilization, and health-related quality of life [QOL]) compared to those who had either condition alone or in combination with other chronic conditions (Oldridge, et al., 2001). Additionally, the impact of multimorbidity on QOL and mortality was two to three times greater for middle-aged adults (51-61 years old) compared to older adults (70 years and older). In other words, the compound effect of certain combinations of diseases can lead to significantly poorer outcomes than having either disease alone and younger individuals appear to be more affected by MCC. Future research needs to focus on understanding the development of MCC from a broader lifestyle perspective as opposed to a medically-oriented perspective (Boyd & Fortin, 2010). Also, designing interventions to target improving health behaviors linked to diseases that cluster together could help patients improve their self-management efforts.

Physical functioning. Empirical evidence indicates that patients with MCC experience significant declines in physical functioning (Fortin et al., 2006) and physical well-being (Bayliss, Bayliss, Ware, & Steiner, 2004). Bayliss and colleagues (2004) completed a four-year study (*N* =1574) assessing health outcomes of patients with MCC (diabetes, coronary artery disease, congestive heart failure (CHF), chronic respiratory disease (CRD), musculoskeletal conditions, and depression). After four years, patients with four or more chronic conditions had a clinically significant decline in physical functioning (as measured by the physical component subscale of the quality of life SF-36 survey; *OR* 2.8), after adjusting for number of chronic conditions and confounding variables (poverty level, gender, race, educational level, employment and marital status). This change was only second to the declines reported by patients with CHF (*OR* 2.9) and it was greater than patients with diabetes (*OR* 2.1) and CRD (*OR* 1.7).

Psychological functioning. Beyond affecting physical functioning, research has shown that having MCC affects other aspects of quality of life. Fortin and colleagues (2006) reported that increases in the number of conditions and severity of problems caused significant declines in mental health even after controlling for patients' perceived social support and a number of important demographic variables. Specifically, having MCC was related to significant declines in energy, social functioning, and role limitations caused by emotional distress.

Similarly, in a qualitative study, Townsend and colleagues (2003) reported on the experiences and self-management strategies of patients with MCC (*N* = 23). Patients reported disruptive beliefs about self-management, disease-related distress, and difficulty with role adjustment and managing their regimen. Most patients reported substantial conflicting thoughts and emotional distress related to their medication regimen; specifically, experiencing fear of medication dependence and perceived lack of control over their symptoms. Also, many reported reluctance to taking medication and uncertainty about its purpose and correct use of medications, suggesting limited understanding of their medication regimen. Finally, patients often reported competing beliefs that medication facilitated one's ability to fulfill social roles and obligations, but it also represented illness, loss, and a threat to one's identity. Subsequently, patients reported coping by engaging in various maladaptive and self-regulation strategies such as, minimizing medication use, avoiding medications, creating complex schedules for remembering their regimen. Collectively this research suggests that distress and uncertainty patients report about the medication regimen is associated with perceived lack of control over one's body, maladaptive coping, and low confidence in managing one's health.

In sum, the day-to-day management of MCC and frequent interactions with the health care system has a significant negative influence on one's quality of life. The physical and psychosocial problems (e.g. polypharmacy, emotional burden, compound effects of diseases) reported by patients appear to be associated with the burden of managing the complex medication regimen in particular. Yet more research is needed to better understand how having MCC affects one's self-efficacy for self-management, psychological well-being, and life satisfaction.

Common Adherence Tasks and Barriers in Treatment for MCC

The goal for treatment when managing MCC, regardless of the chronic condition, is to control symptoms and prevent complications, morbidity, and premature mortality. The most common approach involves prescribing a new medication(s) and titrating old medication(s) (Nace, Grundy, & Nielson, 2012). Regardless of the type or number of chronic conditions, patients are responsible for adhering to the medication regimen, self-monitoring symptoms and medications side effects, and keeping regular medical appointments (Clark et al., 1991; Paharia, 2008). Level of health literacy affects actions and decisions patients make in regard to following their medication regimen (Nutbeam, 2000; von Wagner et al., 2007). Similarly, regardless of number and type of chronic conditions patients experience common challenges or barriers to adhering to their medication regimen (Bayliss, Ellis, Steiner, 2007). Notably, research shows that when patients have adequate knowledge, skills, and confidence their self-efficacy for engaging in self-management tasks and ability to problem-solve barriers improve. These commonalities are discussed below and summarized in Table 1.

Table 1

Commonalities in Treatment for MCC: Medication Adherence

Adherence Tasks	Barriers to Adherence
• Medication Regimen o Understand prescriptions o Fill prescriptions o Create dosing schedule (amount, sequence, timing) o Make dosing adjustments when recommended o Regularly take medications • Self-monitoring o Biomarkers for each condition o Side effects and symptoms o Accurately interpret symptoms • Regularly communicate with provider • Attend appointments	• Limited health literacy o Limited numeracy and oral and reading literacy o Lack of basic knowledge related to chronic conditions • Psychological factors o Low self-efficacy o Psychopathology o Disruptive beliefs about health o Disease-specific distress o Maladaptive cognitive and behavioral coping styles • Sociodemographic factors o Limited education o Low socioeconomic status o Limited access to services and health insurance

Usual care treatment. The Institute of Medicine (IOM, 2012; Nilsen & Olster, 2013) only recently began developing treatment guidelines for patients with MCC. These new initiatives are encouraging, in that that they move away from treating patients on a disease-by-disease basis to improving patient's quality of life and optimizing health outcomes (Department of Health and Human Services, 2010). Consistent with this patient-centered approach and given that mental health problems and psychosocial stress are associated with and exacerbate medical conditions, it is also recommended that the treatment team, patient, and family assess, monitor, and manage the psychosocial sequelae. However, since the new recommendations and more holistic approach to managing MCC have yet to be fully implemented into some settings, particularly rural and low resource primary care clinics, many providers continue to follow guidelines using the single disease approach.

Adherence to medication regimen*.* Once diagnosed with one or more chronic conditions patients begin a pharmacotherapy regimen to help manage or control symptoms, prevent complications, and decrease risk of comorbidities. Research has shown that in single-disease populations, medication taking is more easily followed than making lifestyle changes (Gonder-Frederick, Cox, & Ritterband, 2002). Nonetheless, 50% of medications are not taken as prescribed (Haynes, et al., 2008). The consequences of poor adherence are severe and costly as patients with poor adherence are more likely to be hospitalized for preventable reasons, have greater visits to the emergency department, and increased risk for complications, morbidity, and mortality (Stuart & Briesacher, 2002). Alternatively, good adherence slows disease progression and reduces health care costs. In fact, in a recent review of outcomes for 11 chronic diseases, Boswell and colleagues (2012) reported that improvements in adherence resulted in improvements in 81% (64 out the 71) of clinical outcomes evaluated.

For patients with MCC, medication adherence is more challenging due to the complexity of the regimen and increased risk of medication side effects and interactions. In fact, an average of 50 prescriptions are filled each year among Medicare beneficiaries with MCC. Also as the number of medications and/or chronic conditions increases adherence declines (Roter, et al., 1998). Research shows that certain factors influence medication adherence including health literacy, self-efficacy, quality of life, beliefs about medications, provider communication, issues with the health care system, and sociocultural influences, (Krousel-Wood, et al., 2004). For example, in one study, Hill-Briggs and colleagues (2008) investigated medication adherence of low-income African American patients with co-occurring diabetes, hypertension, and high cholesterol. Patients reported that the most common reasons for poor adherence were running out of medications and forgetting to take medications and that poor adherence was less of problem. Notably, both patients and providers often have limited insight in identifying poor adherence (Osterberg & Blaschke, 2005). The provider tries to control symptoms by changing the medication regimen which may increase its complexity and potentially have negative effects on the patients including, feelings of uncertainty and beliefs that the patient has little control over their body. Perhaps improving health literacy and increasing patient insight about their current medication taking behavior and adherence rates through self-monitoring will improve their confidence in self-management and perceived control over their regimen.

Adherence to self-monitoring and symptom interpretation*.* Another self-management task recommended by providers and shown to improve health outcomes are daily self-monitoring and accurate interpretation of symptoms (Clark et al., 1995). Regular self-monitoring of physical and mental health symptoms decreases the risk for many complications and additional diagnoses by as much as 75% (Wysocki, 2006). Patients are expected to learn and interpret important biomarkers such as normal blood glucose levels before and after meals, blood pressure ranges, weight, pain type and severity.

Together self-monitoring and accurate symptom interpretation help patients learn about their baseline levels, fluctuations over time, reactions to recent changes in the internal or external environment (e.g. changes in medication, physical activity, diet, stress etc.). Moreover, these measures often provide important information such as, reinforcement that their symptoms are well managed, a cue to take medication, or that they are experiencing side effects and/or need to contact their provider. Finally, accurate symptom interpretation enables the patient to problem solve and take immediate action when problems arise which can prevent unnecessary stress and hospitalizations. However, these tasks can be difficult for many patients as one's experience is confounded by limited health literacy (von Wagner, et al., 2009), interactions between medications, stress, symptoms from co-occurring conditions, and changes in physical activity and diet (Townsend et al., 2003).

Adherence to attending medical appointments. To prevent or reduce the likelihood of long-term complications, it is also recommended that the patient, and if possible the family, regularly attend follow-up visits to their primary care provider and appropriate specialty providers. However, due to the fragmentation of health care and economic limitations of many patients with MCC, maneuvering this system can be overwhelming for patients. Notably, new initiatives of the Department of Health and Human Services (HSS) aim to overcome these barriers by: "1) strengthening the health care and public health systems, 2) empowering the individual to use self-care management, 3) equipping health care providers with tools, information, and other interventions, and 4) supporting targeted research about individuals with MCC and effective interventions" (HHS, 2010). Subsequently, the Institute of Medicine began developing treatment guidelines for patients with MCC and funding agencies have begun aligning research programs in order to fill gaps in knowledge about health-care and self-management of MCC (Nilsen & Olster, 2012).

In sum, patients with MCC, medication management is the most common approach to treatment in primary care. Adequate medication adherence requires patients to increase their health-related knowledge and develop good self-management skills. Specifically, patients should have adequate knowledge of 1) how appropriate medication adherence can decrease risk for complications, 2) the prescribed regimen, 3) medication side effects, and 4) disease-specific information (e.g. normal glucose levels, symptoms). Additionally, patients should understand how to translate this knowledge into self-management tasks including making lifestyle changes to ensure consistent medication taking (i.e. proper dose, sequence, and timing) and daily self-monitoring (i.e. symptoms and side effects) as well as attending regular visits with their provider(s). Finally, due to the frequent adjustments providers make to medication regimens, patients would benefit from adopting a flexible approach to taking their medications.

Barriers to Medication Adherence

Adherence has continued to decline despite improvements in pill design (e.g. color, shape, schedule, and administration method), medication efficacy, and public availability of information on medication (Cook, 2007). This decline suggests that patients face other barriers to adhering to their medication regimen such as, limited skills, low self-efficacy, psychological distress, cultural beliefs, and economic limitations

(Cook, 2007; Glasgow, Toobert, & Gillette, 2001). This section will focus specifically on factors that are likely to be amenable to intervention.

Limited health literacy. Health literacy is a critical set of skills for engaging in daily self-management of one's health and significantly influences one's ability to function in the health care environment. The concept of health literacy has evolved particularly since the turn of the century (Edwards et al., 2012; Institute of Medicine, 2004; Jordan et al., 2010; Nutbeam, 2000; von Wagner, 2007). A comprehensive definition developed from this research defines health literacy as the cognitive and social skills essential for gaining access to, understanding, and using health-related information to maintain good health (Nutbeam, 2000). Adequate health literacy thus requires one to also have adequate basic literacy including numeracy and oral and written literacy. Health literacy also overlaps with the concept of self-management as both refer to skills necessary for good medication adherence, regular self-monitoring, and seeking and interacting with health care services. Given these similarities, the measurement of the construct of health literacy has engendered significant empirical scrutiny and researchers have found that multiple factors (e.g. health care population, setting, and self-management tasks) need to be considered when assessing one's level of health literacy (Smith, Nutbeam, McCaffery, 2013).

Some investigators theorize that limited health-related knowledge creates motivational and volitional barriers for adherence (von Wagner, et al. 2009). Indeed, low health literacy has been implicated at all levels of health care from poor self-management to higher overall health care costs and increased risk for morbidity and premature mortality (Berkman, et al., 2011; Clancy, 2011; von Wagoner, et al., 2009). At the level of self-management, individuals with limited health literacy are less likely to take medications appropriately, accurately interpret printed health-related and medication information, and communicate effectively with their providers (Berkman, et al., 2011). Not surprisingly, data from a population-based study of Medicare recipients indicated that individuals with poor health literacy have significantly higher rates of hypertension, diabetes, heart failure, arthritis, and depression compared to individuals with adequate health literacy (Wolf et al., 2005). Drawing from current research, it is hypothesized that patients with MCC and limited health literacy experience compounded difficulties in adhering to the complex medication regimen.

Low self-efficacy. Self-efficacy has been shown to predict a wide-range of health behaviors in patients with chronic conditions, including medication adherence (Bandura, 1997; Elliott, 2008; Marks, Allegrante, Lorig, 2005; Schoenthaler, Ogedegbe, & Allegrante, 2009; Wolf et al., 2007). *Self-efficacy* is a cognitive-behavioral concept and is commonly defined as the confidence one has in his/her ability to perform a task or change his/her thinking, regardless of potential challenges in the environment (Bandura, 1986). According to social cognitive theory (Bandura, 1997), patients with high self-efficacy and positive outcome expectancies are more likely to take responsibility for their health and engage in health promoting behaviors. Indeed, individuals with high levels of self-efficacy and those that report improvements in self-efficacy have better health outcomes and accrue lower health care costs (Barlow, Wright, Turner, & Bancroft, 2005; Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002; Bodenheimer, Lorig, Holman, & Grumbach, 2002; Marks, et al., 2005). Self-efficacy for medication adherence means having confidence to take medications as prescribed across a variety of situations such as during times of psychological, social, and economic stress or after adjustments are made to the regimen, despite having side effects or when asymptomatic. Alternatively, patients with low self-efficacy are more likely to avoid taking medications or only partially adhere during these times.

Although self-efficacy has been widely studied within the context of self-management of chronic conditions, only a few studies have investigated the influence of self-efficacy on medication adherence. Nonetheless, perceptions of self-efficacy appear to be an important mediator in medication adherence (Brus, van de Laar, Taal, Rasker, & Widgman, 1998; Ogedegbe, Mancuso, Allegrante, & Charlson, 2003; Wolf et al., 2007). Among patients with arthritis (*N* = 37) taking a slow-acting drug (i.e. effects occur only after weeks or months of continuous use), self-efficacy, compared to other important demographic variables, perceived barriers, perceived support, and disease-related variables, was the only factor that distinguished between good compared to poor adherence (Brus et al., 1998). Good adherence in this study was considered at least 80% adherence as measured by a pill counting procedure.

Additionally, self-efficacy appears to be an important mediator between health literacy and adherence. In a study with patients with HIV, Wolf and colleagues (2007) reported that self-efficacy mediated the impact of low health literacy on medication adherence. Like the medical regimen for HIV patients, the regimen for MCC involves taking multiple medications on different dosing schedules. This research suggests that interventions aimed at enhancing self-efficacy may also help patients with MCC and limited health literacy improve their medication adherence. However, research on the relationship between self-efficacy, health literacy, and self-management skills is largely disease specific and little is known about their relationship in the context of self-management of MCC.

Psychological factors. There appears to be a bi-directional relationship between mental health problems and most prevalent chronic diseases like heart disease and diabetes. In fact a recent meta-analysis found that individuals with depression are at a significant risk of developing chronic conditions (relative risk for diabetes =1.6; Mezuk, Eaton, Albrecht, & Golden, 2008). On the other hand, having a chronic condition or acute events related to chronic disease (e.g. myocardial infarction) places individuals at a greater risk for developing major depression (Mezak, et al., 2008; Spijkerman, et al., 2005). Regardless of which developed first, depression or chronic medical illness, large-scale epidemiological studies have shown that the presence of psychopathology, particularly anxiety and depressive disorders, substantially increases the risk of all-cause mortality (Sullivan et al., 2012).

The symptoms of depression (e.g. loss of energy, poor concentration, depressed mood) and psychological sequelae make it particularly challenging for individuals with MCC to improve their health literacy and adhere their medication regimen over long periods of time. Further, even patients with sub-clinical symptoms are at risk because their depression may go undetected which results in inadequate treatment or follow-up (Hayes, Wells, Sherbourne, Rogers, & Spritzer, 1995). Subsequently, as severity of depression increases, patients report more functional limitations and declines in quality of life (Noel et al., 2004). After controlling for confounding sociodemographic variables, disease severity, and number of co-occurring conditions, individuals with clinical depression or even subthreshold depression report significantly poorer health literacy, physical functioning, perceived health status, quality of life and social support as much as or greater than patients with chronic medical conditions (Edwards, et. al, 2012; Fortin et al., 2006; Hays et al., 1995; Noel et al., 2004). For example, Hill-Briggs and colleagues (2005) reported that low-income African American patients with clinical depression disproportionately struggled with adhering to their medication regimen compared to nondepressed patients.

Additionally, research has consistently shown that, aside from the presence of depression, health-related distress can negatively affects one's self-management abilities (Gonzalez, Fisher, & Polonsky, 2011). For example, dysfunctional, unrealistic, and/or negative thoughts about one's health and self-management abilities (e.g. "Nothing I can do can change my health" or "I feel fine, therefore I don't need my medication or to check my blood pressure today" or "I'm defective/weak/broken.") negatively affects one's self-efficacy and adherence, thus maintaining an unhealthy lifestyle (Beck, 2011; Ogedebe, et al., 2003). Indeed, maladaptive coping behaviors, such as avoidance, social withdrawal, and substance use, are common in patients with depression and adjustment problems and lead them to disregard treatment recommendations or avoid learning about their illness or taking their medication (Cook, 2007). Programs that include cognitive and behavior based coping strategies that explore and address these factors would help improve patient engagement in self-management.

Sociocultural barriers. There is substantial research on the influence of sociocultural factors on health outcomes, health care access, and treatment adherence rates. Results from studies in low-resource primary care settings report that minority patients are less likely to have access to primary care and have health insurance compared to non-Hispanic White patients (Shi et al., 2013). However, other research suggests that socioeconomic factors, like socioeconomic status and race do not significantly impede medication adherence in chronic conditions (Dimatteo, 2004) and that at least 60% of low income patients are adherent (Cook, 2007). Nonetheless, this still leaves a large portion of patients who do not adhere to their medication regimen.

Factors associated with ethnic minority or low income groups, like lower educational attainment, may help account for greater risk of chronic disease diagnoses and stronger barriers to adherence. In the 2007 National Health Disparities report Hispanics were 4.6 times and African Americans were almost three times more likely than Whites to have below basic health literacy levels as measured by the National Assessment of Adult Literacy (Kutner, Greenberg, Jin, & Paulsen, 2006). Adapting interventions and intervention materials for limited literacy and limited health literacy populations may help improve medication adherence. For example, improving numeracy skills and understanding of oral and written information about health outcomes can enhance patients' knowledge and motivation to adhere to a medication regimen as well as help improve their ability to seek and obtain services and health insurance (Kuhajda, Thorn, Gaskins, Day, & Cabbil, 2011; von Wagner et al., 2009).

Poor social support is also a substantial barrier to medication adherence (Glasgow et al., 2001; Townsend et al., 2003). For example, one's medication dosing schedule can interfere with family or social events; thus, family support (or lack of) can facilitate (or impede) the change process necessary for improving adherence. Although it often may not be feasible for self-management programs to include families, programs can offer training for improving communication skills and help patients become better utilizers of their support system.

Single-disease approach to health care. The current disease-oriented approach to health care creates many barriers for patients with MCC in regard to getting their needs met (Mercer, et al., 2009). Interactions with the health care system become inextricably more complex and difficult when managing multimorbidity (Boyd & Fortin, 2010). For instance, patients are expected to maintain appointments with primary care and specialty providers, who are located at various clinics that are not always in the same community. This can be particularly difficult for patients with limited resources, limited access to care, or multiple psychosocial stressors.

In sum, a few conclusions can be drawn from this review of barriers to medication adherence. Research from the single disease literature on medication adherence consistently indicates that poor self-efficacy and cognitive and behavioral factors have the strongest impact on medication adherence. Future research should address ways interventions can help patients overcome these barriers. Therefore, the following will evaluate the current state of the research on medication adherence interventions and, where appropriate, self-management interventions for specific chronic conditions.

Medication Adherence Interventions for Patients with MCC

Although managing multimorbidity has long been a task of the clinical community, interventions for medication adherence with patients with MCC are relatively new to the research community. Reviews of the literature indicate that the majority of approaches for improving medication adherence focus on disease-specific, education-based interventions in primary care settings (Haynes et al., 2008; Osterberg & Blaschk, 2005; Viswanathan et al., 2012). These programs are designed to provide patients with knowledge about their medications, dosing schedules, and disease-related information and patients determine whether or not to use this information in their daily lives. Although didactic models can bring awareness to the importance of behavior change, the data do not suggest that this approach is effective in facilitating behavior change and improvements in medication adherence and health outcomes. This is consistent with reviews of education-based interventions for disease-specific self-management programs for socially disadvantaged populations (Glazier, Bajcar, Kennie, Willson; 2006; Plack, Herpertz, & Petrak, 2010) and patients with MCC (Smith et al., 2012).

This is likely due to the fact that educational approaches do not attend to the multifaceted needs that characterize many patients with MCC including limited health literacy, poor self-efficacy, significant distress, or limited access to health care. They also do not attend to the unique aspects associated with managing MCC including the regimen complexity, medication interactions, and managing side effects. Thus, education-based interventions may be necessary, but they are not sufficient. It is likely that interventions for medication adherence would have greater success if they combined education and strategies for helping patients overcome psychosocial barriers.

Reviews of clinical trials evaluating medication adherence interventions for patients with MCC are limited. Williams and colleagues (2008) completed the only review of randomized clinical trials (RCTs) (*N* = 8) available, while another review reported on a subset of interventions for MCC (*n* = 3; Viswanathan et al., 2012). Interventions were primarily pharmacist-led and used brief didactic and/or behavioral methods which included providing education, identifying medication-related problems, creating reminder charts, simplifying the regimen, and providing referrals. Nonetheless, the majority of adherence interventions were ineffective and studies had low power, therefore reviewers concluded that the evidence is insufficient and more research with patients with MCC is needed.

De Geest and colleagues' (2006) completed a unique pilot study with patients with MCC that investigated the effects of a self-efficacy driven intervention on medication adherence. The intervention used a combination of strategies including education, problem-solving and goal-setting training with targeted feedback to increase self-efficacy. The approach involved one home visit and three monthly follow-up telephone sessions. Patients (*N* = 13) exhibited improved adherence, as measured by an automated pill counting device in the pill bottle caps; however, they were unable to maintain improvements at follow-up. Although this approach is evidence-based and used both educational and behavioral approaches, modifications in intervention dose or frequency or specific strategies are needed to facilitate long-term improvements in adherence. Further, as previously discussed, psychological distress specific to taking multiple medications is common among patients with MCC, yet current interventions rarely address this aspect of adherence.

Relatively more medication adherence studies with disease-specific populations have been completed, although there is significant heterogeneity between intervention methods (Cook, 2006; Haynes et al., 2012; Vasanwanthan et al., 2012). A meta-analysis completed by Cook (2000; as cited in Cook, 2007) reported interventions with the greatest effect sizes include a combination of educational and psychosocial strategies (mean *d* = 0.74) with self-monitoring (*d* = 1.09) cognitive behavioral therapy (*d* = 0.97), and assertiveness training (*d* = 0.74) having the strongest effects on adherence behaviors. Additionally, a Cochrane review using qualitative analyses concluded that interventions successful in improving adherence had frequent interactions with patients (i.e. one contact per week) and included long term follow-up (> 6 months).

Notably, one pilot trial evaluated how an individualized integrated care approach, designed for a primary care setting, improved medication adherence in patients with depression and type 2 diabetes (Bogner & de Vries, 2008). A care manager served as the interventionist and as a liaison between patients and providers. The brief four week program included three 30 minute in-person sessions and two 15 minute telephone monitoring sessions. Patients exhibited significant improvement in medication adherence, as measured by automated pill counting device, with the intervention group achieving greater than 80% adherence. However, follow-up data were not collected in this sample, thus the long-term effectiveness of this approach is unknown.

Also, research on general self-management interventions for patients with MCC could provide insight into potentially effective methods for adherence interventions. Although this research is only just beginning, a recent review of RCTs (*N* =10; Smith et al., 2012) reported that interventions with improved psychosocial outcomes (e.g. quality of life) and health behaviors (e.g. diet, physical activity) typically included cognitive and behavioral coping strategies, self-management skills training, and structured feedback. Also programs associated with the medical clinic and tailored to specific patient concerns had greater success than those in the community or ones that had preset goals. No studies in this review (Smith et al., 2012) directly intervened on medication adherence indicating a significant gap in research on MCC.

The Chronic Disease Self-Management Program (CDSMP) is a particularly successful intervention for patients with MCC (Lorig et al., 1999, 2005). The intervention was grounded in social cognitive theory and aims to improve self-efficacy through use of cognitive symptom management techniques, dealing with emotions of fear, anger, and depression, communication with others (family, health care professionals), problem-solving, and decision making. The intervention was a peer led group program that met weekly for 2.5 hours for seven weeks. At one year follow-up participants reported significant reductions in health distress and health care utilization and improvements in stress management, self-efficacy, and disability. Notably, after controlling for demographic variables, baseline levels and changes in self-efficacy were related to health-care utilization and engagement in one's daily self-management tasks. This research is consistent with single-disease literature, which indicates that programs that aim to improve self-efficacy results in better self-management. Although this program is impractical for the primary care setting, aspects of the program (i.e. using a group method and combination of strategies) would likely be helpful in facilitating medication-related behavior change.

In conclusion, the evidence for interventions for medication adherence is weak including interventions that add in a behavioral approach with the traditional didactic method. A significant gap in the research is the paucity of studies that are theoretically grounded and designed to help patients with MCC overcome known barriers to medication adherence (e.g. limited health literacy, poor self-efficacy, psychological distress). Based on current research, recommendations for further intervention, development, and clinical research on medication adherence in patient with MCC are listed below:

1. Interventions for should be grounded in theory and build on and apply available evidence for effective single-disease medication adherence and self-management interventions.
2. Common barriers associated with managing MCC should be addressed in interventions including medication regimen complexity, distress, and poor self-efficacy and interventions should be tailored to patients with limited health literacy.
3. To meet the unique needs of patients with MCC, interventions should include an integration of educational, cognitive, behavioral, and emotional strategies. Importantly, goals should be collaborative with consideration of patient values and concerns and follow-up on progress with goals should include problem-solving and structured feedback.
4. Outcome measurement should be prioritized and addressed in the early stages of intervention development. Outcomes to consider include a combination of measures of adherence, as well as measures that assess variables that influence other aspects of managing MCC including, self-efficacy, health-related quality of life, distress, and patient knowledge.

5. Patients with MCC are commonly seen in FQHCs or low resource primary care settings. Thus, interventions should be designed with consideration of the unique needs of these settings.

Self-Efficacy as a Framework for Interventions

Self-efficacy, the primary construct of social cognitive theory (Bandura, 1986), is the foundation of many successful programs in medication adherence and self-management interventions in disease specific studies and the effectiveness of using this model in interventions for patients with MCC is building. Nonetheless, self-efficacy is a complex concept and researchers have only recently begun elucidating the specific social, cognitive, behavioral, and emotional mechanisms that improve self-efficacy and maintain long term behavior change.

In theory, self-efficacy is the link between a patient knowing what to do and actually doing it (Bandura, 2002). Bandura (1997) asserts that self-efficacy is determined and influenced by one's history of successfully doing a task, observing others accomplish a task, and other's verbal persuasion to engage in a task. Research with patients with chronic conditions indicate that cognitive strategies aimed at improving confidence improve one's perception of his/her ability to carry out a task and behavioral activation strategies can facilitate engagement in self-management tasks (Marks, et al., 2005a, 2005b). Further, the more one engages in self-management tasks and learns from past experience, the more confidence one has to overcome problems that impact self-management. Applied to medication adherence interventions, it is hypothesized that programs that include education, training in cognitive-behavioral strategies, individualized goals, and structured feedback will improve one's self-efficacy.

Improvements in self-efficacy for a measureable task like medication adherence could also potentially generalize to improving confidence for engaging in other self-management tasks.

Figure 1 below depicts an evidence-based model for improving medication adherence in patients with MCC by targeting self-efficacy, specifically through improvements in three domains of self-efficacy. Figure 1 provides an overview of the knowledge, cognitive and behavioral targets for improving self-efficacy for medication adherence. Each domain and specific strategies for improving self-efficacy are discussed in the corresponding sections below. It should be noted that strategies identified as primarily falling under one domain are also likely to facilitate improvements in other domains, which collectively enhances self-efficacy. Thus, domains of self-efficacy are described separately but they are inherently interrelated.

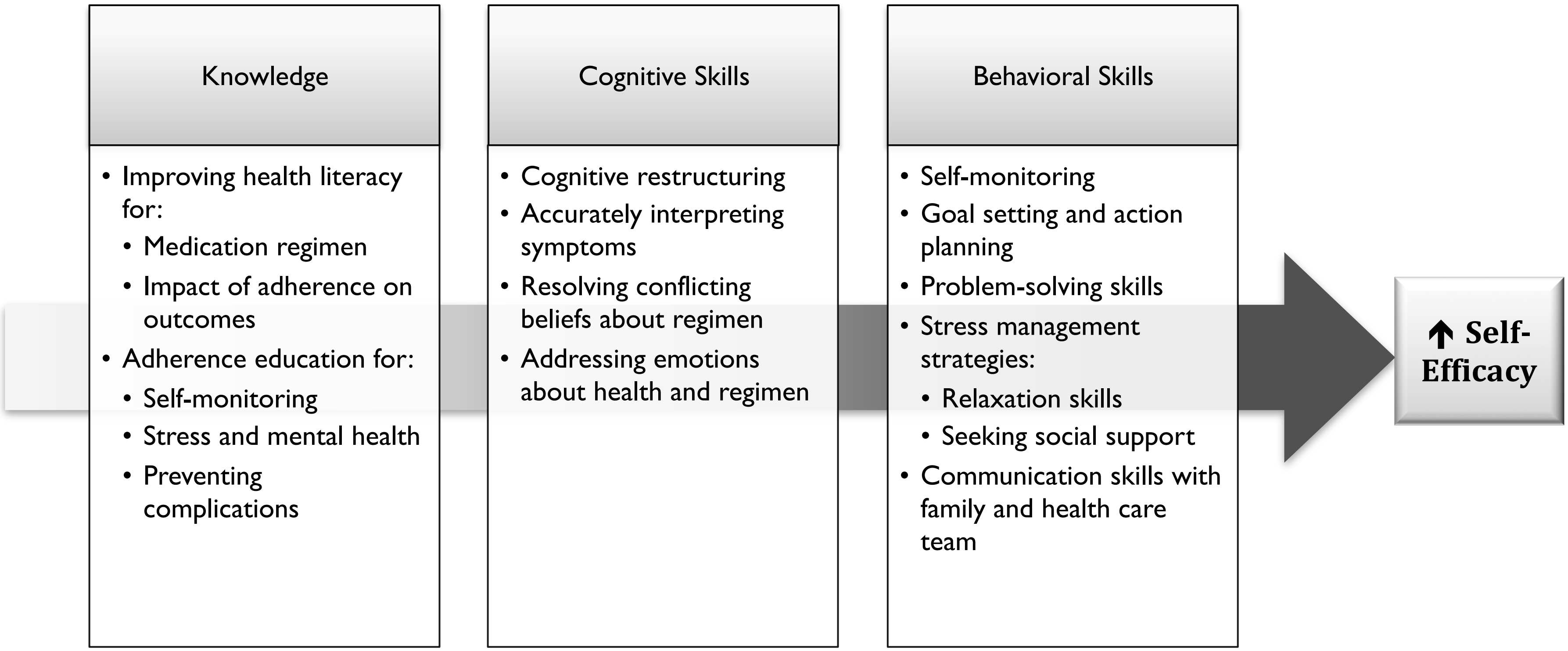

Figure 1. Intervention targets for improving self-efficacy for medication adherence.

Improving self-efficacy: Knowledge. Successful adherence to a complex medication regimen requires understanding of basic health information and how to integrate information about medications and health conditions amidst the competing needs of one’s lifestyle. Therefore, patients taking multiple medications for MCC need to be literate at multiple levels from having basic numeracy skills for calculating and sequencing multiple medications) to knowledge about medications and health conditions to knowledge about how to obtain financial assistance for medications (e.g. insurance, medication assistance programs).

Nutbeam (2000) proposed a multi-level model for health literacy that provides a framework for designing interventions for improving each level of health literacy. Level 1, functional health literacy, refers to factual health and disease-related knowledge as well as knowing how to use the health care system. Interventions for medication adherence can initially improve functional health literacy by helping patients create a schedule for the dose, frequency, and sequence of their medications, provide interactive exercises to practice making adjustments to the regimen, and encourage patients to work with their provider to simplify their regimen. Further, group programs provide valuable experiential learning opportunities about others experiences with working with providers, maintaining adherence through stressful situations, obtaining clinic and community services.

Although it is common for interventions to provide disease-specific and medication-specific education, it would be impractical to provide all of this information for patients with MCC. In fact one review of medication adherence interventions reported that disease-specific education did not significantly alter the effect size of the intervention (Conn, et al., 2009). However, Conn and colleagues reported that interventions that include succinct written instructions for taking medications were more effective (mean *d* = 0.61) compared to those without instructions (mean *d* = 0.29). Programs, therefore, may be more effective through helping patients improve their information seeking skills such as how to discern relevant information from prescription inserts and how to create dosing schedules as well as encourage patients to express concerns and questions to their pharmacist or provider about directions for medication taking. Programs can also help patients learn how to connect with available medication assistance programs in their clinic.

Level 2, interactive health literacy, of Nutbeam's model (2000) is the development of essential cognitive, behavioral and social skills and application of these skills to improve knowledge, motivation, and self-confidence for managing health. The skills associated with this level are typically taught in self-management programs for improving behavioral outcomes and therefore discussed in the next section. Finally, level 3, critical health literacy, is the development of cognitive skills for understanding social and political action in the community and societal determinants of health, thus is linked to population benefit. Some aspects of critical health literacy can be improved through medication adherence intervention such as helping patients understand their right to services and the costs and benefits of recommended services. Research suggests that patients move back and forth through the levels based on their health status and involvement in decision-making (Smith et al., 2013), therefore it is important for programs to provide some flexibility to individualize interventions based on patient needs.

As previously discussed, patients with MCC and limited health literacy may also have limited basic literacy skills. Therefore, discussions and materials should be tailored to the needs of these patients. The National Institutes of Health (NIH, 1994) *Checklist of Key Principles of Effective Low-Literacy Print Materials* is a resource that can be used to guide adaptations to materials in regard to their content and style, layout, visuals, and readability. Some examples of the guidelines include using simple diagrams or pictures, breaking large amounts of information down into small chunks, simplifying language, and creating straightforward instructions (i.e. "how-tos"). Additionally, the educational component of each session should cover one or two important concepts with a limited number of handouts rather than providing pages of text on multiple health-related concepts. These modifications will enhance comprehension as well as decrease feelings of being overwhelmed or burdened by information.

Improving self-efficacy: Cognitive skills. Bandura (1986) asserts that the likelihood of participating in a behavior is dependent upon one's perceived ability to overcome barriers and achieve success as well as one's expectations about the outcome of that behavior. Patients with MCC express uncertainty and have conflicting beliefs about their ability to manage their medications as well as associate negative feelings with taking medication (McSharry, Bishop, Moss-Morris, & Kendrick, 2012). Improving self-efficacy, thus, requires an understanding of how confidence in one's ability to engage in daily self-management can be enhanced and how uncertainty and negative feelings can be alleviated.

Leventhal and colleagues' Common Sense Model (1980, 2011) asserts that when deviations are detected in mental and physical functioning from expected functioning, one attaches meaning to the deviation referred to as a cognitive and emotional representation. Representations are determined by individuals' current knowledge about their health, social comparisons, and past experiences and are used to monitor health threats and guide self-management efforts. It is expected that by increasing knowledge about chronic conditions and medication regimen, uncertainty will decline and self-confidence will improve. Specifically, when patients learn about the symptoms of their diseases, medication side effects, and personal signs of stress, their ability to interpret and manage symptoms will likely improve. Subsequently, individuals will attach adaptive representations to deviations in functioning and their confidence to respond appropriately and overcome problems will improve. Indeed, research shows that patients have greater confidence in their ability to take medications appropriately when they have a clear understanding of their regimen and adherence goals (McSharry et al., 2012).

Patients also have conflicting beliefs about taking their medication, which affects their confidence to engage in the recommended regimen. For example, McSharry and colleagues (2012) investigated the cognitive representations of patients with MCC and found that patients understand that their medication regimen helps them function normally, but it reminds them of their illness which represents a threat to their identity. This conflict is similar to that of patients involved in qualitative research by Townsend and colleagues (2003). Notably, discussion in a group setting can help patients normalize and explore conflicting beliefs about medication management. Additionally, learning evidence-based cognitive strategies can help patients address and resolve discrepant representations about their health and self-management regimen.

Confidence is also affected when patients feel overwhelmed and struggle with managing their medication regimen. As providers attempt to pharmacologically control symptoms and prevent complications, they typically prescribe more and make adjustments to current prescriptions. As a result, patients attempt to accommodate their lifestyle to their evolving medication regimen and changing health status, thus, the complexity of the regimen is burdensome. Essentially, taking medication becomes associated with negative emotions and perceived loss of control over their routine, lifestyle, and body (McSharry et al., 2012; Townsend et al., 2003). Research indicates that when emotional barriers (or maladaptive representations) are addressed patients are better equipped to solve daily problems associated with managing chronic conditions (Krichbaum et al., 2003).

Improving self-efficacy: Behavioral skills. The final domain for improving self-efficacy and self-management is learning behavioral skills. The majority of medication adherence interventions that incorporate a behavioral component often use specific strategies like setting reminders, simplifying the dose regimen, and using medication packaging options (e.g. pill organizers and labeled boxes). In fact, one review (Conn et al., 2009) reported that the most effective behavioral strategy used with older adults was medication packaging. Interventions that used this strategy were associated with larger effect sizes (mean $d = 0.67$) compared to those without that option (mean $d = 0.33$). This section below will discuss broader theoretically grounded approaches that can facilitate behavior change using specific strategies. Moreover, these techniques can potentially be generalized to other self-management tasks. Given the multifaceted needs of patients with MCC it seems particularly critical to provide training that is generalizable to other self-management tasks.

Self-Monitoring. Substantial research suggests that people can not increase their motivation to change or create sustainable change without an adequate understanding of their current patterns and the psychosocial factors influencing them (Bandura, 1991). Self-monitoring provides individuals with feedback about their own behavior and barriers to self-management. Self-monitoring is commonly taught in self-management interventions and interventions that include this strategy are significantly more effective (mean $d = 1.18$) compared to interventions that do not include self-monitoring (mean $d = 0.30$) (Conn et al., 2009; Haynes et al., 2008).

Bandura's (1991) research indicates that the act of self-monitoring can lead to behavior modification and increase perceived locus of control over one's health. Applied to medication adherence, collecting personal data on medication taking behavior, symptoms, and side effects directly engages patients and provides valuable feedback on daily patterns that can be used for setting realistic and achievable goals. Additionally, in the case of multiple medications, self-monitoring may provide information on how to simplify the regimen. Reflecting on personal medication logs and sharing with others personal successes and barriers is therapeutic because patients can express beliefs about self-management, learn how to self-assess by acknowledging personal strengths and identifying opportunities for improvement, and learn from others' experiences. Moreover, once patients learn the skill of self-monitoring for medication adherence, it can generalize to other self-management tasks that require lifestyle modifications (e.g. diet, physical activity).

Goal setting for medication adherence. According to SCT and health behavior change research, goal setting and achievement is a fundamental element that significantly contributes to positive behavior change (Bandura, 1997, Bodenheimer & Handley, 2009; Marks et al., 2005b). The simple underlying assertion is that as people achieve their goals, their self-efficacy improves; alternatively when people fail to achieve their goals their self-efficacy goes down and they abandon their behavior change efforts. Indeed the US Preventative Services Task Force, American Diabetes Association, and American Heart Association all consider goal-setting a critical skill to managing chronic conditions and preventing disease-related complications (Bodenheimer & Handley, 2009). However, interventions for structured goal setting have yet to be incorporated into studies for improving medication adherence.

Because goal-setting is typically a component of a broader intervention, research on specific goal-setting strategies for health behavior change is still in its early stages. Health-related interventions vary in the quality and magnitude of the goal-setting practices, with goals being general (e.g. improve medication adherence) or specific with a detailed action plan (e.g. improve adherence by using reminder cues to take diabetes medication every day, before breakfast). A review of research of goal-setting approaches in primary care settings indicates that successful interventions typically encourage patients and providers to collaboratively create specific short-term goals and interventionists follow-up with patients to provide structured feedback (Bodenheimer & Handley, 2009).

The small changes model (SCM) is a theory-based behavioral approach that incorporates self-monitoring and goal-setting strategies for improving weight management (Lutes & Steinbaugh, 2010; Sbrocco, Nedegaard, Stone & Lewis, 1999). According to the SCM, when specific goal setting criteria are met, self-efficacy for making continued lifestyle changes increases and weight loss is more sustainable. Goals must be relative to one's baseline levels, therefore patients are asked to self-monitor and self-select goals based on current behavioral patterns. Goals must be realistic or manageable so that the patient does not experience too much burden or, in the case of food, deprivation. Finally, goals are traditionally followed-up on a weekly basis and, when appropriate, feedback from other group members and leaders is provided to help patients modify current goals or add new goals.

Recent studies based on the SCM with a community sample of African American women with obesity (Damschroder, Lutes, Goodrich, Gillon, & Lowery, 2010) and a sample of veterans with an average 3.8 MCC (Lutes, et al., 2012), showed continued behavior change and improvements in health outcomes (i.e. weight loss) up to three months after the intervention was complete. In a third study (*N*=25), a six month bi-weekly follow-up program (15 minutes telephone sessions) was added on to the original 10 week program which resulted in clinically significant weight loss at nine month follow-up (Lutes et al., 2010). The SCM has shown to be effective at improving weight loss outcomes using individual and group formats in combination with face-to-face, Internet, and telephone follow-up methods (Lutes & Steinbaugh, 2010; Lutes et al., 2012). Currently, developers are implementing an RCT to evaluate the effectiveness of utilizing community health workers and a culturally tailored adaptation of the SCM treatment with African American women with diabetes.

For many reasons, the SCM approach is potentially generalizable to medication adherence interventions. One of the major limitations in the medication adherence intervention literature is the weak evidence for achieving sustained adherence for medications taken over a long period of time. The SCM aims to create sustainable behavior change through its individualized goal-setting approach. Patients with MCC are typically on a unique medication regimen and this flexible approach allows patients to use their baseline data to inform the selection of their goals (e.g. one medication or aspect of medication taking). Moreover, encouraging patients to self-select a small goal may help increase their perceived control and decrease the overwhelmed feeling that many report related to their regimen (McSharry et al., 2012; Townsend et al., 2003). Finally, the SCM includes elements used in previous research that has improved medication adherence including individualized approaches, addressing patient burden, and structured and supportive feedback. However, the effectiveness of the SCM approach for improving medication adherence has yet to be evaluated.

***Problem-solving for medication adherence*.** Because change does not occur in a vacuum, interventions should include evidence-based strategies that help individuals plan for and overcome psychosocial and economic barriers that impede adherence efforts. In fact, training in effective problem-solving is a recommended evidence-based approach for improving self-efficacy and self-management skills in patients with chronic conditions (Marks et al., 2005b). Problem solving training (PST) is a positive intervention approach that moves away from the pathological approach taken on by the medical field and focuses on building social competence through enhancing problem solving abilities (D'Zurilla & Goldfried, 1971; D'Zurilla & Nezu, 1999). This approach is a self-directed learning process aimed at improving one's abilities to perform necessary tasks in the face of adversity as well as a general coping strategy that can be used to minimize the impact of minor and major stressful events.

Research shows that PST in isolation or as part of a treatment package is an effective method for improving physical and psychosocial outcomes in patients with chronic conditions (Cook, 2006; Hill-Briggs, 2003; Glasgow, Fisher, Skaff, Mullan, & Toobert, 2007; Lorig et al., 2005; Perri et al., 2001) and limited literacy (Hills-Briggs et al., 2011). The extent and manner that PST is implemented in self-management programs varies greatly across studies and settings. Regardless, PST is commonly referred to as a behavioral intervention as many studies provide only problem solving skills training. However, it was designed to address the cognitive and behavioral aspects of problem-solving as well as motivational and pragmatic issues (Cook, 2006; D'Zurilla & Nezu, 1999).

The first element of PST is to create a positive and constructive *problem-solving orientation* by targeting peoples' negative cognitions or conflicting beliefs about their problem solving ability based on past experiences. The ABC method is an example of an orientation strategy (Cook, 2006). With this approach patients are asked to first examine their self-talk by identifying the activating event (A), their beliefs (B), and behavioral and emotional consequences (C) and then reconstruct dysfunctional thoughts into constructive ones. After practicing this with the group in session, patients are assigned homework to identify negative thoughts after an emotional event. The second and more commonly used behavioral element is aimed at improving one’s *problem-solving skills* through a five step goal-directed process. Notably, a review of diabetes self-management interventions reported that interventions that included training in both the cognitive, problem-orientation training, and the behavioral, problem-solving skills, elements have stronger effect sizes than those that only provide behavioral skills training (Malouff et al., 2005). According to D’Zurrila and Nezu (1999) the cognitive element is closely related to the theoretical constructs of perceived control, self-efficacy, and Lazarus’s stress appraisal model (Bandura, 1997; Lazarus & Folkman, 1984). Improvements in problem-solving orientation may be particularly beneficial for those who report distress related to their medication regimen, a common concern for patients with MCC. Developing interventions that include both the cognitive component and behavioral component of PST may enhance the effectiveness.

Research shows that health outcomes are more likely to improve when problem-solving skills are shaped, revisited, and reinforced throughout the intervention (Glasgow et al., 2007, Malouff et al., 2005; Lorig et al., 2005). For example, homework might consist of practicing adopting a positive orientation and using problem-solving skills in a problematic situation. Additionally, a portion of the following program session should be dedicated to reviewing efforts, receiving feedback, and setting new problem-solving goals. Therefore, with experience in overcoming expected (e.g. medication adjustments) or unexpected (i.e. falling ill) problems that interfere with medication adherence efforts, confidence to overcome barriers improves. However, there is a paucity of research available evaluating the effectiveness of PST as a mechanism for improving medication adherence among patients with MCC.

In sum, based on previous research on interventions for medication adherence, there are a few approaches that have helped patients improve their adherence and even fewer that report sustained improvements. Review of the literature suggest that the most successful interventions have used a combination of educational and behavioral strategies. Research from the self-management literature suggests that interventions involving education and training and feedback on cognitive and behavioral skills can promote improvements in self-efficacy and medication adherence for patients with MCC. Each strategy presented here is grounded on social cognitive theory and evidence based cognitive behavioral approaches. Each allows for individualization based on patient needs which will likely be a valuable element in future interventions for patients with complex health conditions. Finally, these approaches are strengthened by the fact that each strategy can be generalized to other self-management tasks, but also target measurable outcome (e.g. medication adherence).

Adapting cognitive and behavioral interventions for limited health literacy populations. When providing cognitive and behavioral skills training for individuals with limited health literacy, a number of considerations must be taken into account. For many cognitive and behavioral interventions, the program only briefly reviews the educational material patients are expected to read and quickly moves into implementing behavior change strategies. As previously discussed, individuals with limited health literacy would benefit from programs that provide tailored information and basic education on critical aspects of adhering to a medication regimen prior to asking individuals to make changes. Another consideration is ensuring that each intervention strategy is effectively communicated. Some methods used in previous research include using the “teach back” method to confirm comprehension, incorporating interactive exercises with case examples that are common in the population (Kuhajda, Thorn, Gaskins, Day, Cabbil, 2011), focusing on select critical strategies (Rothman et al., 2009), and providing feedback on patient success in implementing behavior change strategies.

The cognitive and behavioral strategies discussed above can also be adapted for individuals with limited health literacy. A portion of the initial session may be dedicated to the rationale and process of self-monitoring and training in self-monitoring may include walking patients through how to complete a self-monitoring log. The SCM’s philosophy is useful for patients with limited literacy as the goal setting criteria are concrete and specific to critical behaviors. However, setting the first goal is typically couched within the session that covers many educational topics and strategies for categorizing food intake. Adaptations for limited health literacy may instead dedicate most of one session to education on “small goals” that includes a case example followed by an interactive exercise for creating one’s first goal. Finally, PST handouts are typically written at an advanced reading level using psychological jargon. Similarly, PST incorporates many problem-solving orientation and skills training strategies into its approach. This approach may be adapted for limited health literacy populations by removing jargon and selectively choosing strategies (i.e. ABC method, “teach back” problem-solving skills) that are appropriate for improving medication adherence in limited literacy population.

Providing Evidence-based Interventions in FQHCs

Patients served by FQHCs are disproportionately likely to have MCC. However, most FQHCs have limited resources for meeting the unique needs of this patient population for two primary reasons First, providers have limited interaction per visit per patient due to the number of patients seen in a primary care clinic (Boyd & Fortin, 2010). This makes it difficult to address barriers that can interfere with adherence, such as access to services and behavior change strategies. Second, although patient education about disease management is a standard of practice, it is often disease specific and accomplished using informational pamphlets and lists of resources (Bodenheimer et al., 2002). These methods for providing self-management education or treatment regimen recommendations are not adequate for many patients, particularly for those with MCC and/or limited health literacy.

A recent goal of the Bureau of Primary Health Care (Parekh & Goodman, 2013) and its partners include reducing health disparities in FQHC populations by improving self-management services. Self-management programs situated in the primary care setting can alleviate some of the burden faced by providers and nursing staff (Bodenheimer et al., 2002). The primary care provider can be easily informed and consulted regarding the patient's status and progress. Also, the program can meet the biopsychosocial needs of patients with MCC by meeting them at the point of care, providing assistance in medication adherence, and connecting them with other community or clinic services. Moreover, given the common co-occurrence of mental health problems with chronic diseases, programs can provide an additional venue to assess, monitor, and, if needed, refer patients for behavioral health or specialty mental health treatment.

However, in FQHCs, these programs are often initially supported by federal, state, and foundation grants, but they are not sustainable beyond the period of initial funding. The inability to sustain these programs is likely due to a combination of factors, including ongoing financial constraints, poor collaboration or integration between agencies, interventionist turnover, or reallocation of resources. Thus, engaging individuals involved in direct patient care in identifying the self-management needs of the patient population and collaborating with clinic administrators on the implementation of self-management programs may enhance sustainability (Beacham, Herbst, Streitwiser, Scheu, & Sieber, 2012; Daniels, Campbell, & Dixon, 2014; Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2006).

The current research and literature suggests that patients with MCC have multiple needs related to self-management and that these needs may vary based on sociodemographic factors and the clinical setting. Subsequently, this review stimulated questions regarding the self-management needs of an understudied population in Eastern North Carolina. Therefore, we completed a two-part pilot study. The first part involved a survey aimed at engaging patients and providers of a local FQHC in the research and program development process. The second part used the results of the pilot study to inform development and evaluation of an intervention aimed at improving patient self-management of MCC.

Study 1: Pilot Survey Study of Chronic Disease Self-Management Needs

The objective of the survey was to solicit perspectives from both patients and providers about the self-management needs of patients with chronic conditions. There were three specific aims for this exploratory survey study.

- AIM I: Collect descriptive data on the self-reported self-management needs of patients in a rural clinic with limited resources.

- AIM II: Explore perceptions of chronic disease self-management needs among patients and providers.
- AIM III: Evaluate whether the needs of patients with MCC are different than patients without MCC.

Study 2: Medication Adherence Intervention Study Building on the pilot study and limitations in current research, the current project involved the development and implementation of a health literacy-adapted medication adherence program for patients with MCC. The priority population from which the study sample will be drawn is largely understudied.

The content of the program is grounded in theory and informed by chronic disease research on interventions for medication adherence and self-management. Therefore, the intervention specifically focuses on strategies drawn from SCT, CBT, SCM, and PST. The intervention targets improving self-efficacy with emphasis on improving health literacy related to medication adherence in the initial sessions and emphasis on behavior change for improving medication adherence in latter sessions. Based on the results of the pilot study, program topics on barriers to medication adherence includes problem-solving and coping with stress-related to daily responsibilities and medication-related distress.

Specific aims and hypotheses of the proposed project:

- AIM 1: Obtain descriptive data of an understudied sample of patients with MCC including demographic data, number of chronic conditions, and measures of medication adherence, health literacy, self-efficacy, problem-solving skills, and

QOL.

- AIM II: Examine the relationships between number of chronic conditions and primary outcome (medication adherence) and secondary outcome variables (problem-solving skills, self-efficacy, and QOL) at baseline.
    - Hypothesis 1: There will be a significant negative correlation between number of chronic conditions and primary (medication adherence) and secondary outcomes (health literacy, problem-solving, self-efficacy, and QOL).
    - Hypothesis 2: There will be significant positive correlations between medication adherence, health literacy, self-efficacy, problem-solving, and QOL.
- AIM III: evaluate the preliminary efficacy of an intervention for patients with MCC on primary (medication adherence) and secondary (health literacy, self-efficacy, problem-solving, and QOL) outcomes.
    - Hypothesis 1: Compared to baseline assessment, medication adherence, self-efficacy, problem-solving skills, and QOL will be significantly greater at post-treatment assessment.
    - Hypothesis 2: Change in self-efficacy scores from baseline assessment to post-treatment assessment will predict medication adherence.

Chapter III: Methods

Study Site

The site of both studies was Kinston Community Health Center (KCHC), a rural Federally Qualified Health Center (FQHC) in Lenoir County, North Carolina. According to the 2013 Robert Wood Johnson survey of health outcomes in North Carolina, Lenoir County is ranked 94th out of 100 North Carolina counties for health outcomes as measured by morbidity and mortality and 77th for health factors related to behavioral and social characteristics (e.g. health behaviors, access to and quality of care, socioeconomic factors). KCHC provides health care services to underserved residents who as a whole are often undereducated and underemployed. Also, most patients at KCHC are African American (48%) or Hispanic/Latino (27%) and are uninsured with only approximately 27-32% having some type of insurance, primarily Medicaid and Medicare. Together these statistics underscore the substantial health disparities experienced in this region and need for tailored self-management programs.

In an effort to reduce health disparities in this region there have been ongoing collaborations with KCHC in recent years. From 2010 to 2013 we conducted a diabetes self-management program. We have also completed a case study evaluating implementation of a depression screening protocol and enhancement of behavioral health care at KCHC. Subsequently, collaborative relationships have developed with individuals at each level of service from the front desk and administrative staff to the medical and behavioral health providers. Moreover, successive Chief Executive Officers and other executive officers continue to be receptive to future self-management projects and were involved in the frequent discussions regarding the feasibility and planning of this project. These relationships have led to a gradual increase in referrals to the diabetes self-management program as well as provided exposure of clinical research methods to providers and staff and opportunities for this student researcher to gain additional experience in conducting research in a medical setting.

Institutional Review Board (IRB) Approval.

All research procedures including data collection and storage, recruitment, survey administration, and intervention materials and procedures were approved by the East Carolina University IRB prior to study implementation (See Appendix A for study approvals for the Survey study: UMCIRB-12-001914 and Intervention study: UMCIRB-13-001992).

Chapter IV: Study 1

The pilot study aimed to survey the perspectives from both patients and providers about the self-management needs of patients with chronic conditions. The methods and data analysis and brief discussion specific to the pilot study are presented below.

Method

Participants. Individuals were eligible to participate in the survey if they were at least 18 years or older and presenting for care at the FQHC. Individuals were excluded from the survey if they were under the age of 18, non-English speaking, or were not currently patients of the FQHC. Additionally providers in the family medicine and behavioral health departments were eligible to participate in the survey.

Materials. The patient and provider surveys were developed for this study. The patient survey was designed to be brief and written for individuals with limited primary literacy and limited health literacy. Both patient and provider surveys addressed important domains of care for chronic conditions: chronic disease self-management tasks, patient-provider communication, psychosocial barriers of self-management, and preferences related to a chronic disease self-management program under development at the clinic. Provider and patient versions of the surveys are located in Appendix B.

Procedure. Adult patients were approached in the waiting room and asked if they would be interested in completing an anonymous survey about their health care. Verbal consent was obtained from all patients prior to completing the survey. The research assistant verified literacy levels by asking participants if they felt comfortable completing the survey independently or if they preferred that the survey was read aloud

Analyses

Descriptive statistical analyses were used to identify the prevalence of chronic conditions, and frequency of specific chronic conditions, as well as the frequency with which patients and providers endorsed survey items. Pearson Chi-square test was employed to evaluate differences in frequencies between groups.

Results

Sample characteristics. A total of 53 patients agreed to complete the survey. All providers (*n* = 14) agreed to complete the survey. The majority of patients had 2 or more chronic conditions (62%) and 45% of patients reportedly had three or more chronic conditions. Hypertension was the most prevalent chronic disease reported by 79% of the sample, followed by diabetes (34%), arthritis (26%), high cholesterol (26%), sleep problems (25%), depression/anxiety (23%), chronic pain (21%), asthma (17%), obesity (8%), heart disease (7%), and borderline diabetes (2%).

Group characteristics. Table 2 lists the most frequently identified self-management needs and barriers across each domain by patient and provider group. Weight management and medication adherence were among the top identified self-management improvement needs by patients (49%, 42%, respectively) and providers (86%, 64%, respectively). Patients and providers ranked overcoming stress related to daily responsibilities, emotional distress, and health-related distress as the top three (out of six) psychosocial barriers to self-management. Both patients (88%) and providers (93%) overwhelmingly endorsed updates to providers regarding patient progress in a self-management program as desirable.

Table 2

Chronic disease self-management needs by patient and provider

Patient endorsement	n = 53	Provider endorsement	n = 14
Self-management tasks		**Self-management tasks**	
Making lifestyle changes	49%	Weight management/loss	86%
Weight management/loss	49%	Medication adherence	64%
Medication adherence	42%	Patient-provider communication	43%
Patient-provider communication		**Patient-provider communication**	
Health care goal-setting/decision-making	35%	Communicate challenges in keeping appointments	64%
Communicate symptom side-effects, symptom changes	29%	Health care goal-setting/decision-making	57%
Psychosocial barriers		**Psychosocial barriers**	
Stress related to daily responsibilities	40%	Stress related to daily responsibilities	64%
Emotional distress	34%	Emotional distress	50%
Health distress	32%	Health distress	43%
		Family relationships	43%
Self-management program updates		**Self-management program updates**	
Patient updates provider	54%	Update in health record	71%
Update in health record	46%	Patient updates provider	21%

Group differences. Pearson Chi-square test and Fisher's Exact test were used to identify differences between groups. Providers were significantly more likely (64%) than were patients (17%) to indicate that patients would benefit from improving communication about keeping appointments $\chi^2(1, N = 65) = 8.34$, $p = 0.008$, $OR = 2.67$. Patients were significantly more likely (44%) than providers (21%) to prefer the face-to-face communication $\chi^2(1, N = 62) = 4.67$, $p = 0.031$.

Differences between patient groups based on the number of chronic conditions self-reported by patients were also examined. Notably, 38% of patients with 3 or more chronic conditions endorsed a desire to improve self-management of MCC while there was no endorsement among patients with less than 3 chronic conditions, $\chi^2(1, N = 53) = 13.10$, $p < 0.001$. Additionally, patients with 3 or more chronic conditions were significantly more likely (44%) to endorse needing improvement in pain management compared to patients with less than 3 chronic conditions (17%), χ^2 (1, N = 53) = 6.47, p = 0.011, *OR* = 2.94. Patients with 3 or more chronic conditions were twice as likely (54%) as patients with less than 3 chronic conditions (27%) to report that stress related to daily responsibilities interfered with self-management efforts, χ^2 (1, N = 53) = 3.86, p = 0.049, *OR* = 2.75. Patients with two or more chronic conditions (45%) also were significantly more likely to endorsed stress related to daily responsibilities compared to patients with less than two chronic conditions (23%), χ^2 (1, N = 50) = 5.56, p = 0.018, *OR* = 2.65.

Implications for Intervention Priorities

Sixty percent of patients surveyed in this clinic reported having MCC, which is more than double the national estimate indicating that 25% of patients in primary care have MCC (Boyd & Fortin, 2010). Collectively, providers and patients endorsed similar self-management needs and psychosocial barriers. Both groups agreed that weight management and medication adherence scales were the most important self-management needs; however, providers more frequently endorsed these topics as important. Specifically, weight management was ranked by 86% of providers versus 49% of patients and medication adherence was ranked by 64% of providers versus 46% of patients. This suggests that providers collectively agree on which self-management needs are the highest priority, but their patients may have less insight into the relative importance of these areas. Both groups similarly ranked managing stress related to daily responsibilities, emotions, and health-related distress as the greatest barriers to self-management. Lastly, consistent with the recent shift toward patient-centered care, improvement in communication about health-care decision making and goal setting were also among the highest ranked communication needs by all participants.

Weight management and medication adherence were the top identified self-management improvement needs by patients and providers, which is consistent with priorities in the public health domain. For many reasons it is more appropriate to intervene on medication adherence before focusing on other lifestyle changes, including weight management. First, achieving medication adherence is the single most important modifiable aspect of managing MCC because it provides an immediate health risk reduction (Sabate, 2003). Second, providing a medication adherence intervention at the point of care where medications are primarily managed creates unique and convenient opportunities to facilitate patient-providers communication (another critical aspect associated with better health outcomes in patients with MCC). Third, lifestyle change interventions focus on changing multiple health behaviors, but it may be more appropriate to focus on one type of behavior change (i.e. medication adherence) with the priority population. Patients in this population are more likely to have limited health literacy and little, if any, experience in self-management programs. Therefore, focusing on a single measurable behavior decreases the cognitive load and creates extra time for exposure to and honing of behavior change skills. These skills can be subsequently generalized to address more complex lifestyle changes, like weight loss. Fourth, all patients with MCC are on a medication regimen, yet not all patients with MCC are overweight or obese. Fifth, research from the literature indicates that, for patients with MCC, the medication regimen is the most challenging and distress aspect of managing their health. For these reasons part two of this project describes and evaluates an intervention that focuses on medication adherence for patients with MCC.

Chapter V: Methods for Study 2

The intervention study aimed to evaluate the relationship among variables and effects of the intervention on primary and secondary outcome variables in a sample of patients with MCC. The methods and data analysis specific to the intervention study are presented below.

Method

Participants. Participants were patients of the Kinston Community Health Center. Eligibility criteria included: 1) at least 18 years or older and 2) diagnosed with two or more chronic diseases. Patients were excluded from the study if they were under the age of 18, non-English speaking, below sixth grade reading level, diagnosed with cognitive impairment, reported suicidality or psychotic symptoms, or appeared to be a better fit for one-on-one intervention. If patients were eligible but did not have medication access through insurance or were not yet enrolled in the clinic's medication assistance program, they were referred to the program coordinator to get enrolled which served to further integrate the program into the clinic setting. Enrollment in the medication assistance program was not an eligibility requirement for the study.

Recruitment. Research with members of minority groups living in rural communities suggests that additional strategies are necessary to enhance recruitment and retention (Burns, Skoward, Skelly, Leemon, & Carlson, 2008). Therefore the researchers worked closely with individuals within the clinic before, during, and after the planning and implementation of the research project and the intervention materials were tailored to meet the needs of the populations and to be culturally congruent. Also advertisements were posted around the KCHC waiting rooms and exam rooms and patients could self-refer by calling the number listed. Providers were also a source of recruitment and were notified of the study and participant eligibility criteria. Providers could directly refer the patients to the program recruiter or provide informational handouts to patients whom might benefit from the program. If patients expressed interest in the program, they were invited to complete an enrollment session that day or scheduled for a future date, which included informed consent, an introduction to program materials, and a baseline assessment of psychosocial health outcomes.

The consent form was written at a sixth grade reading level, which was determined using sentence by sentence analysis with Microsoft Word's Readability Statistics program. This document was read to the patient and time was provided for the patient to ask questions about the experience of being a research participant and participating in the intervention. Each participant was provided a copy of the consent form to take home.

Intervention mode and duration. The program utilized a closed-group format with 4-7 group members in each group. There were seven contacts made with the participants. The first contact was at enrollment (1.5 hr session), which consisted of informed consent, introduction to group materials, and baseline assessment. Group sessions were held weekly for 4 weeks (1.5 hr each). Follow-up included 2 weekly individual telephone sessions (30 min each). Post-treatment assessment occurred within one week of last phone contact (Figure 3).

Intervention materials. Participants received a packet of program materials throughout the program. The packet contained educational handouts and worksheets, medication self-monitoring record book, and a dosing schedule for current medications.

The intervention materials were adapted for limited primary literacy and limited health literacy populations using the *Checklist of Key Principles of Effective Low-Literacy Print Materials* developed by the NCI (2003). Individualized dosing schedules were compiled from the results of the baseline assessments, medical record chart review, and designed so participants can log and monitor outcome changes over time. Participants completed the self-monitoring logs over the course of the program for the purpose of tracking weekly self-selected goals and medication taking behaviors.

Group session format. A detailed session-by-session outline is available in Appendix C and a brief overview of the session content is available in Table 3. Core skills and interventions were adapted from the SCM (Lutes & Steinbaugh, 2010) and PST (D'Zurilla & Nezu, 2009; Cook, 2009) to enhance medication adherence.

Although specific content varied across sessions, each session followed the same agenda including: agenda setting, check-in, topic introduction, group discussion, didactics, skills training and practice, goal-setting, and feedback. At the start of each session, participants were welcomed back to group and the agenda was announced. The group proceeded into an initial check-in on how the participant's weeks went and brief impressions of goal achievement efforts. Next, the new topic and skill was introduced and there was a time for the group members to discuss and reflect on their experiences with that topic (e.g. thoughts and feelings about topic, personal barriers, successes at coping, etc.). Following this discussion the group leader provided psychoeducation on the medication adherence topic and engaged participants in an interactive exercise (see Table 3). The latter part of the group meeting was dedicated to setting goals, which included developing personalized action plans. During this time leaders reinforced successes and provided feedback.

Table 3

Overview of Session Content

	Primary Objective(s)	Education	Skills Training
Session 1	• Enhance motivation for improving medication adherence • Build cohesion	• Program philosophy • Group rules and process • Self-monitoring • Goal-setting	• Self-monitoring • Goal-setting
Session 2	• Reinforce self-monitoring and goal-setting skills • Improve health literacy	• Medication prescriptions • Dosing schedules	• Refine self-monitoring and goal-setting • Create a dosing schedule • Use a pill organizer
Session 3	• Reinforce goal-setting skills • Enhance insight for adherence • Improve problem-solving orientation	• Medication adherence problems • Problem-solving orientation	• Goal-setting • The ABC Method
Session 4	• Reinforce goal-setting skills • Reinforce ABC skills • Improve problem-solving skills	• Problem-solving approach • Problem-solving skills training	• Goal-setting • Problem-solving skills
Phone Sessions 5-6	• Reinforce goal-setting skills • Reinforce problem-solving orientation and skills	• None	• Feedback on goal-setting and problem-solving • Planning for future problems.

Individualized booster telephone sessions. Booster sessions were intended to provide individualized follow-up, reinforcement, and feedback on participants' problem-solving skills for medication adherence. Conversations followed a similar agenda to group sessions, with the exception of introducing a new topic, instead, previously learned skills were revisited as needed. During this session, the leader provided specific recommendations in order to facilitate problem-solving and solution identification. At the end the leader and participant created an action plan and scheduled the next phone session.

Participant compensation. Participants were informed during enrollment that they would receive compensation for enrolling and completing the program and follow-up assessment. They received $30 in gas cards to offset any transportation costs accrued while commuting to the clinic for program sessions and assessments. Participants received one $15 gas card at enrollment and one $15 gas card after post treatment data were collected. Participants who did not have or could not arrange for transportation were provided transportation via the clinic's outreach service van. Participants who utilized the clinic's transport van did not receive the gas card.

Referral procedure and collaboration. In an effort to provide collaborative patient-centered care, the medical providers and behavioral health provider at KCHC were contacted throughout the project regarding their patients. Two scenarios have been identified for when contacting providers would be appropriate. One scenario was in the event that the participant exhibits or reports substantial distress, suicidal thoughts, or concerning medical symptoms. The medical provider was contacted immediately and updated on the participant's presenting symptoms or the participant was taken to the on-site walk-in clinic for treatment. Additionally, the behavioral health provider, a licensed psychologist, was involved in planning program implementation and available on site as needed for consult and referrals. The other scenario was to facilitate coordinated care on behalf of the participant. Per the results of the patient and provider survey, the program leader updated providers on participant progress. During the informed consent process these procedures were reviewed and the group leader explained methods of disclosure with the participant. The participants were asked if they would like the program leader to update their provider on their progress over the course of the intervention. All participants were given the option to opt out of provider updates.

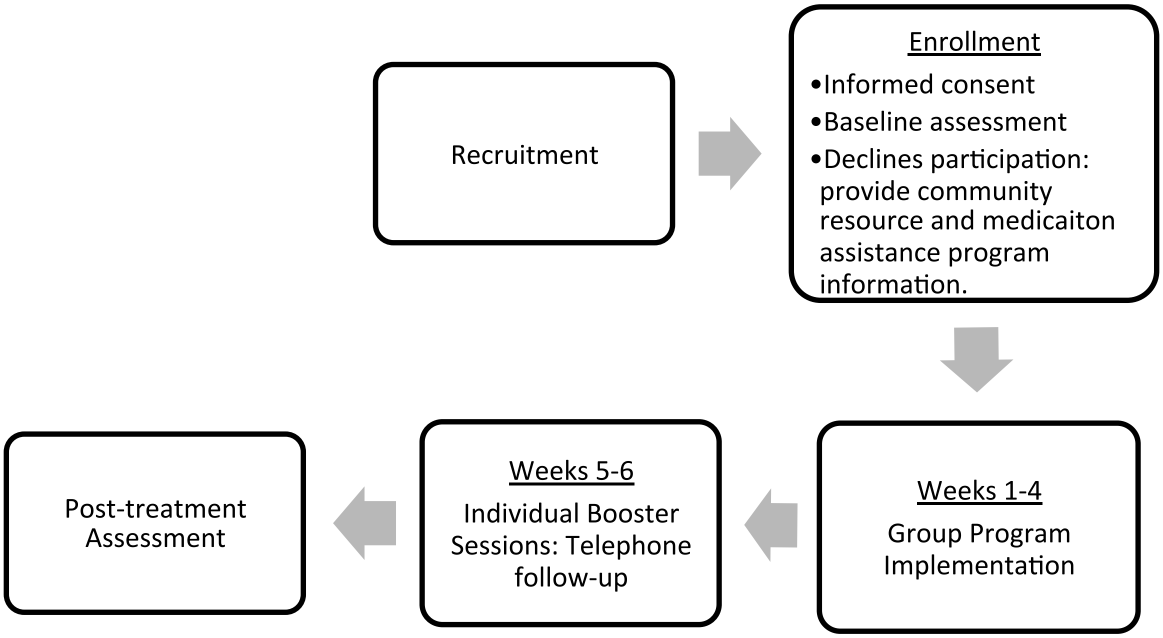

Figure 2. Flow diagram of project procedures

Assessment of Primary and Secondary Outcomes

Medication adherence. Medication adherence in patients with MCC, the primary outcome in the present study, is most commonly assessed using self-report measures and daily self-monitoring logs. Morisky and colleagues (2008) developed and validated an eight-item Morisky Medication Adherence Scale (MMAS) based on the theory that medication adherence is influenced by a number of factors including psychosocial barriers and regimen complexity. The MMAS was validated in a large study (*N* = 1367) (Morisky et al., 2008). It was determined to have good reliability (alpha = 0.83) and to be a valid predictor of health outcomes (e.g. blood pressure control). Cut points were chosen based on the scale's relationship with blood pressure control, such that patients with well-controlled blood pressure earn higher scores. On the MMAS, high adherence correlates with a score of 0, medium adherence with scores of 1 or 2, and low adherence with scores greater than 2. Regarding missing data, the authors of the MMAS utilize the completion criteria of 75% in order for a questionnaire to be considered valid. Reliability for the scale with the current sample fell just short of acceptable with internal-consistency of $\alpha = .69$.

Patients were also asked to complete a daily medication self-monitoring log of up to three medications. The log was designed to match the patient's unique dosing schedule, and patients simply checked off when they took their medication. Baseline medication adherence was determined by the first week of self-monitoring, and patients were asked to make no changes to their current patterns. The log had a space for the patient to add the number of times they were supposed to take their medications and add the number of times they actually took their medications for each day.

Health literacy. Although there is no gold standard for assessing health literacy, research suggests that the Test of Functional Health Literacy in Adults short form (S-TOFLHA) to be the most reliable and valid measure of functional health literacy (Baker, Williams, Paker, Gazmararian, Nurss, 1998; von Wagner et al., 2009). Reliability and validity studies demonstrated that the STOFHLA has strong internal consistency (alpha = 0.97) and that it is highly correlated with other measures of health literacy including the Rapid Estimate of Adult Literacy in Medicine (Davis, Crouch, & Long, 1992) and the full TOFHLA, with $r = 0.81$ and 0.91, respectively.

The STOFHLA is a 36-item timed test (maximum time = 7 minutes) that uses 2 reading passages from the original extended version of the assessment. The STOFHLA assess reading comprehension via two passages about different healthcare scenarios; one is written at 4.3 grade reading level and the other is written at a 10.4 grade reading level. In each passage, words are omitted and the participant is asked to select the omitted word from four multiple-choice options. A total score between 0-16 indicates *inadequate health literacy*, a score between 17-22 indicates *marginal health literacy*, and a score between 23-36 indicates *adequate health literacy*. Reliability for the scale with the current sample was good with internal-consistency of $\alpha = .969$.

Health-related problem solving*.* The Health-related Problem Solving Scale (HPSS; Hill-Briggs, Gennell, Kukarni, Klick, Brancati, 2007) is designed based on problem solving theory (D'Zurilla & Nezu, 1999) and chronic disease self-management model (Hill-Briggs, 2003). The scale has 50 items with 5-point Likert style response option format and can be completed in 5-10 minutes. Questions are derived from a health care population and assess problem-solving difficulties and intervention effectiveness (i.e. change in abilities over time; Hill-Briggs, Cooper, Loman, Brancati, Cooper, 2003). The scale has seven subscales that relate to the 7 domains of problem-solving theory: effective problem solving, impulsive problem solving, avoidant problem solving, positive learning, negative learning, positive orientation/motivation, and negative orientation/motivation (Hill-Briggs et al., 2007). Higher scores on the subscales indicate more of that problem-solving characteristic and higher HPSS total score indicate better problem-solving. In the validation study of the HPSS (Hill-Briggs et al., 2007), average Total HPSS score was 19.7 (*SD* = 4.0) and mean HbA1c was significantly greater in participants scoring below 18.5 compared to those with scores greater than 21.9. Cronbach's alphas were 0.86 and 0.89 for diabetes and HIV minority populations, respectively, and positive subscales were weakly correlated with their corresponding negative subscales. Further, the HPSS total score and subscale scores strongly and significantly correlate with health outcomes (e.g. HbA1c, hospitalizations, ED visits). This will be the first study using the HPSS to evaluate problem-solving in a multimorbidity sample. Reliability for the HPSS scale with the current sample was good with internal-consistency of $\alpha = .924$.

Health-related quality of life. The World Health Organization developed a quality of life measure for health care populations that is available in the public domain. The World Health Organization Quality of Life – BREF scale (WHO QOL-BREF) is a brief measure of quality of life with only 26 items compared to the original 100 item measure (Murphy, Herrman, Hawthorne, Pinzone, Evert, 2000). The scale assesses general quality of life with two questions and four domains (physical, psychological, social relationships, environment) using 5-point Likert scale response options. Raw scores are transformed into scaled scores (0-100) with higher scores indicating higher quality of life. Cronbach's alphas for the four domains were as follows physical health = .86, psychological = .76, social relationships .66, and environment = .80 and test-retest reliabilities across domains ranged from .66 to .87. The scale is highly correlated with single item measures of general quality of life and all four scales significantly differentiate between healthy and chronically ill populations. Cases were deleted if 20% of the participant's data was missing. Reliability for the scale with the current sample was good with internal-consistency of α = .831.

Self-Efficacy. The Chronic Disease Self-efficacy Scale (CDSES, Lorig et al., 1996) assesses patients' self-efficacy for managing their chronic conditions and developed out of Bandura's self-efficacy theory (1986). The 32-item scale with 10-point Likert style response options assessing three categories of self-efficacy beliefs and confidence: to perform specific behaviors (e.g. exercise regularly, communicate with physician and family, obtain information about disease), to manage disease generally (e.g. manage condition on regular basis, engage in regimen tasks and reduce disease-specific distress), and to achieve outcomes (e.g. engage in chores and pleasurable activities, manage symptoms and depression, etc). Scores are calculated by obtaining the mean in each category and scores closer to 10 indicate higher self-efficacy. Reliability for the CDSES with the current sample was good with internal-consistency of α = .961.

The Medication Adherence Self-efficacy Scale (MASES, Ogedegbe, Mancuso, Allegrante, & Charleston, 2003) assesses patients' perceived self-efficacy for taking anti-hypertensive medications. The 26-item questionnaire asks patients to rate their confidence in their ability to take medications all of the time across various situations. Response options include *not at all sure, somewhat sure, very sure* and are scored 1, 2, or 3, respectively. Psychometric research (Ogedegbe, et al., 2003) involving patients with hypertension indicated that that the MASES is internally consistent with a reliability coefficient $r = 0.95$. Additionally, patients with controlled blood pressure generally scored higher ($M = 2.54$) compared to patients with uncontrolled blood pressure ($M = 2.48$). Although group differences were not statistically significant, these scores were in the predicted direction and provided preliminary evidence for an inverse relationship between self-efficacy and blood pressure. Reliability for the MASES with the current sample was good with internal-consistency of $\alpha = .916$.

Table 4

Overview of Study Outcomes by Measures

Outcomes	Assessment Measure	Description
Primary Outcome		
Medication adherence	MMAS (8 items)	Self-report measure of medication self-management
	Daily self-monitoring log	Percentage of medication taken divided by prescribed recommendations
Secondary Outcomes		
Health Literacy	STOFLHA (36 items)	A brief assessment of health literacy using health-related items
Health-related quality of life	QOL (26 items)	Brief self-report of quality of life specific to populations with chronic conditions
Problem-solving	HPSS (50 items)	Self-report of ability to overcome barriers to self-management and cope.
Self-efficacy	CDSES (32 items)	Self-report of perceived self-efficacy for health care self-management
	MASES (26 items)	Self-report of confidence for taking medications across situations

Note: CDSES Chronic Disease Self-efficacy Scale (CDSES) Health-related Problem Solving Scale, (HPSS), Medication Adherence Self-efficacy Scale (MASES), Morisky Medication Adherence Scale (MMAS), Test of Functional Health Literacy in Adults – short form (STOFLHA), World Health Organization Quality of Life scale (QOL)

Power

A power analysis was completed using the statistical software, G*power version 3 (Buchner, Erdfelder, & Faul, 1997). Although the average effect size (*d*) for educational and behavioral interventions for medication adherence is 0.54, significant heterogeneity among studies makes it difficult to draw definitive conclusions regarding the effectiveness of current interventions (Kripalani et al., 2007). Therefore, a conservative and small effect size of 0.3 was chosen based on the limited available evidence for studies involving similar populations that also utilize the proposed dose and mode of treatment and integration of strategies. Based on two-samples repeated measures *t*-test, a sample size of 55 is needed to have at least 80% power and traditional .05 criterion of statistical significance.

Attrition analyses for studies of medication adherence interventions (educational + behavioral components) for patients with MCC report retention ranging from 82% to 100%. However, characteristics that are common in this population (i.e. limited transportation and economic resources, distrust of researchers, and lack of infrastructure for research) are known barriers for completing programs and increasing attrition (Loftin, Barnett, Bunn, & Sullivan, 2005). Retention for another chronic disease intervention study recently completed at KCHC was 16 out of 39 patients or 41%. As previously discussed, the lab has established a collaborative relationship with KCHC and employed strategies that enhance recruitment and retention. Therefore a conservative projected attrition estimate of 50% was used and the proposed project attempted to enroll 64 patients.

Chapter VI: Results for Study 2

Participant Attrition

In an effort to provide information regarding recruitment and retention in rural primary care research, Figure 4 depicts participant flow from referral to post-treatment assessment. The most effective method of recruitment was through direct provider referral which produced 118 out of 119 referrals. Referred patients were contacted by telephone or upon arrival at the clinic for their medical appointment. At this time, the program coordinator briefly provided information about the program and answered any questions; those who expressed interest (*n* = 54) scheduled an interest meeting/appointment with the program coordinator. Despite reminder calls, twenty-five patients never attended their scheduled appointment and some were rescheduled up to three times. The program coordinator discontinued contact after the third missed appointment.

Of the 29 patients who attended the interest meeting, 20 completed the informed consent process including baseline assessment and were assigned to a group. Reasons for not enrolling include ineligibility (*n* = 7) and disinterest (*n* = 2). The first group meeting was scheduled after at least four participants were assigned to a group. Therefore, the delay between the interest meeting and first group meeting ranged from two to five weeks. There was some attrition during this delay as contact was lost with one individual, one obtained a job, and two became “too busy.” Therefore, 16 participants began the group intervention and 13 participants completed. Overall, attrition from the baseline assessment was 35%. However, once participants attended the first group meeting attrition decreased to 15%.

With regard to attendance throughout the intervention, completers received 79% of the intervention contacts. Attendance rates throughout the intervention were high as completers attended 85% of the group sessions (44 out of 52) and 77% of the telephone sessions (20 out of 26). Two of the missed group meeting were completed with 30 minute in person makeup before the next group meeting.

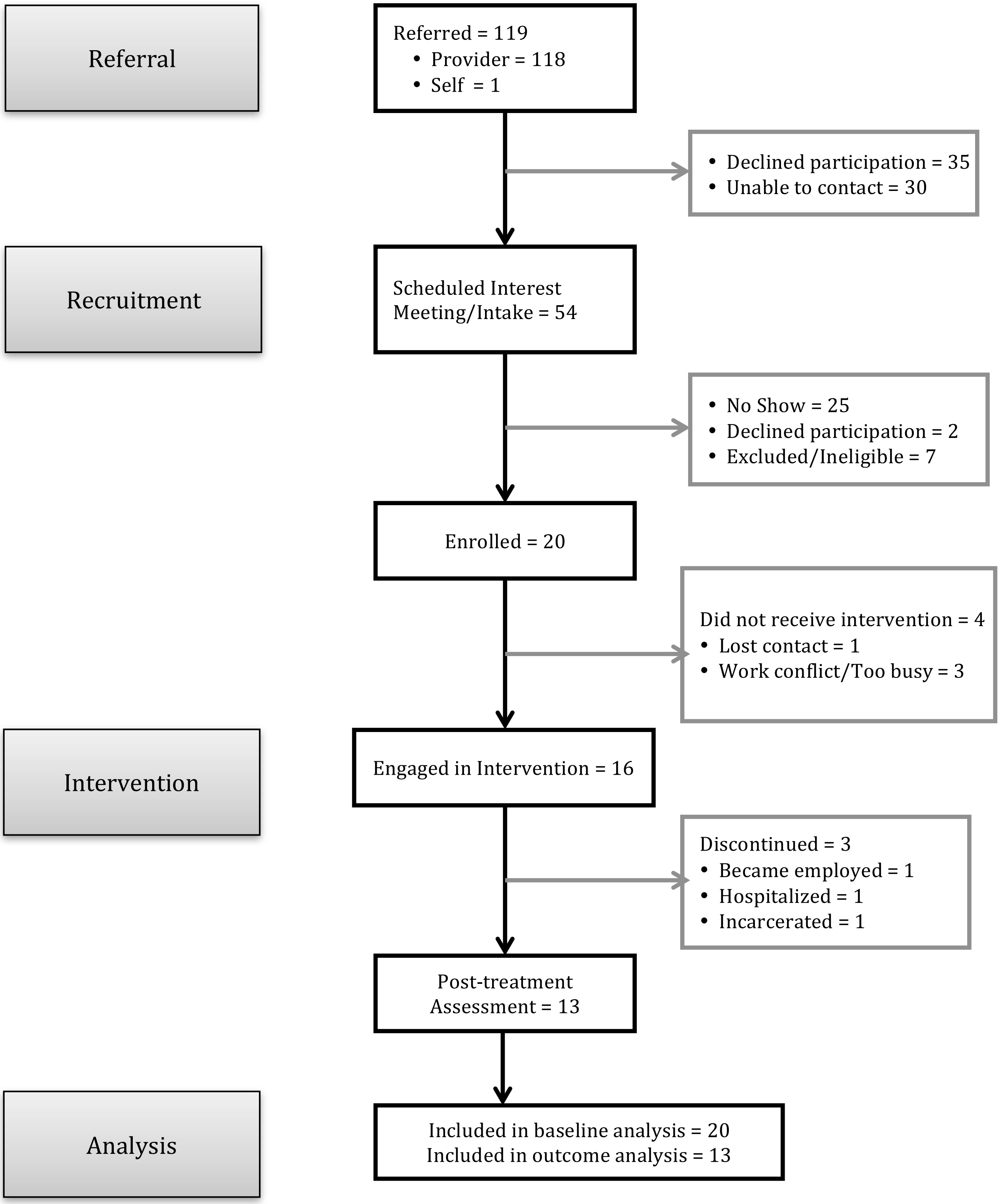

Figure 3 Flow diagram of recruitment and retention.

Baseline Results

Sociodemographic characteristics. Univariate statistical analyses were completed to determine the socio-demographic characteristics of the sample (*N* = 20, Table 5). The sample was evenly balanced by sex (50% male), on average 56 years old, and predominantly Black (95%). Participants were predominantly unemployed or disabled (85%), reported an annual income of less than $10,500 (75%). Sixty-two percent of participants reported having at least a high school education and 60% had average health literacy as measured by the STOFHLA. Additionally, participants were managing, on average, five chronic conditions and prescribed seven long-term medications. Ninety-five percent (*n* = 19) of the sample reported receiving medication assistance through Medicare/Medicaid (40%), private insurance (15%), or the clinic's PAP (40%).

Descriptive analyses were completed for the primary variable, medication adherence, and secondary variables, health literacy, self-efficacy, problem-solving, and QOL. Table 5 presents the baseline characteristics of the original sample of 20 participants.

Table 5
Participant Baseline Demographic and Psychosocial Characteristics (N = 20)

Demographic	**Mean (SD), %**
Age (yr)	56.75(8.67)
Chronic Conditions	5.40 (2.28)
Medications	7.00 (3.28)
Sex (% Male)	50%
Race (% Black)	95%
Employment (% Unemployed/Disabled)	75%
Education	

Less than High School	40%
High School/Some College	60%
Income Level	
<10,500	76%
10,500-22,500	10%
22,501-34,999	14%
Health Literacy Level	
Inadequate	30%
Marginal	10%
Adequate	60%
Medication Assistance	
None	5%
Medicaid/Medicare	40%
Other Insurance	15%
Prescription Assistance Program	40%
Psychosocial Measures	
MMAS	4.65 (2.37)
MASES	2.25 (0.43)
HPSS	
Total Score	17.65 (3.71)
Effective	16.45 (6.47)
Impulsive	8.40 (6.98)
Avoidant	7.20 (6.29)
Positive Transfer	10.50 (3.90)
Negative Transfer	15.50 (7.96)
Positive Orientation	12.10 (2.90)
Negative Orientation	6.15 (5.36)
STOFHLA	25.44 (9.31)
CDSES	
Total Average	7.04 (1.86)
Exercise Regularly	6.02 (2.88)
Obtain Information	7.85 (3.07)
Obtain Help	6.99 (2.17)
Communicate Physician	9.27 (0.98)
Manage Disease	6.89 (1.70)
Do Chores	6.83 (2.81)
Social/Recreational	6.92 (2.11)
Manage Symptoms	5.95 (2.44)
Manage Depression	6.57 (2.55)
QOL	
Physical	50.17 (15.52)

Psychological	46.67 (10.52)
Environmental	56.25 (14.48)
Social	60.83 (17.75)

Note: CDSES Chronic Disease Self-efficacy Scale (CDSES) Health-related Problem Solving Scale, (HPSS), Medication Adherence Self-efficacy Scale (MASES), Morisky Medication Adherence Scale (MMAS), Test of Functional Health Literacy in Adults – short form (STOFLHA), World Health Organization Quality of Life scale (QOL)

Association between demographics and psychosocial variables. Correlation analyses and *t*-tests were employed to determine whether demographic characteristics were associated with the primary and secondary psychosocial variables. Results indicated that self-efficacy for self-management of chronic disease symptoms and QOL for physical health was statistically significantly associated with increases with age (*r* = .455, *p* = .044; *r* = .447, *p* = .048, respectively). Also, number of medications was statistically significantly correlated with number of chronic conditions (*r* = .496, *p* = .031, STOFHLA (*r* = .673, *p* = .003), MASES (*r* = .552, *p* = .014), CDSES do chores (*r* = -.447, *p* = .048). This indicates that participants with higher number of chronic conditions also reported a greater number of medications. Also participants prescribed a greater number of medications also reported higher self-efficacy for adhering to their medication regimen and higher scores on the health literacy. However, as medication prescriptions increased, participants report poorer self-efficacy for doing everyday chores. Group analyses indicated that at baseline self-reported medication adherence women had statistically significantly better scores (*M* = 4.90, *SD* = 2.96) compared to men (*M* = 4.40, *SD* = 1.71), *F*(1, 18) = 4.94, *p* = .039.

Association between MCC and psychosocial variables. Correlational analyses were employed to estimate the magnitude of associations between the number of chronic conditions and baseline measures of medication adherence, health literacy, self-efficacy, problem-solving skills, and QOL (Table 6). Generally, there were no significant associations among the variables, with the exception of a statistically significant positive correlation with the STOFHLA ($r = 0.528$, $p = 0.036$). This indicates that as the number of chronic conditions increased so did scores on the health literacy assessment.

Table 6

Correlations between number of chronic conditions and baseline measures

Outcome Measures	**Number of Chronic Conditions**
MMAS	-0.021
STOFHLA	0.528**
HPSS	
Total	-0.018
Effective	0.308
Impulsive	0.152
Avoidant	0.042
Positive Transfer	0.385*
Negative Transfer	0.151
Positive Orientation	-0.070
Negative Orientation	0.249
MASES	0.321
CDSES	-0.338
QOL	
Physical	-0.310
Psych	-0.069
Environment	0.040
Social	0.007

*$p < 0.10$, **$p < 0.05$

Note: CDSES Chronic Disease Self-efficacy Scale (CDSES) Health-related Problem Solving Scale, (HPSS), Medication Adherence Self-efficacy Scale (MASES), Morisky Medication Adherence Scale (MMAS), Test of Functional Health Literacy in Adults-short form (STOFLHA), World Health Organization Quality of Life scale (QOL)

Associations between psychosocial variables. Correlational analyses were also employed to determine whether there are associations between the baseline measures of the primary variable, medication adherence, and secondary variables, health literacy, self-efficacy, problem-solving, and QOL (Table 7).

Medication adherence. Results indicated that medication adherence (MMAS) had negative statistically significant associations with the HPSS Total score (*r* =-0.489, *p* = 0.024) and HPSS Impulsive/Careless (*r* =-0.521, *p* = 0.015). Higher scores on the MMAS are indicative of adherence problems, therefore, in this sample poorer adherence was associated with poorer overall health-related problem-solving skills and a more impulsive or careless problem-solving style. Also poorer medication adherence was statistically significantly associated with lower quality of one's living environment (*r* =-0.566, *p* = 0.009).

Medication adherence self-efficacy. A statistically significant positive association was found between the MASES and HPSS Positive Orientation/Motivation (*r* = 0.496, *p* = 0.022). This indicates that a positive problem-solving orientation is associated with greater self-efficacy for following a medication regimen.

Chronic disease self-efficacy. There were statistically significant positive associations between overall average scores on the CDSES and the Total HPSS score (*r* = 0.593, *p* = .006), HPSS Positive Orientation subscale (*r* = 0.483, *p* = .031), Physical QOL (*r* = 0.684, *p* = .001), Environmental QOL (*r* = 0.593, *p* = .006), and Social QOL (*r* = 0.479, *p* =.032). This indicates that better problem-solving skills and a positive problem-solving orientation is associated with greater self-efficacy for chronic disease self-management. Also participants who reported better chronic disease self-efficacy also reported higher physical, social, and environmental quality of life.

The overall average on the CDSES was negatively and statistically significantly associated with HPSS Avoidant Problem Solving subscale (*r* = -0.444, *p* = .050), Negative Orientation Subscale (*r* = -0.537, *p* = .015). These results indicate that lower self-efficacy for chronic disease self-management was associated with a more avoidant problem-solving style and a more negative orientation towards problems.

Health literacy. Statistically significant positive associations were found between the STOFHLA and CDSES Communicating with Physicians (*r* = 0.595, *p* = 0.007). This indicates that, in this sample, higher health literacy is associated with greater self-efficacy for communicating with providers.

Health-related problem-solving. HPSS Total score was statistically significantly associated with multiple CDSES subscales including Obtaining Help from Community, Family, and Friends (*r* = 0.443, *p* = 0.044), Manage Disease in General (*r* = 0.759, *p* < 0.001), Social/Recreational Activities (*r* = 0.528, *p* = 0.014), Manage Symptoms (*r* = 0.551, *p* = 0.010), Manage Depression (*r* = 0.574, *p* = 0.006), QOL Environment (*r* = 0.673, *p* = 0.001) and QOL Social Relationships (*r* = 0.563, *p* = 0.010). These results indicate that, in this sample, greater health-related problem solving skills are associated with greater perceived self-efficacy across multiple chronic disease management domains and greater environmental and social quality of life.

Quality of life. The QOL Environment subscale had positive statistically significant association with the CDSES subscales Manage Disease in General and Manage Symptoms (*r* = 0.567, *p* = 0.009; *r* = 0.598, *p* = 0.005, respectively). These results indicate that as the quality of one’s living environment improves, participants tended to report higher self-efficacy for self-managing chronic diseases and their symptoms. Results indicated that there was a positive statistically significant association between QOL Social Relationship subscale and the CDSES subscales Manage Disease in General and Social/Recreational Activities ($r = 0.601$, $p = 0.005$; $r = 0.591$, $p = 0.006$, respectively). These results indicate that as the quality of one’s social life and relationships improves, participants tend to endorse greater self-efficacy for self-managing chronic disease and engaging in social and recreational activities.

Table 7

Correlations between baseline measures (N = 20)

	MMAS	STOFHLA	MASES	CDSES	HPSS Total	HPSS Effective	HPSS Impulsive	HPSS Avoidant	HPSS Positive Transfer	HPSS Negative Transfer	HPSS Positive Orientation	HPSS Negative Orientation	QOL Phys	QOL Psych	Q E
STOFHLA	.167	___													
MASES	-.186	.490**	___												
CDSES	-.190	-.060	-.141	___											
HPSS															
Total	-.554**	.154	.194	.593*	___										
Effective	-.209	.241	.095	.427*	.341	___									
Impulsive	.582**	.081	-.073	-.287	-.849**	-.026	___								
Avoidant	.429*	-.069	-.155	-.444**	-.861**	.024	-.764**	___							
Positive Transfer	-.259	.306	.217	.222	.237	.738**	.037	.135	___						
Negative Transfer	.361	.098	.034	-.314	-.732**	.243	.780**	.849**	.337	___					
Positive Orientation	-.240	.232	-.500**	.407*	.581**	.390*	-.322	-.327	.414*	-.087	___				
Negative Orientation	.381*	-.064	-.019	-.465**	-.836**	.065	-.794**	-.871**	.238	-.872**	-.292	___			
QOL															
Physical	-.443**	-.432*	-.160	.684**	.425*	.184	-.254	-.418*	-.098	.401*	.292	.429*	___		
Psych	-.296	-.407*	-.146	.279	.067	-.006	-.124	-.059	-.134	-.115	.119	-.033	.541**	___	
Environ	-.566**	-.073	.072	.593**	.673**	-.683**	-.485**	-.441*	-.381*	-.258	.509**	-.377	.598**	.445**	___
Social	-.364	-.058	-.053	.479**	.563**	-.467**	-.501**	-.413*	.285	-.195	.285	-.405*	.339	.018	.53

* $p < 0.10$, ** $p < 0.05$

Note: CDSES Chronic Disease Self-efficacy Scale (CDSES) Health-related Problem Solving Scale, (HPSS), Medication Adherence Self-efficacy Scale (MASES), Moris Medication Adherence Scale (MMAS), Test of Functional Health Literacy in Adults – short form (STOFLHA), World Health Organization Quality of Life scale (QOL)

Post-Treatment Outcomes

Post-treatment outcome analyses were conducted for the participants (*n* = 13) who completed both pre- and post-treatment assessments Results are presented in Table 8. Program efficacy was evaluated using within subjects repeated-measures means comparison. Cohen's conventions were used to interpret effect size estimates of Cohen's *d* (small = .2, medium = .5, large = .8) and confidence intervals for statistically significant changes in outcomes. Given the large number of *t*-tests, it is expected that if all 23 null hypotheses were true, then one would likely be significant due to Type I error (determined using the calculation .05(23) = 1.15).

Medication adherence and self-efficacy. There were no significant differences detected on self-reported medication adherence (MMAS) and self-efficacy (MASES). However, there were trends toward significance such that post-treatment self-reported medication adherence and self-efficacy were somewhat improved from baseline ($p < 0.10$).

Health-related problem solving. Results indicated that there were statistically significant improvements at post-intervention on the Effective Problem-Solving subscale (*M* = 21.15, *SD* = 7.39) from baseline (*M* = 16.15, *SD* = 7.47), *t* (12) = 2.50, *p* = .028, *d* = .69, 95% CI [0.073-1.291]. Also, post-intervention scores (*M* = 13.23, *SD* = 3.22) on the Positive Transfer subscale statistically significantly improved from baseline scores (*M* = 10.69, *SD* = 4.29), *t* (12) = 3.06, *p* = .010, *d* = .85, 95% CI [0.197, 1.475]. Both improvements were indicative of moderate to large effect sizes. Results indicated that the HPSS Total score also improved, but the change from baseline to post-treatment fell short of statistical significance at the .05 level.

Chronic disease self-efficacy. Results indicated that post intervention scores (*M* = 8.05, *SD* = 1.63) for self-efficacy for managing chronic disease in general had statistically significant improvements from baseline (*M* = 6.91, *SD* = 1.84), *t* (12) = 3.45, *p* = .005, *d* = .96, 95% CI [0.281-1.606]. Also post-intervention scores for self-efficacy for engaging in social/recreational activities (*M* = 7.92, *SD* = 1.75) were statistically significantly improved from baseline (*M* = 7.08, *SD* = 2.22), *t* (12) = 2.38, *p* = .005, *d* = .66, 95% CI [0.046, 1.252]. The pre-post change in overall average score on the CDSES, and self-efficacy for exercising regularly, and ability to do chores, all fell short of statistical significance (*p* < 0.10). There were no statistically significant differences detected on measures of health literacy (STOFHLA) and quality of life (QOL) from baseline to post-treatment.

Table 8

Results of baseline and post-treatment outcomes analyses (N = 13)

Measure	**Baseline** *M* (SD)	**Post-treatment** *M* (SD)	***t***	***p***	***d***
MMAS	5.23 (2.17)	4.08 (1.66)	-1.93	0.077*	
MASES	2.30 (0.42)	2.51 (0.38)	1.86	0.088*	
HPSS					
Total Score	17.99 (3.64)	19.68 (3.11)	2.02	0.067*	
Effective	16.15 (7.47)	21.15 (7.39)	2.50	0.028**	0.69
Impulsive	8.08 (6.09)	7.62 (4.59)	-0.27	0.795	
Avoidant	6.38 (5.27)	5.92 (3.15)	-0.41	0.687	
Positive Transfer	10.69 (4.29)	13.23 (3.22)	3.06	0.010**	0.85
Negative Transfer	15.54 (5.49)	14.08 (6.40)	-0.71	0.495	
Positive Orientation	12.54 (2.70)	13.54 (3.10)	1.52	0.156	
Negative Orientation	5.69 (4.53)	4.92 (3.95)	-0.57	0.577	
STOFHLA	27.58 (8.59)	29.58 (9.20)	-0.73	0.111	
CDSES					
Total Average	7.23 (2.42)	7.92 (1.81)	2.10	0.059*	
Exercise Regularly	5.59 (3.21)	7.23 (2.80)	2.17	0.051*	
Obtain Information	7.62 (3.20)	8.84 (1.91)	1.49	0.162	
Obtain Help	7.42 (2.01)	7.79 (2.08)	0.81	0.435	
Communicate Physician	9.34 (1.00)	9.10 (1.56)	-0.60	0.561	
Manage Disease	6.91 (1.84)	8.05 (1.63)	3.45	0.005**	0.96
Do Chores	6.67 (2.65)	7.85 (1.87)	1.99	0.070*	
Social/Recreational	7.08 (2.22)	7.92 (1.75)	2.38	0.035**	0.66
Manage Symptoms	6.23 (2.76)	6.54 (2.82)	0.61	0.553	
Manage Depression	6.76 (2.60)	7.15 (2.42)	1.32	0.210	
QOL					
Physical	48.35 (15.05)	48.90 (18.58)	0.13	0.902	
Psychological	46.79 (10.09)	48.40 (10.14)	0.41	0.687	
Environmental	56.01 (16.85)	60.34 (15.01)	1.08	0.300	
Social	60.90 (19.66)	65.38 (17.63)	1.24	0.237	

*$p < 0.10$, **$p < .05$

Note: CDSES Chronic Disease Self-efficacy Scale (CDSES) Health-related Problem Solving Scale, (HPSS), Medication Adherence Self-efficacy Scale (MASES), Morisky Medication Adherence Scale (MMAS), Test of Functional Health Literacy in Adults – short form (STOFLHA), World Health Organization Quality of Life scale (QOL)

Predicting medication adherence. Finally, multiple regression analysis was employed to determine whether change in self-efficacy scores uniquely predicts medication adherence. The proposed model included change in self-efficacy scores, health literacy (STOFHLA), number of medications, number of chronic conditions, and education. The model was insignificant indicating that neither change in MASES or CDSES scores significantly predicts self-reported medication adherence.

Post-hoc and Exploratory Results

Post-hoc analyses were employed to determine whether participants who completed the intervention differed from those who did not complete the intervention or differed from the original sample on demographic or psychosocial variables. Completers (n = 13) were demographically similar and scored similarly on outcome measures at baseline when compared to the total sample (N = 20) and when compared to those who did not completed the intervention (n = 7).

Additionally, correlational analyses with the completers sample were employed to determine whether the associations reported among baseline variables in the analyses of the original sample remained significant. Generally, the associations and direction of relationships reported above remained statistically significant with $p < .05$ or at a lesser magnitude of $p < .10$. However, four relationships did not remain significant with the completers-only analyses (the number of chronic conditions and health literacy, medication adherence and physical health QOL, medication adherence self-efficacy with health literacy and problem-solving positive orientation).

Finally, an exploratory pre-post analysis using an intent-to-treat approach was employed. This included a conservative repeated measures analysis with baseline scores of the noncompleters as post-treatment scores. The results were not significantly different than those previously reported.

Chapter VII: Discussion

Prescription medications are the most common treatment approach for chronic conditions. However, data indicate that about 50% of medications are not taken as prescribed and patients and providers frequently endorse adherence to the medication regimen as a significant burden and area for improvement among patients. This study adds to the limited research, to date, focused on evaluating effectiveness of behavioral interventions for improving medication adherence in this population. Of note, the primary care clinic is the point of care of for many rural patients with MCC and in the clinic where this intervention was implemented, the estimated prevalence rate of MCC (45%) is almost twice the national estimates (25%).

Informed by the findings of the pilot survey study (Study 1) the primary aims of the intervention study (Study 2) were three-fold: 1) describe demographic and psychosocial characteristics of patients with MCC, 2) examine the relationships between number of chronic conditions and baseline primary (medication adherence) and secondary (health literacy, self-efficacy, problem-solving, and QOL) variables, and 3) examine the relationship between primary and secondary variables at baseline and evaluate the preliminary efficacy of a medication adherence intervention for patients with MCC on improving outcomes.

Demographic and Psychosocial Characteristics of Patients with MCC

The first aim of Study 2 was describe the demographic and psychosocial characteristics of patients with MCC. This sample of rural primary care patients represented a largely understudied group in the literature. The sample was predominantly of low socioeconomic status, Black, 53 years old, and were unemployed or disabled. When compared to current epidemiological research on same-aged peers (Anderson, 2010; Boyd & Fortin, 2010), this sample is managing substantially more chronic conditions and taking more medications. The data reported in both studies is, however, consistent with research that indicates there is an increasing trend of MCC among patients at younger ages (Mercer, Smith, Wyke, O'Dowd, Watt, 2009) and an elevated risk of MCC among rural, low-income, and racial and ethnic minority groups (Shi, et al., 2013).

Study 2 adds to the sparse literature on health literacy in individuals with MCC. While the majority of the sample had adequate levels (60%) of health literacy, the remaining fell in the inadequate (30%) or marginal (10%) categories. Individuals who have inadequate health literacy are likely to have difficulty understanding instructions printed on prescription bottles or instructions for preparing for medical procedures. Individuals with marginal health literacy perform better on these tasks but are likely to still have difficulty comprehending materials explaining basic rights and responsibilities (e.g. insurance informational forms). The Department of Health and Human Services (2003) report indicated that a third of adults have less than adequate health literacy. The likelihood of having limited health literacy appears to be greater in this sample than in the general population. This is consistent with other research reporting that ethnic minority groups and patients with MCC multiple chronic conditions are more likely to have limited health literacy (Morrow et al., 2006). The prevalence rate of 40% is nonetheless concerning because individuals with low health literacy are less likely to adhere to their medication regimen, accurately interpret printed health-related and medication information, and communicate effectively with their providers (Berkman, et al., 2011).

Indeed, the sample in Study 2 reported poor adherence to their medication regimen. In rural populations, barriers to adherence often include financial or transportation limitations for obtaining their medications, which could be true of this rural low-income sample. Patients with MCC also report psychological factors for poor adherence; specifically, they express uncertainty and conflicting beliefs about medication taking (Mc Sharry et al., 2012) and they associate medications with negative emotions or loss of personal control (Townsend et al., 2003).

The results from Study 2 add to the limited literature on problem-solving skills and self-efficacy reported by patients with MCC. This sample had lower total problem-solving scores, lower scores on subscales measuring effective/positive problem-solving and higher scores on ineffective/negative problem-solving subscales compared to the scores reported from single disease studies (Hill-Briggs et al., 2007, 2011). Again, this may be due to the complexity that comes with managing MCC and a complicated medication regimen. Notably, scores on measures of chronic disease and medication adherence self-efficacy tended to be consistent with normative data (Lorig et al., 1996, Ogedegbe, et al., 2003) with the overall average at 7.04 and average baseline scores on the chronic disease self-efficacy ranged from 5.62 – 9.21 across domains. Participants endorsed higher self-efficacy for communicating with their provider and relatively lower self-efficacy for managing depression, managing symptoms, and exercising regularly. With regard to medication adherence self-efficacy this sample indicated they were, on average, somewhat sure to very sure that they could take their medications across most situations.

This is one of the first investigations using the WHOQOL-BREF scale to evaluate QOL in patients with MCC and a predominantly minority sample. The average baseline physical and psychological QOL scores in this sample were two standard deviations lower than healthy individuals aged 50-59 years (Hawthorne, Herrman, & Murphy, 2006) and one and half standard deviations lower than healthy adults (Skevington & McCate, 2012). In a population-based study, Skevington and McCrate (2012) reported data on the QOL of patients grouped by various physical or psychological conditions. The current sample's physical and psychological QOL scores were at least one standard deviation lower than patients with diabetes recruited from primary care clinics and similar to patients with cardiovascular disease (i.e. history of heart transplant or stroke). This sample's social and environmental QOL scores were similar to normative data on healthy samples and subgroups of chronic conditions. The results of this study indicate that, for rural primary care patients with MCC, physical and psychological QOL warrant particular attention as areas for future intervention and social and environmental QOL could be examined as potential buffers or strengths in studies addressing quality of life

Collectively, baseline results of Study 2 indicate that patients with MCC report limited problem-solving skills and poor medication adherence and poor physical and psychological QOL, however scores on self-efficacy measures are consistent with other chronic disease populations. Based on these results and current research, patients with MCC may benefit from interventions that focus on improving problem-solving skills and enhancing self-efficacy to improve medication adherence and health outcomes.

Relationships Between Variables at Baseline

The second aim of Study 2 was to examine the relationships between the number of chronic conditions and primary (medication adherence) and secondary variables (health literacy, problem-solving, self-efficacy, and QOL). It was hypothesized that variables would be negatively associated with number of chronic conditions, however the results indicated that MCC was not associated with any study variables with the exception of health literacy.

The positive relationship between number of chronic conditions and health literacy scores reported in this study is inconsistent with past research (Howard, Gazmarariam, & Parker, 2005; Morrow, et al., 2006). This finding could perhaps be due to the fact that patients with MCC have frequent interactions with the health care system. Subsequently, these patients gain experience with and learn how to accurately complete the tasks that are assessed by the STOFHLA (e.g. preparing for an x-ray appointment). Also, methodology differences among studies may account for the inconsistent reports. Some studies measure health literacy using the Newest Vital Sign (Weiss, et al., 2005), a six-item assessment of quantitative skills and ability to interpret information from a nutrition label. While the NVS and STOFHLA are correlated, they assess fundamentally different constructs of health literacy.

Notably, results from studies using more advanced statistical models indicate that the relationship between health literacy and chronic conditions is complex. One study reported that lower health literacy scores are associated with specific conditions (e.g. depression, arthritis, hypertension), while there was no associated between health literacy and other conditions (e.g. diabetes, pulmonary disease; Kim, 2009). Other studies with primary care patients indicate that other important psychosocial and demographic variables such as age, income, and cognitive abilities (i.e. processing speed) account for variance in health literacy scores (Hudon et al., 2012; Morrow et al., 2006). Although the research consistently states that health literacy is important factor influencing self-management and health outcomes, more research is needed to elucidate important factors that contribute to health literacy in this population.

The lack of association between MCC and medication adherence scores is also inconsistent with past research (Gallacher et al., 2014; Roter et al., 1998). The relationship between MCC and adherence may be better explained as a dichotomy such that that once patients are diagnosed with a certain number of chronic conditions they are at a significantly greater risk of having poor medication adherence. Indeed, participants had on average 5 chronic conditions and reported poor adherence, which supports the theory that patients with more than one chronic condition are likely to have poor adherence. Perhaps once patients are managing MCC, factors other than number of chronic conditions are better indicators of adherence such as number of medications, health insurance/prescription assistance, or presence of a mental health disorder.

The second aim of Study 2 also hypothesized that there would be positive associations between the outcome variables, medication adherence, self-efficacy, problem-solving, and quality of life in patients with MCC. The results indicated that problem-solving was associated with medication adherence, medication adherence self-efficacy, and overall CDSES and CDSES domains for obtaining help from family, friends, and community, managing chronic disease in general, and managing depression. These results are consistent with diabetes research that indicates better problem solving is associated with better adherence and an impulsive problem solving approach is associated with poorer adherence (see review Hill-Briggs, 2003). Also consistent with diabetes and multimorbidity research, are the positive associations between total problem-solving score and the positive orientation subscale with CDSES and medication adherence self-efficacy, respectively. Previous research with this population indicates that patients who report a sense of losing control over their health and low self-efficacy for managing health report greater difficulty adhering to their regimen (Aljasem, Peyrot, Wissow, Rubin, 2001; Mc Sharry et al., 2012). In contrast, problem-solving theory asserts that individuals with a positive problem solving orientation view problems as learning opportunities have positive expectation and high self-efficacy (Cook, 2006).

Furthermore, research with diabetes and HIV populations indicate that higher Total HPSS scores are associated with better disease outcomes (i.e. A1C and CD4; Hill-Brigg et al., 2007) and decreased hospitalizations. While health outcome and health care utilization variables were not measured in this study, HPSS scores tended to be lower which may be indicative of patient risk for poor outcomes and greater hospitalizations in this sample. This is one of the first studies to examine the relationship between HPSS scores, adherence, self-efficacy, and QOL, more research is needed to explore how health-related problem solving skills influence adherence and disease outcomes in this population.

The lack of association between medication adherence and self-efficacy has been reported in other research (Rubin, 2005, Sarkar, Fisher, & Schillinger, 2006). This suggests that other psychological factors (e.g. mood, problem-solving skills, beliefs), treatment factors (e.g. medication side effects, regimen complexity), and demographic and broader systemic factors (economic, access to and quality of health care) may mediate or moderate the relationship between self-efficacy and adherence in this population. Indeed, in this study problem-solving orientation and skills were associated with both medication adherence and several domains of chronic disease self-efficacy. Research using more sophisticated analyses to elucidate these relationships is warranted.

The finding that greater environmental and social QOL of life was associated with higher self-efficacy for managing chronic disease and better problem-solving skills is consistent with the research (Hill-Briggs & Gemmell, 2007; Marks et al., 2005). In a review Marks and colleagues report that self-efficacy for chronic disease self-management is associated with quality of life and influences patients perception of their quality of life. Additionally, interventions that target improvements in self-efficacy and include a problem-solving component have been shown to improve quality of life for patients with chronic conditions. While many studies with health populations use the SF-36, the “gold standard” measure of QOL, the WHOQOL is unique in its ability to assess environmental QOL, which is a lesser studied but important factor contributing to health care management. Indeed, public health research indicates that community and environmental variables such as poverty and neighborhood violence play a role in risk of morbidity and poor health behaviors (Davey-Smith et al., 1998). Given that this sample had normative environmental QOL scores, this study provides some clarity with regard to how environmental QOL is related to other important self-management factors.

Intervention Efficacy on Psychosocial Outcomes

The third aim of Study 2 sought to evaluate the preliminary efficacy of a pilot intervention for improving medication adherence. The hypotheses that medication adherence, medication self-efficacy, and QOL scores would improve significantly from baseline to post-treatment were not supported. The hypotheses that chronic disease self-efficacy and HPSS would improve from baseline to post-treatment was supported for subscales on each measure. Results indicated that post-treatment scores significantly improved from baseline on measures of HPSS subscales effective problem solving and positive transfer problem solving and self-efficacy for engaging in chronic disease self-management and social/recreational activities.

Although there has been recent emphasis placed on increasing research with patients with MCC and interventions to improve medication adherence, there are very few studies that are directly comparable to the current intervention. As reported in previous reviews (Haynes et al., 2013; Williams et al., 2008) existing medication adherence interventions vary in duration (from one point of contact to weekly for six months), method (e.g. who delivers it, individual or group mode), and medium (e.g. in person, telephone or print media). Moreover, many interventions are limited in that they only provide education and, if additional counseling is offered, strategies are rarely developed from a theoretical framework.

The hypothesis that the primary outcome variable, medication adherence, would significantly improve was not supported. While self-reported medication adherence improved, this change fell short of significance ($p = 0.077$). A study with renal transplant patients with MCC tested a self-efficacy enhancing intervention reported significant improvements in medication adherence as measured by electronic monitoring, however improvements were not maintained at six month follow-up (De Geest et al., 2006). This study was similar to the current study in that it included specific strategies for improving medication adherence education, problem-solving, and goal-setting. However, it differed in modality, as there were only four monthly interventionist contacts (one in-home session with the patient and family and three telephone follow-up sessions) and researchers did not assess for self-reported self-efficacy or problem-solving. The current study is novel as it assesses self-efficacy and problem-solving which have been theoretically linked to adherence and self-management behaviors. Thus, it provides valuable data and helps fill gaps in the research investigating if and how these factors drive changes in patient adherence behaviors. In order to better assess medication adherence behaviors future studies may include an additional measure of adherence (e.g. prescription refill data, electronic pill monitoring). Additionally longer follow-up (i.e. more telephone sessions, during visits with primary care provides) would allow for more individualized feedback and skill-building that could enhance improvements in medication adherence behaviors.

Self-reported self-efficacy for engaging in chronic disease self-management and social activities improved significantly. This suggests that participants felt more confident in their ability to act in ways that are consistent with good self-management and participate in social activities. There are many reasons why participation in the current intervention may have improved self-efficacy in these domains. Past research has shown that poor self-efficacy for self-management is associated with limited health literacy (Nutbeam, 2000), negative feelings, and lack of control for medication regimen

(Mc Sharry et al., 2012). Therefore, intervention was designed to improve self-efficacy through improving health literacy for understanding prescriptions and improving cognitive-behavioral skills for managing health. Additionally, behavioral training was provided on how to self-monitor health behaviors, use a pill organizer and create a simplified individualized dosing schedule. These aspects of the intervention may have contributed to improvements in patients feelings of control over their regimen, functional health literacy, as well as the moderate to large effects on self-efficacy for general chronic disease self-management (d = 0.66). Indeed, Conn and colleagues reported that interventions that include succinct instructions on medication taking were more effective (mean d = 0.61) compared to those without instructions (mean d = 0.29). Lastly, the small to moderate effects (d = 0.46) on self-efficacy for engaging in social activities may be explained by the focus on improving problem orientation as well as the positive experiences obtained by participating in a group-based program.

Significant improvements in effective problem-solving skills indicates that participants became more skilled at using a rational process of sequential steps for identifying a problem, examining solutions and barriers, acting on solutions, and learning from the experience. Relatedly, improvements in HPSS positive transfer subscale suggests that participants reported improved ability to transfer knowledge from past experiences to new situations. Two of the four group sessions focused on improving problem-solving orientation and skills using culturally and low literacy tailored strategies. This approach is consistent with the research reporting that interventions targeting problem solving effectively improve health outcomes; specifically, larger effect sizes are significantly associated with interventions that address problem orientation (d

= 1.00) and assign homework (*d* = 1.02, Malouff et al., 2007). In this study, the effect sizes for improving problem-solving orientation and positive transfer were 0.69 and 0.85, respectively, which is greater than current medication adherence interventions using a combination of educational and behavioral strategies (*d* = 0.56). More research is needed to elucidate how effective strategies from problem-solving therapy can be adapted for interventions for patients managing MCC and complex medication regimens.

Limitations

Study 2 is not without its limitations including small sample size and attrition, assessment methods, and lack of a usual care or control group. The results should be interpreted within the context of these limitations.

The small sample size in these studies significantly limits the power and increases the risk of Type II error. With low power it is possible that significant associations and intervention effects could not be detected. Future studies with larger sample sizes can help determine whether the findings that fell short of significance would rise to significance. Additionally, the significant findings and moderate to large effect sizes reported in the Study 2 suggest that more studies are needed to evaluate whether the associations and intervention effectiveness can be replicated.

The small sample size could have resulted from a number of factors that are particularly salient in a rural primary care clinic environment, such as ineffective recruitment and enrollment methods and difficulty retaining participants. Despite use of recommended strategies to enhance recruitment and retention (Burns, et al., 2008), close evaluation revealed important information about recruitment and specific points when sample size was affected by attrition. Flyer advertisements did not appear to be effective as nearly all referrals came from providers (118/119). While providers made many referrals, the majority of these patients were not interested (55%). Some methods that may improve recruitment in future studies include identifying patients who have MCC *and* a high number of prescriptions or asking all patients with MCC who present for care to complete a one-item questionnaire asking about interest in the program or medication adherence.

Additionally, only 29 of the 54 patients with MCC (54%) who scheduled an appointment for an interest meeting actually attended. In this population transportation is common barrier for engagement (Burns, et al., 2008) and this may have contributed to why many did not attend the initial meeting. Although the program offered transportation to patients after enrollment, only 2 participants used the van transport option. It is possible that many of the patients who expressed interest would have attended the initial meeting and enrolled if transportation were offered for the initial meeting. Once patients attended the interest meeting more than two thirds enrolled which suggests that patients with MCC who are interested and attend the initial meeting are likely to enroll in the program. Research that investigates effective methods for recruitment and explores barriers for retention is needed.

Compared to a previous study in this setting the attrition rate of 35% is slightly improved, and dropped to 15% after participants attended the first group meeting. However it is greater than rates reported in previous studies (Haynes et al., 2008). It is recommended for future studies that the time between enrollment and the first group meeting should be brief so the likelihood of participant drop out due to shifting priorities or stage of change is decreased. Nonetheless, some attrition is to be expected in this population as economic and social stressors that impact participation rates tend to be more prevalent (Loftin, et al., 2005)

Measurement limitations also need to be considered in the context of current findings. There is significant psychometric research on measuring medication adherence. Research indicates that patients provide inaccurate accounts of their adherence due to poor insight and motivation to be perceived positively (DiMatteo, 2004). However, self-report remains the most common method because it is practical and low cost. Further other methods such as electronic monitoring of pill bottles and pharmacy refills are expensive and have their own limitations to provide accurate measures of medication-taking behavior. Moreover, Thorpe and colleagues (2009) reported that symptom control was similarly predicted by an objective measure of medication adherence (i.e. refill rates at a pharmacy) and self-report. It is likely that the poor adherence reported by participants in this study is accurate as some research indicates that if a person endorses poor adherence then it is likely an accurate report (Choo et al., 1999). Moreover, the results of the current study may be an underestimation of the improvement in medication adherence . Based on current research, self-reported medication adherence scores at baseline are likely an overestimation of actual adherence and scores at post-treatment may be more accurate due to improvements in insight knowledge and behaviors that were gained during the intervention from self-monitoring and other learned strategies.

Another limitation in measurement is the tool used to assess medication adherence self-efficacy. Ongoing psychometric research with the MASES has demonstrated that it is limited in its variability and predictive power (Fernandez, Chaplin, Shoenthaler, & Ogdegbe, 2008). The MASES-R was validated using two forms of medication adherence data (self-reported adherence and electronic monitoring). Notable revisions including reduce the questionnaire to 13 items and the response options have been expanded from a 3- to a 4-point scale. Specifically the expansion removed the *somewhat sure* response option and, in its place, are the options *a little sure* and *fairly sure*. Preliminary research with the MASES-R demonstrated that the expanded the response scale provides more information about which individuals report very low to moderately low self-efficacy. Thus, the revised version demonstrates improved utility in practice and research over its original version with regard to identifying individuals who may benefit from intervention and measuring change in self-efficacy over time. In the current study the average score on the MASES is 2.25 (SD = 0.43), meaning that responses fell around *somewhat sure*. Future study with the MASES-R in this population is needed to assess for patients with very low or moderate self-efficacy.

Finally, Study 2 is limited due to the pre-post test design and lack of a control or usual care group. Without a control group it is difficult to say with certainty that the significant changes are due solely to the effects of the intervention. Improvements may be attributed to health changes that can affect motivation to take medications or the Hawthorne effect, which accounts for participant behavior change that is due to awareness of being observed. Nonetheless, the pre-post study design is appropriate for evaluating the feasibility and preliminary efficacy of this novel intervention.

Conclusions and Future Directions

Further research with patients with MCC and medication adherence is sorely needed. In conclusion, Studies 1 and 2 make a significant contribution to a limited but growing literature base. Although Study 2 raises more questions than it answers about relationships between variables and methods of intervention in this population. Future studies need to investigate whether variables other than number of chronic conditions are better indicators of adherence. Relatedly, more sophisticated analyses are needed to elucidate the relationship between quality of life, health literacy, self-efficacy, and medication adherence. Findings from this research may help inform which patients might benefit from intervention as well as potential barriers to adherence and targets for intervention.

The frequently cited randomized controlled trials by Lorig and colleagues (1999, 2005) is a self-efficacy based group intervention (i.e. CDSMP) that resulted in significant and sustained reductions in participant health distress and improvements in health care utilization. The intervention in the current study was similar as it combined and adapted evidence-based strategies from the single-disease literature in order to improve self-efficacy in patients with MCC. However, the CDSMP was designed to improve multiple health behaviors, while the current study was innovative in its aim to specifically enhance self-efficacy for medication adherence. These studies provide a foundation from which future investigations can be developed that test specific hypotheses about the influence that the individual strategies have on changing medication-taking behavior.

Further, the current investigation was novel as it was designed to be brief and practical for low-resource primary care settings like FQHCs. The frequency, dose, and duration of many programs is impractical for this setting (e.g. CDSMP’s 2.5 hr sessions that occur weekly for 7 weeks). Future studies need to evaluate variations in intervention intensity in order to determine the most effective dosing schedule that facilitates clinically and statistically significant change in self-efficacy and health outcomes. Researchers also need to provide information on effective methods for collaborating with stake-holders and providers and maintaining program feasibility in the primary care context. This research would have significant implications with regard to program implementation and improvements on clinical outcomes.

In sum, participants in the intervention experienced improvements on measures of medication adherence, health-related problem-solving, medication adherence self-efficacy, and chronic disease self-efficacy, however some positive changes fell short of statistical significance. Studies with larger samples sizes and more sophisticated designs are needed to establish the efficacy of this intervention, as well as the durability and magnitude of treatment effects. This larger scale research needs to also assess for changes in disease-specific and multiple morbidity clinical outcomes and health care utilization.

REFERENCES

Administration on Aging (2011). Profile of older Americans: Aging statistics. Retrieved from http://www.aoa.gov/aoaroot/aging_statistics/index.aspx

Aljasem, L. I., Peyrot, M., Wissow, L., & Rubin, R. R. (2001). The impact of barriers and self-efficacy on self-care behaviors in type 2 diabetes. *Diabetes Education, 27,* 393-404. doi: 10.1177/014572170102700309

American Association of Diabetes Educators (2011). American Association of Diabetes Educators (AADE) Position Statement - AADE7. Retrieved from http://www.diabeteseducator.org/ProfessionalResources/AADE7/

Anderson, R. M., Funnell, M. M., Butler, P. M., Arnold, M. S., Fitzgerald, J. T., & Feste, C. C. (1995). Patient empowerment: Results of a randomized controlled trial. *Diabetes Care*, *18*, 943-949. doi: 10.2337/diacare.18.7.943

Anderson, G. (2010). *Chronic care: Making the case for ongoing care*. Princeton, NJ: Robert Woods Johnson Foundation.

Anderson-Rothman, A., & Wagner, E. H. (2003). Chronic illness management: What is the role of primary care? *Annals of Internal Medicine, 138*, 256. doi: 10.7326/0003-4819-138-3-200302040-00034

Arnold, M. S., Butler, P. M., Anderson, R. M., Funnell, M. M., & Feste, C. (1995). Guidelines for facilitating a patient empowerment program. *The Diabetes Educator, 21*, 308-312. doi: 10.1177/014572179502100408

Baker D. W., Williams M. V., Parker R. M., Gazmararian J. A., & Nurss J. (1999). Development of a brief test to measure functional health literacy. *Patient Education & Counseling*, *38*, 33-42. doi: 10.1016/s0738-3991(98)00116-5

Bandura, A. (1986). *Social foundations of thought and action: A social cognitive theory.* Englewood Cliffs, NJ: Prentice Hall.

Bandura, A. (1991). Social cognitive theory of self-regulation. *Organizational Behavior and Human Decision Processes, 50*, 248-287. doi: 10.1016/0749-5978(91)90022-L

Bandura, A. (1997). *Self-Efficacy: The exercise of control.* New York, NY: Freeman.

Barlow, J., Wright, C., Turner, A., & Bancroft, G. (2005). A 12-month follow-up study of self-management training for people with chronic disease: Are changes maintained over time? *British Journal of Health Psychology, 10*, 589-599. doi: 10.1348/135910705X26317

Barlow, J., Wright, C., Sheasby, J., Turner, A., & Hainsworth, J. (2002). Self-management approaches for people with chronic conditions: A review. *Patient Education & Counseling, 48*, 177-187. doi: 10.1016/S0738-3991(02)00032-0

Bayliss, E. A., Bayliss, M. S., Ware, J. E., & Steiner, J. F. (2004). Predicting declines in physical function in persons with multiple chronic medical conditions: What we can learn from the medical problem list. *Health and Quality of Life Outcomes, 2*, 47. doi: 10.1186/1477-7525-2-47

Bayliss, E. A., Ellis, J. L., & Steiner, J. F. (2007). Barriers to self-management and quality-of-life outcomes in seniors with multimorbidities. *The Annals of Family Medicine, 5*, 395-402. doi: 10.1370/afm.722

Beacham, A., Herbst, A., Streitwieser, T., Scheu, E., & Sieber, W. (2012) Primary care medical provider attitudes regarding mental health and behavioral medicine in integrated and non-integrated primary care practice settings. *Journal of Clinical Psychology in Medical Settings, 19*, 364-375. doi: 10.1007/s10880-011-9283-y

Beck, J. (2011). *Cognitive behavior therapy: Basics and beyond* (2nd Ed.). New York NY: Guilford Press.

Berkman, N. D., Sheridan, S. L., Donahue, K. E., Halpern, D. J., & Crotty, K. (2011). Low health literacy and health outcomes: An updated systematic review. *Annals of Internal Medicine, 155*, 97-107. doi: 10.7326/0003-4819-155-2-201107190-00005

Bodenheimer, T. & Handley, M. A. (2009). Goal-setting for behavior change in primary care: An exploration and status report. *Patient Education and Counseling, 76*, 174-180. doi: 10.1016/j.pec.2009.06.001

Bodenheimer, T., Lorig, K., Holman, H., & Grumbach, K. (2002). Patient self-management of chronic disease in primary care. *Journal of the American Medical Association, 288*, 2469-2475. doi: 10.1001/jama.288.19.2469

Bogner, H. R., & de Vries, H. F. (2008). Integration of depression and hypertension treatment: A pilot randomized controlled trial. *The Annals of Family Medicine*, *6*, 295-301. doi: 10.1370/afm.843

Boswell, K. A., Cook, C. L., Burch, S. P., Eaddy, M. T., & Cantrell, C. R. (2012). Associating medication adherence with improved outcomes: A systematic literature review. *American Journal of Pharmacy Benefits*, *4*, e97-e108. Retrieved from http://www.ajpblive.com/media/pdf/AJPB_12julaug_Boswell_e97to108apdx.pdf.

Boyd, C. M., & Fortin, M. (2010). Future of multimorbidity research: How should understanding of multimorbidity inform health system design. *Public Health*

Review, *32*, 451-474. Retrieved from http://www.publichealthreviews.eu/upload/pdf_files/8/PHR_32_2_Boyd.pdf

Boyer, B. A. (2008). Diabetes. In Boyer, B. A., & Paharia, M. I. (Eds.). *Comprehensive handbook of clinical health psychology (*179-200). Hoboken, NJ: Wiley.

Brus, H., van de Laar, M., Taal, E., Rasker, J., & Wiegman, O. (1999). Determinants of compliance with medication in patients with rheumatoid arthritis: The importance of self-efficacy expectations. *Patient Education and Counseling, 36*, 57-64. doi: 10.1016/S0738-3991(98)00087-1

Buchner, A., Erdfelder, E., & Faul, F. (1997). How to Use G*Power. Retrieved from http://www.psycho.uniduesseldorf.de/aap/projects/gpower/how_to_use_gpower.html

Burns, D., Skoward, A. C. M., Skelly, A. H., Leemon, J., & Carlson J. (2008). Effective recruitment and retention strategies for older members of rural minorities. *The Diabetes Educator, 34*, 1045-1052.

Center for Disease Control (2011) National Center for Chronic Disease Prevention and Health Promotion, Division of Diabetes Translation. Retrieved from http://www.cdc.gov/diabetes/atlas/countydata/atlas.html

Choo P. W., Rand C. S., Inui T. S., et al., (1999). Validation of patient reports, automated pharmacy records, and pill counts with electronic monitoring of adherence to antihypertensive therapy. *Medical Care, 37,* 846-57. doi: 10.1097/00005650-199909000-00002

Clancy, C. M. (2011). Patient engagement in health care. *Health Services Research, 46*, 389-393. doi: 10.1111/j.1475-6773.2011.01254.x

Clark, N. M., Becker, M. H., Janz, N. K., Lorig, K., Rakowski, W., & Anderson, L. (1991). Self-management of chronic disease by older adults: A review and questions for research. *Journal of Aging and Health, 3*, 3-27. doi:10.1177/089826439100300101

Conn, V. S., Hafdahl, A. R., Cooper, P. S., Ruppar, T. M, Mehr, D. R., & Russell, C. L. (2009). Interventions to improve medication adherence among older adults: Meta-analysis of adherence outcomes among randomized controlled trials. *The Gerontologist, 49*, 447-462. doi: 10.1093/geront/gnp037

Cook, P. F., (2006). Adherence to Medications. In W.T. O'Donohue & E. R. Levensky. (Eds.) *Promoting treatment adherence: A practical handbook for health care providers* (183-202). San Francisco, CA: Sage Publications.

Daniels, L.M., Dixon, K., Campbell, L.C. (2014). Building capacity for behavioral health services and clinical research in a rural primary care clinic: A case study. *Aims Public Health, 1 (2),* 60-75. doi: 10.3934/publichealth.2014.2.60

D'Zurilla, M. R. & Goldfried T. J. (1971). Problem solving and behavior modification. *Journal of Abnormal Psychology, 78,* 107–126. doi: 10.1037/h0031360

D'Zurilla, T. J., & Nezu, A. (1999). *Problem-solving therapy: A social competence approach to clinical intervention.* New York, NY: Springer Publishing Co.

Damschroder, L. J., Lutes, L. D., Goodrich, D. E., Gillon, L., & Lowery, J. C. (2010). A small-change approach delivered via telephone promotes weight loss in veterans: Results from the ASPIRE-VA pilot study. *Patient Education and Counseling, 79*, 262-266. doi: 10.1016/j.pec.2009.09.025

Davey-Smith, G., Hart, C., Watt, G., Hole, D., & Hawthorne, V. (1998). Individual social class, area-based deprivation, cardiovascular disease risk factors, and mortality. *Journal of Epidemiology and Community Health*, *52*, 399-405. doi: 10.1136/jech.52.6.399

De Geest, S., Schäfer-Keller, P., Denhaerynck, K., Thannberger, N., Köfer, S., Bock, A., . . . Steiger, J. (2006). Supporting medication adherence in renal transplantation (SMART): A pilot RCT to improve adherence to immunosuppressive regimens. *Clinical Transplantation, 20*, 359-368. doi: 10.1111/j.1399-0012.2006.00493.x

DeSalvo, K. B., Bloser, N., Reynolds, K., He, J., & Muntner, P. (2005). Mortality prediction with a single general self-rated health question. *Journal of General Internal Medicine*, *21*, 267-275. doi: 10.1111/j.1525-1497.2005.00291.x

DiMatteo, M. R. (2004). Variations in patients' adherence to medical recommendations: A quantitative review of 50 years of research. *Medical Care*, *42*, 200-209. Retrieved from: http://journals.lww.com/lww-medicalcare/Abstract/2004/03000/Variations_in_Patients__Adherence_to_Medical.2.aspx

Edwards, M., Wood, F., Davies, M., & Edwards, A. (2012). The development of health literacy in patients with a long-term health condition: The health literacy pathway model. *BMC Public Health, 12*, 130. doi: 10.1186/1471-2458-12-130

Evers, K. E., & Quintiliani, L. M. (2013). Advances in multiple health behavior change research. *Translational Behavioral Medicine, 3,* 59-61. doi: 10.1007/s13142-013-0198-z

Fortin, M., Bravo, G., Hudon, C., Lapointe, L., Almirall, J., Dubois, M., & Vanasse, A. (2006). Relationship between multimorbidity and health-related quality of life of patients in primary care. *Quality of Life Research, 15*, 83-91. doi: 10.1007/s11136-005-8661-z

Fortin, M., Stewart, M., Poitras, M. E., Almirall, J., & Maddocks, H. (2012). A systematic review of prevalence studies on multimorbidity: Toward a more uniform methodology. *The Annals of Family Medicine*, *10*, 142-151. doi: 10.1370/afm.1337

Gallacher, K. I., Batty, G. D., McLean, G., Mercer, S. W., Guthrie, B., May, C. R., ... Mair, F. S. (2014). Stroke, multimorbidity and polypharmacy in a nationally representative sample of 1,424,378 patients in Scotland: Implications for treatment burden. *BMC Medicine*, *12*, 151. doi: 10.1186/preaccept-1272432928127782

Gijsen, R., Hoeymans, N., Schellevis, F. G., Ruwaard, D., Satariano, W. A., & van den Bos, G. A. (2001). Causes and consequences of comorbidity: A review. *Journal of Clinical Epidemiology*, *54*, 661-674. doi: 10.1016/s0895-4356(00)00363-2

Glasgow, R. E., Fisher, L., Skaff, M., Mullan, J., & Toobert, D. J. (2007). Problem solving and diabetes self-management: Investigation in a large, multiracial sample. *Diabetes Care, 30*, 33-37. doi: 10.2337/dc06-1390

Glasgow, R. E., Klesges, L. M., Dzewaltowski, D. A., Bull, S. S., & Estabrooks, P. (2004). The future of health behavior change research: What is needed to improve translation of research into health promotion practice? *Annals of Behavioral Medicine, 27*, 3-12. doi: 10.1207/s15324796abm2701_2

Glasgow, R. E., Toobert, D. J. & Gillette, C. D. (2001). Psychosocial barriers to diabetes self-management and quality of life. *Diabetes Spectrum, 14*, 33. doi: 10.2337/diaspect.14.1.33

Glazier, R. H., Bajcar, J., Kennie, N. R., & Willson, K. (2006). A systematic review of interventions to improve diabetes care in socially disadvantaged populations *Diabetes Care, 29*, 1675-1688. doi: 10.2337/dc05-1942

Gonder-Frederick, L. A., Cox, D. J., & Ritterband, L. M. (2002). Diabetes and behavioral medicine: The second decade. *Journal of Consulting and Clinical Psychology, 70,* 611–625. doi: 10.1037//0022-006x.70.3.611

Gonzalez, J. S., Fisher, L., & Polonsky, W. H. (2011). Depression in diabetes: Have we been missing something important? *Diabetes Care, 34*, 236-239. doi:10.2337/dc10-1970

Griffin, S. (1998). Educational and psychosocial interventions for adults with diabetes: A survey of the range and types of interventions, the extent to which they have been evaluated in controlled trials and a description of their relative effectiveness as reported in existing reviews. *Report to the British Diabetic Association, Final Draft, June 1998*. British Diabetic Association.

Hawthorne, G., Herrman, H., & Murphy, B. (2006). Interpreting the WHOQOL-BREF: Preliminary population norms and effect sizes. *Social Indicators Research*, *77*, 37-59. doi: 10.1007/s11205-005-5552-1

Haynes, R. B., Ackloo, E., Sahota, N., McDonald, H. P., & Yao, X. (2008). *Interventions for enhancing medication adherence*. England: John Wiley & Sons. doi: 10.1002/14651858.CD000011.pub3

Hays, R. D., Wells, K. B., Sherbourne, C. D., Rogers, W., & Spritzer, K. (1995). Functioning and well-being outcomes of patients with depression compared with chronic general medical illnesses. *Archives of General Psychiatry, 52*, 11. doi: 10.1001/archpsyc.1995.03950130011002

Hill-Briggs, F. (2003). Problem solving in diabetes self-management: A model of chronic illness self-management behavior. *Annals of Behavioral Medicine, 25*, 182-193. doi: 10.1207/s15324796abm2503_04

Hill-Briggs, F., & Gemmell, L. (2007). Problem solving in diabetes self-management and control: A systematic review of the literature *The Diabetes Educator, 33*, 1032-1052. doi: 10.1177/0145721707308412

Hill-Briggs F., Gemmell L., Kulkarni B., Klick B., & Brancati F.L. (2007). Associations of patient health-related problem solving with disease control, emergency department visits, and hospitalizations in HIV and diabetes clinic samples. *Journal of General Internal Medicine*, *22*, 649–654. doi: 10.1007/s11606-006-0091-2

Hill-Briggs, F., Lazo, M., Peyrot, M., Doswell, A., Chang, Y. T., Hill, M. N., . . . Brancati, F. L. (2011). Effect of problem-solving-based diabetes self-management training on diabetes control in a low income patient sample. *Journal of General Internal Medicine, 26*, 972-978. doi: 10.1007/s11606-011-1689-6

Hill-Briggs, F., Renosky, R., Lazo, M., Bone, L., Hill, M., Levine, D., . . . Peyrot, M. (2008). Development and pilot evaluation of literacy-adapted diabetes and CVD education in urban, diabetic African Americans*. Journal of General Internal Medicine, 23*, 1491-1494. doi:10.1007/s11606-008-0679-9.

Hudon, C., Fortin, M., Poitras, M. E., & Almirall, J. (2012). The relationship between literacy and multimorbidity in a primary care setting. *BMC Family Practice*, *13*, 33. doi: 10.1186/1471-2296-13-33

Institute of Medicine (2004). Health literacy: A prescription to end confusion. National Academies Press, Washington, D.C. doi: 10.5860/choice.42-4059

Institute of Medicine (2012). Multiple chronic conditions & clinical practice guideline meetings. Retrieved from http://iom.edu/Activities/Quality/VSRT/2012-MAY-29.aspx.

Krichbaum, K., Aarestad, V., & Buethe, M. (2003). Exploring the connection between self-efficacy and effective diabetes self-management. *The Diabetes Educator, 29*, 653-662. doi: 10.1177/014572170302900411

Kripalani S., Yao X., & Haynes R. (2007). Interventions to enhance medication adherence in chronic medical conditions: A systematic review. *Archives of Internal Medicine, 167,* 540-549. doi: 10.1001/archinte.167.6.540.

Krousel-Wood M., Thomas S., Muntner P., & Morisky, D. (2004). Medication adherence: A key factor in achieving blood pressure control and good clinical outcomes in hypertensive patients. *Current Opinion in Cardiology, 19,* 357-362. doi: 10.1097/01.hco.0000126978.03828.9e

Kuhajda M.C., Thorn B.E., Gaskins S.W., Day M.A., & Cabbil C.M. (2011). Literacy and cultural adaptations for cognitive behavioral therapy in a rural pain population. *Translational Behavioral Medicine: Practice, Policy and Research*,*1,* 216-223. doi: 10.1007/s13142-011-0026-2

Kutner, M., Greenburg, E., Jin, Y., & Paulsen, C. (2006). The health literacy of America's adults: Results from the 2003 National Assessment of Adult Literacy. NCES 2006-483. *National Center for Education Statistics*. doi: 10.1037/e530912012-001

Lazarus, R. S., & Folkman, S. (1984). *Stress, appraisal, and coping*. New York: Springer.

Leeman, J., Skelly, A. H., Burns, D., Carlson, J., & Soward, A. (2008). Tailoring a diabetes self-care intervention for use with older, rural African American women. *The Diabetes Educator, 34*, 310-317. doi: 10.1177/0145721708316623

Leventhal, H., Leventhal, E. A., & Breland, J. Y. (2011). Cognitive science speaks to the 'Common-Sense' of chronic illness management. *Annals of Behavioral Medicine, 41,* 152–163. doi: 10.1007/s12160-010-9246-9

Leventhal, H., Meyer, D., & Nerenz, D. (1980). The common sense representation of illness danger. S. Rachman (Ed.), *Contributions to medical psychology* (2nd ed., pp. 7–30). New York, NY: Pergamon Press.

Loftin, W. A., Barnett, S. K., Bunn, P. S., Sullivan, P. (2005). Recruitment and retention of rural African Americans in diabetes research: Lessons learned. *Diabetes Educator, 31,* 251-259. doi: 10.1177/0145721705275517

Lorig, K. R., & Holman, H. R. (2003). Self-management education: History, definition, outcomes, and mechanisms. *Annals of Behavioral Medicine, 26*, 1-7. doi: 10.1207/s15324796abm2601_01

Lorig, K., Ritter, P., & Jacquez, A. (2005). Outcomes of border health Spanish/English chronic disease self-management programs. *Diabetes Educator, 31*, 401-409. doi: 10.1177/0145721705276574

Lorig, K., Ritter, P., & Plant, K. (2005). A disease-specific self-help program compared with a generalized chronic disease self-help program for arthritis patients. *Arthritis & Rheumatism-Arthritis Care & Research, 53*, 950-957. doi: 10.1002/art.21604

Lorig K., Stewart A.L., Ritter P. (1996) Outcome measures for health education and other health care interventions. Thousand Oaks, CA: Sage Publications.

Lutes, L. D., Daiss, S. R., Barger, S. D., Read, M., Steinbaugh, E., & Winett, R. A. (2012). Small changes approach promotes initial and continued weight loss with a phone-based follow-up: Nine-month outcomes from ASPIRES II. *American Journal of Health Promotion, 26*, 235-238. doi: 10.4278/ajhp.090706-quan-216

Lutes, L. D., & Steinbaugh, E. K. (2010). Theoretical models for pedometer use in physical activity interventions. *Physical Therapy Reviews, 15*, 143-153. doi: 10.1179/1743288X10Y.0000000002

Malouff, J. M., Thorsteinsson, E. B., & Schutte, N. S. (2007). The efficacy of problem solving therapy in reducing mental and physical health problems: A meta-analysis. *Clinical Psychology Review, 27*, 46-57. doi:10.1016/j.cpr.2005.12.005

Marks, R., Allegrante, J. P., & Lorig, K. (2005). A review and synthesis of research evidence for self-efficacy-enhancing interventions for reducing chronic disability: Implications for health education practice (part I). *Health Promotion Practice, 6*, 37-43. doi:10.1177/1524839904266790

Marks, R., Allegrante, J. P., & Lorig, K. (2005). A review and synthesis of research evidence for self-efficacy-enhancing interventions for reducing chronic disability: Implications for health education practice (part II) *Health Promotion Practice, 6*, 148-156. doi:10.1177/1524839904266792

McInnis, T., Webb, E., & Strand. L. (2012, June). The patient centered primary care collaborative: Integrating comprehensive medication management to optimize patient outcomes resource guide. (2nd ed.). Washington D.C.: Patient Centered Primary Care Collaborative. Retrieved from: https://www.pcpcc.org/sites/default/files/media/medmanagement.pdf

Mc Sharry, J., Bishop, F. L., Moss-Morris, R., & Kendrick, T. (2013). 'The chicken and egg thing': Cognitive representations and self-management of multimorbidity in people with diabetes and depression. *Psychology & Health, 28*, 103. doi:10.1080/08870446.2012.716438

Melek, S. & Norris, D. (2008) Millman research report: Chronic conditions and comorbid psychological disorders. Seattle, WA: Milliman.

Mercer, S. W., Smith, S. M., Wyke, S., O'Dowd, T., & Watt, G. C. (2009). Multimorbidity in primary care: Developing the research agenda, *Family Practice, 26*, 79-80. doi:10.1093/fampra/cmp020

Mezuk, B., Eaton, W. W., Albrecht, S., & Golden, S. H. (2008). Depression and type 2 diabetes over the lifespan a meta-analysis. *Diabetes Care*, *31*, 2383-2390. doi: 10.2337/dc08-0985

Michie, S., Abraham, C., Whittington, C., McAteer, J., Gupta, S. (2009). Effective techniques in healthy eating and physical activity interventions: A meta-regression. *Health Psychology, 28,* 690-701. doi: 10.1037/a0016136

Mokdad A. H., Marks J. S., Stroup J. S., Gerberding J.L. (2004). Actual causes of death in the United States, 2000. *Journal of the American Medical Association, 291,* 1238-1245. doi: 10.1001/jama.291.10.1238

Morisky, D. E., Ang, A., Krousel-Wood, M., & Ward, H. J. (2008). Predictive validity of a medication adherence measure in an outpatient setting. *The Journal of Clinical Hypertension, 10*, 348-354. doi:10.1111/j.1751-7176.2008.07572.x

Morrow, D., Clark, D., Tu, W., Wu, J., Weiner, M., Steinley, D., & Murray, M. D. (2006). Correlates of health literacy in patients with chronic heart failure. *The Gerontologist*, *46*, 669-676. doi: 10.1093/geront/46.5.669

Murphy B., Herrman H., Hawthorne G., Pinzone T., & Evert H. (2000). Australian WHOQoL instruments: User's manual and interpretation guide. Australian WHOQoL Field Study Centre, Melbourne, Australia.

National Institutes of Health, U.S. Department of Health and Human Services, Public Health Service, National Cancer Insittute, (1994). Clear and simple: Developing effective print materials. NIH Publications #95-3594. Available at http://devcompage.com/wp-content/uploads/2010/12/Clear_n_Simple.pdf

Nace, D. K., Nielsen, M., & Grundy, P. (2012). *The Patient Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes.* (2nd ed.) Washington D.C.: Patient-Centered Primary Care Collaborative. Retrieved from http://www.accp.com/docs/positions/misc/CMM%20Resource%20Guide.pdf

Nilsen, W. J., & Olster, D. H., (2013). News from NIH: Effective behavioral treatments for patients with multiple chronic conditions. *Translational Behavioral Medicine, 3,* 1-2. doi: 10.1007/s13142-012-0184-x

Noel, P., Williams, J., Unutzer, J., Worchel, J., Lee, S., Cornell, J., . . . Harpole, L. (2004). Depression and comorbid illness in elderly primary care patients: Impact on multiple domains of health status and well-being. *Annals of Family Medicine, 2*, 555-562. doi: 10.1370/afm.143

Norman, G. R., Sloan. J. A., & Wyrwich, K. W. (2003). Interpretation of changes in health-related quality of life: The remarkable universality of half a standard deviation. *Medical Care, 41,* 46-57. doi: 10.1097/01.mlr.0000062554.74615.4c

Nutbeam, D. (2000). Health literacy as a public health goal: A challenge for contemporary health education and communication strategies into the 21st century. *Health Promotion International*, *15*, 259-267. doi: 10.1093/heapro/15.3.259

Ogedegbe, G., Mancuso, C. A., Allegrante, J. P., & Charlson, M. E. (2003). Development and evaluation of a medication adherence self-efficacy scale in hypertensive African American patients. *Journal of Clinical Epidemiology, 56*, 520-529. doi: 10.1016/s0895-4356(03)00053-2

Oldridge, N. B., Stump, T. E., Nothwehr, F. K., & Clark, D. O. (2001). Prevalence and outcomes of comorbid metabolic and cardiovascular conditions in middle- and older-age adults. *Journal of Clinical Epidemiology*, *54*, 928-934. doi: 10.1016/s0895-4356(01)00350-x

Osterberg, L., & Blaschke, T. (2005). Adherence to medication. *New England Journal of Medicine*, *353*, 487-497. doi: 10.1056/nejmra050100

Paharia, M. I. (2008). Chronic disease prevention. In Boyer, B. A., & Paharia, M. I. (Eds.). *Comprehensive handbook of clinical health psychology* (55-80). Hoboken, NJ: Wiley.

Parekh, A. K., & Goodman, R. A. (2013). The HHS strategic framework on multiple chronic conditions: genesis and focus on research. *Journal of Comorbidity*, *3*(2), 22-29.

Perri, M. G., Nezu, A. M., McKelvey, W. F., Shermer, R. L., Renjilian, D. A., & Viegener, B. J. (2001). Relapse prevention training and problem-solving therapy in the long-term management of obesity. *Journal of Consulting and Clinical Psychology, 69*, 722-726. doi:10.1037/0022-006X.69.4.722

Plack, Herpertz, Petrak, (2010), Behavioral medicine interventions in diabetes. *Current Opinion in Psychiatry, 23,* 131-138.

Radloff, L. S. (1977). The CES-D scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement, 1*, 385-401. doi: 10.1177/014662167700100306

Reeves, M. J., Rafferty, A. P. (2005). Healthy lifestyle characteristics among adults in the United States, 2000. *Archives of Internal Medicine, 165*, 854–857. doi: 10.1016/j.accreview.2005.08.022

Roter, D. L., Hall, J. A., Merisca, R., Nordstrom, B., Cretin, D., & Svarstad, B. (1998). Effectiveness of interventions to improve patient compliance: A meta-analysis. *Medical Care, 36*, 1138-1161. doi: 10.1097/00005650-199808000-00004

Rothman, R. L., DeWalt, D. A., Malone, R., Bryant, B., Shintani, A., Crigler, B., . . . Pignone, M. (2004). Influence of patient literacy on the effectiveness of a primary care-based diabetes disease management program. *The Journal of the American Medical Association, 292*, 1711-1716. doi:10.1001/jama.292.14.1711

Rothman, A., & Wagner, E. H. (2003). Chronic illness management: What is the role of primary care? *Annals of Internal Medicine*, *138*, 256. doi: 10.7326/0003-4819-138-3-200302040-00034

Rubin, R. (2005). Adherence to pharmacologic therapy in patients with type 2 diabetes mellitus. *American Journal of Medicine, 45,* 151-159. doi: 10.1016/j.amjmed.2005.04.012

Sabate, E. (2003). Adherence to long-term therapies: Evidence for action. Geneva, Switzerland: World Health Organization.

Sarkar, U., Fisher, L., Schillinger, D. (2006). Is self-efficacy associated with diabetes in self-management across race/ethnicity and health literacy? *Diabetes Care, 29*, 823-829. doi: 10.2337/diacare.29.04.06.dc05-1615

Sbrocco, T., Nedegaard, R. C., Stone, J. M., & Lewis, E. L. (1999). Behavioral choice treatment promotes continuing weight loss: Preliminary results of a cognitive-behavioral decision-based treatment for obesity. *Journal of Consulting and Clinical Psychology, 67*, 260-266. doi:10.1037/0022-006X.67.2.260

Schoenthaler, A., Ogedegbe, G., & Allegrante, J. P. (2009). Self-efficacy mediates the relationship between depressive symptoms and medication adherence among hypertensive African Americans. *Health Education & Behavior*, *36*, 127-137. doi: 10.1177/1090198107309459

Schroeder, S. A. (2007). We can do better – improving the health of the American people. *New England Journal of Medicine, 357,* 1221-1228. doi: 10.1056/nejmsa073350

Shi, L., Lebrun-Harris, L. A., Daly, C. A., Sharma, R., Sripipatana, A., Hayashi, A. S., & Ngo-Metzger, Q. (2013). Reducing disparities in access to primary care and patient satisfaction with care: The role of health centers. *Journal of Health Care for the Poor and Underserved*, *24*, 56-66. doi: 10.1353/hpu.2013.0022

Skevington, S. M. & McCrate, F. M. (2012). Expecting a good quality of life in health: Assessing people with diverse diseases and conditions using the WHOQOL-BREF. *Health Expectations, 15*, 49–62. doi: 10.1111/j.1369-7625.2010.00650.x

Smith, S. M., Soubhi, H., Fortin, M., Hudon, C., & O'Dowd, T. (2012). Interventions for improving outcomes in patients with multimorbidity in primary care and community settings. *Cochrane Database of Systematic Reviews, 4*. doi:10.1002/14651858.CD006560.pub2

Smith, S. K., Nutbeam, D., & McCaffery, K. J. (2013). Insights into the concept and measurement of health literacy from a study of shared decision-making in a low literacy population. *Journal of Health Psychology, 18,* 1011-1022. doi:10.1177/1359105312468192

Spijkerman, T., de Jonge, P., van den Brink, R. H., Jansen, J. H., May, J. F., Crijns, H. J., & Ormel, J. (2005). Depression following myocardial infarction: First-ever versus ongoing and recurrent episodes. *General Hospital Psychiatry*, *27*, 411-417. doi: 10.1016/j.genhosppsych.2005.05.007

Starfield, B. (2011). Challenges to primary care from co- and multi-morbidity. *Primary Health Care Research & Development, 12*, 1. doi:10.1017/S1463423610000484

Stuart B. & Briesacher B. (2002). Medication decisions – right and wrong. *Medical Care Research and Review, 59,* 123–145. doi: 10.1177/1077558702059002001

Sullivan, P., Mark D., O'Connor, P., Feeney, P., Hire, D., Simmons, . . . Katon, W. J., (2012). Depression predicts all-cause mortality: Epidemiological evaluation from the ACCORD HRQL substudy. *Diabetes Care, 35*, 1708-15. doi: 10.2337/dc11-1791

Taylor, J. (2004). The fundamentals of community health centers. National Health Policy Forum, Washington D.C.

Thorpe, C. T., Bryson, C. L., Maciejewski, M. L., & Bosworth, H. B. (2009). Medication acquisition and self-reported adherence in veterans with hypertension. *Medical Care*, *47*, 474-481. doi: 10.1097/mlr.0b013e31818e7d4d

Townsend, A., Hunt, K., & Wyke, S. (2003). Managing multiple morbidity in mid-life: A qualitative study of attitudes to drug use. *British Medical Journal, 327*, 837-840. doi: 10.1136/bmj.327.7419.837

Tudor-Locke, C., Williams J. E., Reis, J. P., & Pluto, D. (2002). Utility of pedometers for assessing physical activity: Convergent validity. *Sports Medicine, 32,* 795-808. doi: 10.2165/00007256-200232120-00004

Viswanathan, M., Golin, C. E., Jones, C. D., Ashok, M., Blalock, S. J., Wines, R. C. M., . . . Lohr, K. N. (2012). Interventions to improve adherence to self-administered medications for chronic diseases in the United States. *Annals of Internal Medicine*, *157*, 785-795. doi: 10.7326/0003-4819-157-11-201212040-00538

von Wagner, C., Steptoe, A., Wolf, M. S., & Wardle, J. (2009). Health literacy and health actions: A review and a framework from health psychology. *Health Education & Behavior, 36*, 860-877. doi:10.1177/1090198108322819

Webb, M. S., de Ybarra, D. R., Baker, E. A., Reis, I. M., & Carey, M. P. (2010). Cognitive–behavioral therapy to promote smoking cessation among African American smokers: A randomized clinical trial. *Journal of Consulting and Clinical Psychology*, *78*, 24-33. doi: 10.1037/a0017669

Weiss B. D., Maysm M. Z., Martz W., Castro K. M., DeWalt D. A., Pignone M. P., … Hale F. A. Quick assessment of literacy in primary care: The newest vital sign. *Annals of Family Medicine, 3,* 514-522. doi: 10.1370/afm.405

Williams, A., Manias, E., & Walker, R. (2008). Interventions to improve medication adherence in people with multiple chronic conditions: A systematic review. *Journal of Advanced Nursing*, *63*, 132-143. doi: 10.1111/j.1365-2648.2008.04656.x

Wolff, J. L., Starfield, B., & Anderson, G. (2002). Prevalence, expenditures, and complications of multiple chronic conditions in the elderly. *Annals of Internal Medicine*, *162*, 2269-2276. doi: 10.1001/archinte.162.20.2269

Wysocki, T. (2006). Behavioral assessment and intervention in pediatric diabetes. *Behavior Modification*, *30*, 72-92. doi: 10.1177/0145445505284275

Appendix A: Institutional Review Board Approvals

Pilot Survey Study

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board Office
4N-70 Brody Medical Sciences Building· Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office **252-744-2914** · Fax **252-744-2284** · www.ecu.edu/irb

Notification of Exempt Certification

From: Social/Behavioral IRB
To: Laura Daniels
CC:
Lisa Campbell
Date: 11/30/2012
Re: UMCIRB 12-001914
Patient and Provider Survey of Chronic Disease Management Needs

I am pleased to inform you that your research submission has been certified as exempt on 11/30/2012. This study is eligible for Exempt Certification under category #2.

It is your responsibility to ensure that this research is conducted in the manner reported in your application and/or protocol, as well as being consistent with the ethical principles of the Belmont Report and your profession.

This research study does not require any additional interaction with the UMCIRB unless there are proposed changes to this study. Any change, prior to implementing that change, must be submitted to the UMCIRB for review and approval. The UMCIRB will determine if the change impacts the eligibility of the research for exempt status. If more substantive review is required, you will be notified within five business days.

The UMCIRB office will hold your exemption application for a period of five years from the date of this letter. If you wish to continue this protocol beyond this period, you will need to submit an Exemption Certification request at least 30 days before the end of the five year period.

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

Intervention Study

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board Office
4N-70 Brody Medical Sciences Building· Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office **252-744-2914_** · Fax **252-744-2284_** · **www.ecu.edu/irb**

Notification of Initial Approval: Expedited

From: Social/Behavioral IRB
To: Laura Daniels
CC:
Lisa Campbell
Laura Daniels
Date: 11/25/2013
Re: UMCIRB 13-001992
Pilot Intervention for Medication Adherence with Patients with MCC

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s) is for the period of 11/22/2013 to 11/21/2014. The research study is eligible for review under expedited category #7. The Chairperson (or designee) deemed this study no more than minimal risk.

Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The Investigator must adhere to all reporting requirements for this study.

Approved consent documents with the IRB approval date stamped on the document should be used to consent participants (consent documents with the IRB approval date stamp are found under the Documents tab in the study workspace).

The approval includes the following items:

Name	Description
Chronic disease self-efficacy scale_Stanford.docx	Surveys and Questionnaires
Daniels Dissertation Proposal_Committee Document.docx	Study Protocol or Grant Application
Demographic Questionnaire.docx	Data Collection Sheet
Demographic Questionnaire.docx	Surveys and Questionnaires
Health Problem Solving Scale & Scoring.docx	Surveys and Questionnaires
Informed Consent_Medication Adherence for MCC_Final.docx	Consent Forms
Med Ad_phone flyer.pub	Recruitment Documents/Scripts
Med Ad_Recruitment Handout_blue (1).pub	Recruitment Documents/Scripts
Medication Self-efficacy Scale_MASES.docx	Surveys and Questionnaires
Morisky Medication Adherence Scale_Scoring.pdf	Surveys and Questionnaires
Script for Recruitment calls.docx	Recruitment Documents/Scripts

TOFHLA - Large Print Version.pdf	Surveys and Questionnaires
WHO Quality of Life.docx	Surveys and Questionnaires

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

IRB00000705 East Carolina U IRB #1 (Biomedical) IORG0000418
IRB00003781 East Carolina U IRB #2 (Behavioral/SS) IORG0000418

Appendix B: Patient and Provider Surveys

Created by: Laura Daniels, MA

Chronic Disease Management Program Topics: Health Care Team Survey

Please complete the following **anonymous** survey

1. What is your role at KCHC?

☐ Provider ☐ CMA ☐ Other (indicate role):___________________

2. What are the most important things your patients can do to improve management of their health care?

Choose up to 3

Medication adherence
Symptom self-monitoring
Lifestyle modifications
Weight management
Pain Management
Managing comorbid chronic diseases
Communicate with provider
Other: ______________________

3. Patient communication with their health care team plays a role in managing one's health. Would you like your patients to improve communication on any of the following topics?

☐ Yes (Choose 2 below) **☐ No (Proceed to question 3)**

Challenges in keeping appointments
Discussing symptom side-effects, symptom changes
Contacting provider between appointments
Engaging in shared decision-making (e.g. collaborating on personal health care goals or medication regimen
Other: ____

4. Regarding patients' psychosocial barriers for managing chronic conditions, which areas do patients need the most support?

Choose up to 3

Emotional distress
Distress about health
Work stress
Stress related to daily tasks or responsibilities
Spouse-Partner relationship
Family relationships
Other: ____________________

5. If your patient participated in a chronic disease self-management program, would you like updates on their progress or health-related goals?

☐ **Yes** (see question 6)   ☐ **No**

6. What would be your preferred method of receiving an update on your patient's goals? ***Choose up to 2***

Brief summary in paper format

Brief note in the patient's EMR

Face-to-face update from program coordinator

Face-to-face update from patient

Other: ________________________________

Chronic Disease Management: Patient Survey

Please complete the following **anonymous** survey

1. Please check any of the following problems that apply to you:

Diabetes
Arthritis
Heart disease
Obesity
High blood pressure
Asthma

Depression/Anxiety
High cholesterol
Borderline diabetes
Chronic Pain
Sleep problems

2. What are the most important things that you want to do or learn to improve your health? ***Choose up to 3***

Taking medication as prescribed
Monitoring symptoms
Making lifestyle changes
Managing weight/weight loss
Managing pain
Managing multiple chronic diseases
Communicating with provide

3. Patient communication with their health care team plays a role in managing one's health. Would you like to improve communication with your doctor on any of the following topics?

☐ **Yes (Choose up to 2 below)** ☐ **No (Proceed to question 4)**

Discussing challenges in keeping appointments
Discussing symptom side-effects, symptom changes
Contacting provider between appointments
Setting specific goals for improving my health

4. Sometimes our own thoughts, feelings, or lifestyle choices make it difficult to make healthy changes. Other times it is something or someone in our environment. Which of the following topics make it difficult for you to manage your health or are impacted by your health condition?

Choose up to 3

Emotional distress
Distress about health
Work stress
Stress related to daily tasks or responsibilities
Spouse-Partner relationship
Family relationship

5. If you were participating in a chronic disease self-management program, would you want your provider to be updated on your progress or health goals?

☐ **Yes** (see question 6) ☐ **No**

6. How would you like your provider updated on your progress or goals if you participated in a health program? ***Choose up to 2***

Update in your health record
Face-to-face update from program coordinator
I would like to update my doctor during my visit
Other: ________________________________

Appendix C: Session-by-Session Outline

Enrollment Session

1. Informed Consent
2. Baseline assessment
    a. Demographics (participant number, name, sex, age, race/ethnicity phone number, address, birth date, education, Rx assistance)
    b. Chronic conditions (type, number)
    c. Medications (type, number)
    d. Primary and secondary outcomes assessment
3. Introduction to program materials
4. Obtain from EMR current medications list.
5. Homework: Prior to first group meeting participant should use this list to verify medication list at home and bring to first group meeting.
6. If necessary, refer to Medication Assistance Program.

Session 1: Overview and Self-monitoring

✓ Handouts/materials
    1. Gas cards
    2. Overview of program philosophy and objectives handout
    3. Self-monitoring log worksheet (2)
    4. Goal-setting action plan worksheet

1. Welcome and introductions (10 min)
2. Program overview (10 min)
    a. Philosophy: Enhancing knowledge and skills for taking medications and overcoming challenges to adherence using a small change approach
    b. Group rules and expectations
    c. Basic agenda for sessions
3. Group discussion: Medication concerns, challenges (15 min)
4. Didactic (20 min):
    a. Self-monitoring - obtaining a baseline (10 min)
    b. Goal-setting - setting small goals and creating an action plan (10 min)
5. Activities (25-30 min):
    a. Decisional balance for taking medications will occur after group discussion (5 min)
    b. Complete a sample self-monitoring log during didactic component (10 min)
    c. Setting first small change goal during didactic component (10 min)
6. Goals-setting and homework (5 min):
    a. Homework: Begin self-monitoring
    b. Small Change Goal: Number of days self-monitoring
    c. Handout gas cards

Session 2: Taking Control of Your Medication Schedule

✓ Handouts/materials
    1. Personal pill organizer

    2. Example prescription bottle and information leaflet
    3. Dosing schedule worksheet
    4. Self-monitoring log
    5. Goals-setting action plan worksheet

1. Welcome back and overview of session agenda (2 min)
2. Check-in: successes and challenges in self-monitoring and report baseline self-monitoring (10 min)
3. Discussion (10 min):
    a. What did you learn about your patterns?
    b. When is it easy/hard to remember to take medications?
    c. What medications are difficult/easy to adhere to?
    d. Issues of control of one's schedule?
4. Didactic: Health Literacy (28 min)
    a. Interpreting prescription information and dosing recommendations (15 min)
    b. Simplifying the dosing schedule using a model schedule (10 min)
    c. Prescription changes: Not if, but when (3 min)
5. Activities (25 min):
    a. Interpreting a sample prescription instructions and information leaflet include with didactic component
    b. Creating an individualized dosing schedule include with didactic component (10 min)
    c. Filling your pill organizer (15 min)
6. Group discussion: Reflections on completed dosing schedule (5 min)
7. Goal-setting and Homework (10 min):
    a. Homework: continue self-monitoring self-selected medications based on check-in discussion.
    b. Small Change Goal: Focus on improving adherence for one medication

Session 3: Tools for Success: Your Attitude

- ✓ Handouts/materials
    1. Tools for Success: Your Attitude/ABC handout
    2. ABC worksheet (2)
    3. Self-monitoring Log
    4. Goal-setting Action Plan worksheet

1. Welcome back and overview of session agenda (2 min)
2. Check-in: Successes/challenges with achieving goal, collect weekly adherence data (15 min)
3. Discussion (10 min):
    a. What did you learn about yourself while working on this goal?
    b. What problems arose?
    c. How did the pill organizer help?
4. Didactic: Tools for Success (19 min)
    a. Case Example: Negative Ned (or group member example from check-in) (2 min)

    b. Case Example: Positive Pat (or group member example from check-in) (2 min)
    c. ABC approach to dealing with problems (15 min)
5. Discussion (15 min):
    a. Differences in Ned and Pat's antecedents, behaviors, and consequences? (3 min)
    b. Reflections on the ABC approach. How aware are you of the ABC's when you miss a dose/avoid a dose? (10 min)
    c. Can you see your self trying out this approach to understanding problems? (2 min)
6. Activity: Complete ABC worksheet for case examples (or personal example) (10 min)
7. Goal-setting and Homework:
    a. Homework: Continue self-monitoring.
    b. Small Change Goal: Modify last weeks goal, maintain goal, or add another medication goal?
    c. Homework: Complete ABC worksheet with problem (e.g. missed dose occurs)

<u>Session 4: Tools For Success: Your Actions</u>

✓ Handouts/materials
    1. Tools for Success: Your Actions/Problem-solving Skills handout
    2. Problem-solving worksheet
    3. Self-monitoring Log
    4. Goal-setting Action Plan worksheet

1. Welcome back and overview of session agenda (2 min)
2. Check-in: Successes/challenges to achieving goal, collect adherence data (10 min)
3. Discussion (15 min):
    a. What problems make it difficult to take your medications?
    b. Ask if anyone is willing to share their ABC experience?
    c. What other problems have you learned that affect adherence? Side effects? Beliefs about medications?
4. Didactic: Tools for Success (19 min)
    a. Case example: Avoidant Angie (or group member example) (2 min)
    b. Case example: Productive Pat (or group member example) (2 min)
    c. Problem solving skills training (15 min)
5. Discussion (18 min):
    a. Differences in Angie and Pat's approach and outcomes (5 min)
    b. Reflections on the problem solving process. How do you overcome problems? How do you get back to taking medications regularly? (10 min)
    c. Can you see yourself trying out this approach to solving problems? (3 min)
6. Activity: Complete problem-solving worksheet for case example and personal example (15 min)
7. Goal-setting and Homework (2 min):
    a. Homework: continue self-monitoring

    b. Small Change Goal: Modify last weeks goal, maintain goal, or add another goal?
    c. Homework: Complete problem-solving worksheet for one problem this week.
8. Last session reflection (5 min)
9. Preview for phone meeting and sign-up for individual session times (5 min)

Phone Session 1:

✓ Handouts/materials
    1. Tools for Success: Your Attitude and Your Action worksheet
    2. Self-monitoring Log
    3. Goal-setting Action Plan worksheet

1. Check-in (8 min):
    a. Successes/challenges in meeting goal
    b. Collect adherence data
    c. Review problem-solving efforts
2. Discussion with feedback (5-10 min):
    a. What was difficult about using the problem solving skills?
    b. What other problems came up?
3. Individualized Activity: ABC or Problem-solving skills Worksheet (10 min)
4. Goal-setting and Homework (5 min):
    a. Homework: continue self-monitoring
    b. Small Change Goal: Modify last weeks goal, maintain goal, or add another medication goal?
    c. Homework: Complete problem-solving worksheet for one problem.

Phone Session 2:

✓ Handouts/materials
    1. Future problems worksheet
    2. Self-monitoring Log
    3. Goal-setting Action Plan worksheet

1. Check-in (8 min):
    a. Success/challenges in meeting goals
    b. Collect adherence data
    c. Problem-solving experience
2. Discussion with feedback (5-10 min):
    a. What have you learned over the past few weeks about the challenges in taking medications as prescribed?
    b. What have you learned helps with improving your adherence?
3. Individualized Activity: Identifying future problems (10 min).
4. Goal-setting and Homework (5 min):
    a. Homework: Continue self-monitoring
    b. Small Change Goal: Modify last weeks goal, maintain goal, or add another goal?
    c. Schedule post treatment session

Post-treatment Individual Meeting and Assessment

1. Solicit personal reflection of program
2. Collect post-treatment primary and secondary outcome data
3. Provide progress chart of medication adherence
4. Provide gas card