

LITERACY IN ARTHRITIS

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ABSTRACT

ANITA ASHOK BHAT: Literacy in Arthritis
(Under the direction of Bruce J Fried, PhD)

Purpose: To evaluate the association between literacy, measured by Rapid Estimate of Adult Literacy in Medicine (REALM) and arthritis health outcomes in a cross-sectional and longitudinal study. Further, to evaluate the effect of literacy and psychosocial variables on arthritis health outcomes in the longitudinal study.

Methods: REALM was administered to 447 participants at baseline in two community-based randomized controlled trials of life style interventions designed for sedentary adults with arthritis, *People with Arthritis Can Exercise (PACE)* (an 8-week exercise program) and *Active Living Every Day (ALED)* (a 20-week physical activity behavioral modification intervention). These studies were sufficiently similar to allow combining the two data sets to examine associations of literacy with health outcomes measured at baseline and at the end of the intervention, the Health Assessment Questionnaire (HAQ), and arthritis symptoms pain, fatigue, and stiffness Visual Analogue Scales (VAS). Descriptive statistics were conducted. Bivariate and multivariate analyses were done.

Longitudinal model had 391 participants. Helplessness was measured using the Rheumatology Attitudes Index (RAI) and outcome expectation for exercise (OEE) was measured by OEE.

Results: Amid 447 individuals, 89 (20%) had REALM score below 61, which indicates a reading level of 8th grade or less. Individuals with low literacy did not have worse arthritis health outcomes than individuals with adequate literacy. Descriptive statistics of the longitudinal model were similar to the cross-sectional model. Disability after intervention was not predicted by helplessness, literacy or OEE in adjusted models. Pain, fatigue and stiffness after the intervention were all significantly predicted by helplessness at various magnitudes in adjusted models, but OEE and literacy were not significant predictors.

Conclusion: One in five of our patient population had low literacy. Participants with low literacy did not have worse arthritis health outcomes than individuals with adequate literacy. When literacy, helplessness and OEE were examined as predictors of arthritis outcomes in lifestyle intervention trials; neither literacy, nor psychosocial variables predicted disability. However, helplessness predicted symptoms of pain, fatigue and stiffness.

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LIST OF ABBREVIATIONS

AA	African American
AHRQ	Agency for Healthcare Research and Quality
ALED	Active Living Every Day
BMI	Body Mass Index
HALS	Health Activities Literacy Scale
HAQ	Health Assessment Questionnaire
IOM	Institute of Medicine
IRB	Institutional Review Board
MHAQ	Modified Health Assessment Questionnaire
MITT	Modified Intention to Treat
MODEMS	Musculoskeletal Outcomes Data Evaluation & Management System
NALS	National Adult Literacy Survey
NAAL	National Assessment of Adult Literacy
NVS	Newest Vital Sign
PACE	People with Arthritis Can Exercise
PAR	Program Announcement with Review
RA	Rheumatoid Arthritis
RAI	Rheumatology Attitudes Index
RCT	Randomized Controlled Trial
REALM	Rapid Estimate of Adult Literacy in Medicine
TOFHLA	Test of Functional Health Literacy in Adults
VAS	Visual Analog Scales

Chapter 1 Introduction

1.1 Overview of existing research

The relationship of literacy and health in the United States is a topic of growing interest for researchers, policy makers and healthcare providers. First, studies have generally focused on understanding the impact of literacy on health knowledge and behaviors rather than on health outcomes (Kalichman & Rompa, 2000; Kalichman et al., 2000; Williams et al., 1998; Williams et al., 1998). Most important, however, is the ultimate impact of health interventions on measurable health outcomes in low literacy individuals. Second, most studies have been cross-sectional, which limits our ability to understand the causal pathways (including mediators) through which literacy influences health (DeWalt et al., 2004). To date, there are only five longitudinal published studies that have examined whether interventions improve health outcomes in chronic diseases; namely diabetes, depression and heart failure (Rothman et al., 2004; Rothman et al., 2004; Weiss et al., 2006; DeWalt et al., 2006; Sisk et al., 2006)

1.2 Limitations of existing research

To the best of our knowledge there are no published longitudinal studies in other chronic diseases that have examined whether interventions improve health outcomes in low literacy individuals. Arthritis affects more than 47% of individuals 65 years of age and older, making it the most prevalent

chronic condition in adults (Fried, 2000). Involving patients in their care is critical because managing arthritis generally involves both medications and lifestyle changes, including exercise and diet modifications. Often, clinicians use written materials to educate patients about their arthritis and its treatments. Arthritis interventions help people with arthritis and other rheumatic conditions to maximize their abilities and reduce pain and other arthritis-related problems (Brady et al., 2003).

The ability to read and comprehend prescription bottles, appointment slips, and other essential health-related material requires adequate literacy (Gordon et al., 2002; Rudd, Rosenfeld and Gall, 2007) Also, we know that the majority of patients older than 60 years perform at the lowest levels of literacy because their reading and comprehension abilities are influenced by their cognition, and their vision and hearing status (Safeer and Keenan, 2005). Hence, arthritis patients in the older age group are even more affected. Individuals with low literacy have several adverse health outcomes (Literacy and health outcomes, 2004).

It is important to assess the impact of low literacy on arthritis outcomes so as to target the vulnerable population with appropriate interventions. Do interventions mitigate the effects of low literacy on arthritis outcomes? The findings will be critical in designing interventions to target the low literacy groups or in advancing the literature to look at other strategies.

Prospective studies of rheumatoid arthritis patients support the central role of helplessness as a predictor for level of pain, disability, and depression

over time (Evers et al., 2001; DeVellis & Blalock, 1992; Smith et al., 1994). Callahan and colleagues (1996) showed that higher mortality in rheumatoid arthritis patients was associated with both higher helplessness scores and lower levels of formal education. No study has looked at psychological variables like helplessness and exercise outcome expectation and whether they mediate the effect of low literacy on health outcomes.

1.3 Purpose of this dissertation

Larson and Schumacher (1992) found that the Arthritis Foundation literature was at 8th to 13th grade reading level, which may be too difficult for a significant number of their patients. Researchers in rheumatology have focused on assessments of health related materials as well as the mismatch between the print materials and the reading skills of the arthritis patients (Rudd, Rosenfeld and Gall, 2007), but not on the relationship between literacy and health outcomes. Contributions from rheumatology in this area are much needed. Only one cross-sectional study of 127 patients in a UK tertiary referral center (Gordon et al., 2002) and one abstract by Pincus and colleagues (2000) have addressed the level of literacy in arthritis patients and its impact on disease severity and function. The study conducted by Gordon and colleagues (2002) reported that people with lower literacy had more anxiety and hospital visits, but equal function. The abstract by Pincus and colleagues (2000) estimated literacy in 88 patients attending an academic rheumatology unit and reported that patients with lower Rapid Estimate of

Adult Literacy in Medicine (REALM) score had worse modified health assessment questionnaire (MHAQ), pain, and global status scores than people with higher literacy. This proposed research will be the *first of its kind along three dimensions*. *First*, it will be the largest cross-sectional (n=447) and longitudinal study (n=391) addressing literacy in individuals with arthritis. *Second*, unlike previous studies, this study includes sedentary adults from a broad cross-section of the population with any type of arthritis or joint pain. Subjects were recruited from urban and rural areas across North Carolina, which included family practice offices, community centers, senior centers, health departments, healthcare systems, and fitness centers. Participants were also recruited from advertisements in local newspapers. *Third*, to our knowledge, this is the first study in arthritis which will examine whether an intervention can mitigate literacy related disparities in arthritis, and if helplessness and exercise outcome expectation are critical in designing appropriate and effective interventions.

This study will address the important issues mentioned earlier. Empirically, it will focus on the following questions:

1. To evaluate the associations between literacy and arthritis outcomes, specifically (a) arthritis symptoms and (b) self-reported functional status.
2. To determine whether (a) life style interventions have a differential short-term impact on arthritis outcomes for individuals with low and adequate literacy, and (b) literacy has a

differential impact on arthritis outcomes for those exposed and those not exposed to the intervention.

3. To assess the impact of helplessness and exercise outcome expectation on the relationship between literacy and health outcomes, by mediation.
4. To assess the impact of helplessness and exercise outcome expectation on the effectiveness of the intervention in improving health outcomes, as a mediator. Also, to determine if literacy has differential impact on helplessness and exercise outcome expectation for those exposed to the intervention and those who are not exposed to the intervention.

The results of this dissertation research will be used to develop interventions specifically designed for individuals with arthritis and low literacy. Further, if psychosocial factors like helplessness and exercise outcome expectation impact the relationship between literacy and health outcomes, they could inform the development of these interventions. Because individuals with low literacy generally have more chronic disease, it is expected that the design elements of such interventions will have applicability to disease management regimes for other chronic conditions. Ultimately, such interventions should help us move towards the *Healthy People 2010* goal of eliminating literacy-related health disparities in the United States (US Department of Health and Human Services, 2000).

1.4 Policy significance

The issue of literacy is at the forefront of much discussion among policy makers and health services researchers. The IOM patient safety Report (2000) *To Err is Human*, stresses that literacy is an important aspect of addressing patient safety and is fundamental to quality care. The 2004 Institute of Medicine (IOM) Report *Health Literacy: A Prescription to End Confusion*, noted that efforts to improve quality, reduce costs, and reduce disparities cannot succeed without simultaneous improvements in literacy. Several Institutes and Centers of the National Institutes of Health (NIH) and Agency for Healthcare Research and Quality (AHRQ) issued a Program Announcement with Review (PAR) focusing on “*Understanding and Promoting Health Literacy*” in June 2004, which was reissued in April 2007. The PAR encouraged research in areas such as: nature and scope, variation over life course, mediators and moderators of low literacy, impact and consequences, education and training, interventions, and new technologies.

The research is consistent with several IOM reports that identify health literacy as one of twenty priority areas in which quality improvement could transform healthcare in America (IOM Report *Priority Areas for National Action: Transforming Health Care Quality*, 2003). The IOM recognized that sharing the same knowledge between clinicians and patients and their families is fundamental to successful self-management. It identified self-management and health literacy as a cross-cutting priority, representing an

opportunity to improve quality of care for various priority areas, including arthritis.

This research fits well into this policy agenda, and successful completion of the proposed research will provide insights about the impact of literacy on outcomes for sedentary adults with arthritis. Moreover, since low literacy leads to worse health outcomes and increased hospitalizations and higher health care costs (Baker et al., 1998), this research may motivate payers to implement interventions for low literacy patients hence narrowing the gap in health disparities.

Health inequalities are among the most critical concerns for the health care system and for the nation as a whole. Eradication of all-encompassing health disparities across race and ethnicity is a major goal of current US health research, practice and policy (Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, 2003; Lavizzo-Mourey et al., 2005). Literacy may provide an exceptionally effective area to focus the fight to eliminate health disparities. Interventions as proposed in this research could improve health outcomes among low literacy patients.

Finally, this research may be useful in strengthening health information knowledge, thereby advancing one of the national goals of *Healthy People 2010* (US Department of Health and Human Services, 2000).

1.5 Structure of this dissertation

A literature review defining literacy, its measurement, its relation with self management, and the role of literacy in health disparities are presented in Chapter 2. Further, the role of interventions in improving health outcomes for low literacy patients and the role of psychosocial variables i.e. helplessness and exercise outcome expectation are examined. Lastly, unanswered questions are addressed. This literature review is not intended to be comprehensive, but intended to provide background and justification for the dissertation questions.

The conceptual model that was used in this dissertation is presented in the third chapter, followed by overview and study design. Later the data analysis and sample attrition are discussed.

Chapter 4 discusses the descriptive statistics for the cross-sectional and the longitudinal model. Bivariate and multivariate analysis of all four aims is addressed. Chapter 5 summarizes the study and discusses the prevalence of low literacy. Further, the relationship between literacy and educational status is examined. The last three sections address implications for future research and practice, limitations of this dissertation and conclusion.

Chapter 2 Literature review

2.1 Self-Management in chronic disease

Fully half of American adults have a chronic condition, a number that will continue to rise as our population ages and medical advances extend life (Improving Chronic Illness Care, 2007). The 25% of Medicare recipients with ≥ 4 chronic conditions account for 2/3 of Medicare expenditures (Hoffman, Rice, and Sung, 1996; Wagner, 2001). Because maximizing the quality of life for patients with chronic disease often involves medications and life style changes (Lubkin, 2002), promoting self-management is essential (Wagner et al., 2001). Self-management is the ability of the patient to deal with all aspects of a chronic illness (Barlow et al., 2002). The Institute of Medicine (Crossing the Quality Chasm, 2001) recognized self-management education as an important aspect of quality care. Self-management by patients is not an optional component of care, but inevitable since clinicians are present for only a fraction of the patient's life and nearly all outcomes are mediated through patient behavior (Glasgow et al., 2003). Hence, patients assume a central role in their care and well-being (Glasgow et al., 2003).

People who develop feelings of personal helplessness, passive acceptance, and unsuitable coping behaviors (i.e., "loss of control with arthritis") may less likely embrace healthy or problem-solving behaviors (Nicassio et al., 1985). Nicassio and colleagues (1985) suggested that helplessness may prove a useful predictor in identifying individuals less likely

to adhere to behavior change suggestions. Further, Stein and colleagues (1988) demonstrated a significant correlation between helplessness and levels of adherence with medication, exercise and rest regimens. Similarly, patients with lower helplessness and better perceived control of arthritis were more likely to adhere to joint protection, which is a self-management technique that enables people with rheumatoid arthritis to reduce pain, inflammation, and joint stress, and reduce risks of deformity (Hammond, Lincoln, and Sutcliffe, 1999). Similar correlations have been found for management of asthma and diabetes (Emtner, Hedin, and Stalenheim, 1998; Kutner, Delamater, and Santiago, 1990).

Life situations of most asthma patients before a 10 week rehabilitation program were characterized by helplessness at exacerbations, insecurity about medications, and/or concern about future health. The 10 week group rehabilitation program covered physical training, theoretical and practical education in medication, self-management strategies and physiotherapy. After 3 years of the program, nearly all patients' lives were characterized by improved self-management, increased physical activity and a sense of security. Almost half of the patients expressed a wish to take responsibility for their asthma (Emtner, Hedin, and Stalenheim, 1998).

Learned helplessness is related to long-term problems with metabolic control in diabetic youth. However, helplessness was not found to be associated with regimen adherence (Kutner, Delamater, and Santiago, 1990).

Self-management education interventions consist of organized learning experiences designed to facilitate adoption of health-promoting behaviors (Warsi et al., 2004). Interventions have been studied in such chronic diseases as diabetes, asthma, and arthritis. A review of studies assessing interventions to improve diabetes outcomes in primary care revealed that adding patient-oriented interventions leads to improvements in outcomes such as glycemic control (Renders et al., 2001). In trials focused on adult asthma, self-management produced greater reductions in nocturnal symptoms, hospitalizations, and emergency department use than did usual care (Gibson et al., 2002). One meta-analysis suggested that arthritis self-management education programs lead to small but significant reductions in pain and disability (Warsi et al., 2003). A more recent meta-analysis concluded that, whereas self-management programs for diabetes mellitus and hypertension probably produce clinically important benefits, osteoarthritis self-management programs do not appear to have clinically beneficial effects on pain or function (Chodosh et al., 2005). Potential explanations for such disparate conclusions revolve around differences in reading levels, internet access, education levels in the populations studied, and failure to identify the essential elements of any self-management program (Chodosh et al., 2005). Moreover, some publication bias against reporting null or negative trials of self-management interventions existed clearly in reporting of glycosylated hemoglobin levels in diabetes trials and systolic and diastolic blood pressures in hypertensive patients (Warsi et al., 2004). Also, goals of arthritis self-management

interventions are more difficult to define and measure than those of achieving an optimal fasting blood glucose level or blood pressure (Warsi et al., 2004).

In a metaregression for all self-management programs, it was found that interventions involving face-to-face contact were associated with better outcomes; no other trial characteristics were associated with better outcomes (Warsi et al., 2004).

2.2 Health Literacy

Definition of health literacy and its impact

In 1999, the American Medical Association Ad Hoc Committee on Health Literacy defined health literacy as “the constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment,” including “the ability to read and comprehend prescription bottles, appointment slips, and other essential health-related material.” In 2000, *Healthy People 2010* (US Department of Health and Human Services) and in 2004 IOM Report *Health Literacy: A Prescription to End Confusion* used a similar definition to define health literacy: “The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions”. These definitions depict health literacy as a set of *individual capacities* (Baker, 2006) that are constant over time and may improve with education or decline with age or impairment of cognitive function (Baker et al., 2000).

Taking a view that extends beyond the characteristics of the individual, health literacy may be construed as the ability of an individual to function effectively in a specific health care setting. Taking such a perspective, health literacy is dependent on both individual characteristics and the unique features of the health care system (Baker, 2006). Uniqueness of the health care system may depend upon the medical problem treated, characteristics of the health care provider, and the systems and processes involved in the provision of care. Baker (2006) defined health literacy as the *dynamic state* of an individual during the health care encounter. If health knowledge is part of health literacy, then health literacy can be defined as an attained level of knowledge or proficiency that depends upon an individual's capacity and motivation to learn and the resources provided by the health care system (Baker, 2006).

In 1993, the National Adult Literacy Survey (NALS) tested functional literacy in three skill domains—quantitative, prose and document (Kirsch et al., 1993). Though few American adults were completely illiterate, nearly one fourth of American adults (21-23%) scored in Level 1, the lowest literacy level, incapable of doing tasks as underlining the meaning of a term in a passage or locating an intersection on a street map (Kirsch et al., 1993). An additional 25-28% of American adults scored in the second lowest level, not able to perform tasks like writing a brief letter explaining a billing error. Another 31-32% Americans scored in Level 3 set apart by the capacity to make low-level inferences from comparatively long texts. Between 15-17% scored in Level 4,

which needed a capability to produce information from long or complicated passages (Kirsh et al., 1993). Barely 5% of respondents scored in the highest level, Level 5, which necessitated contrasting of complicated information and high-level inference (Kirsh et al., 1993).

The NALS was instrumental in bringing to the forefront the national literacy crisis in the United States. Because the NALS did not include health-related items (Ad Hoc Committee on Literacy, 1999), the survey may have understated the number of individuals whose level of literacy inhibited their interactions with the health care system. The 2003 National Assessment of Adult Literacy (NAAL) found essentially the same profile as the NALS of literacy and quantitative skills in the adult population of the United States (Kutner, Greenberg, and Baer, 2006).

Low health literacy is often associated with shame and embarrassment, which may inhibit patients with low health literacy from disclosing their reading difficulties and seeking needed help (Parikh et al., 1996). The problems of misunderstanding information are aggravated by language and cultural differences. Three percent of non-literate adults in 1992 and two percent of non-literate adults in 2003 could not be tested because of language difficulty by the NALS and NAAL respectively (Kutner, Greenberg, and Baer, 2006).

The 1992 NALS reported that 44% of adults aged 65 years or older scored in the lowest reading level (level 1); they could not perform the basic reading tasks necessary to fully function in society (Kirsh et al., 1993).

Besides the 1992 NALS, other studies showed higher prevalence of low health literacy in elderly indigent population. Low health literacy is prevalent among patients with chronic medical conditions, including arthritis (Kalichman & Rompa, 2000; Kalichman et al., 2000; Kalichman, Ramachandran, and Katz, 1999; Williams et al., 1998; Williams et al., 1998), especially among those who are indigent and/or receive Medicare (Williams et al., 1995; Gazmararian et al., 1999). In the largest study of functional health literacy in two public hospitals, 81% of English-speaking patients 60 years or older had inadequate or marginal functional literacy than younger patients to function in the health care system (Williams et al., 1995). Among Medicare enrollees \geq 65 years with at least one chronic disease, 36% of the patients had inadequate or marginal literacy (Gazmararian et al., 1999).

2.3 Are we well equipped to measure health literacy?

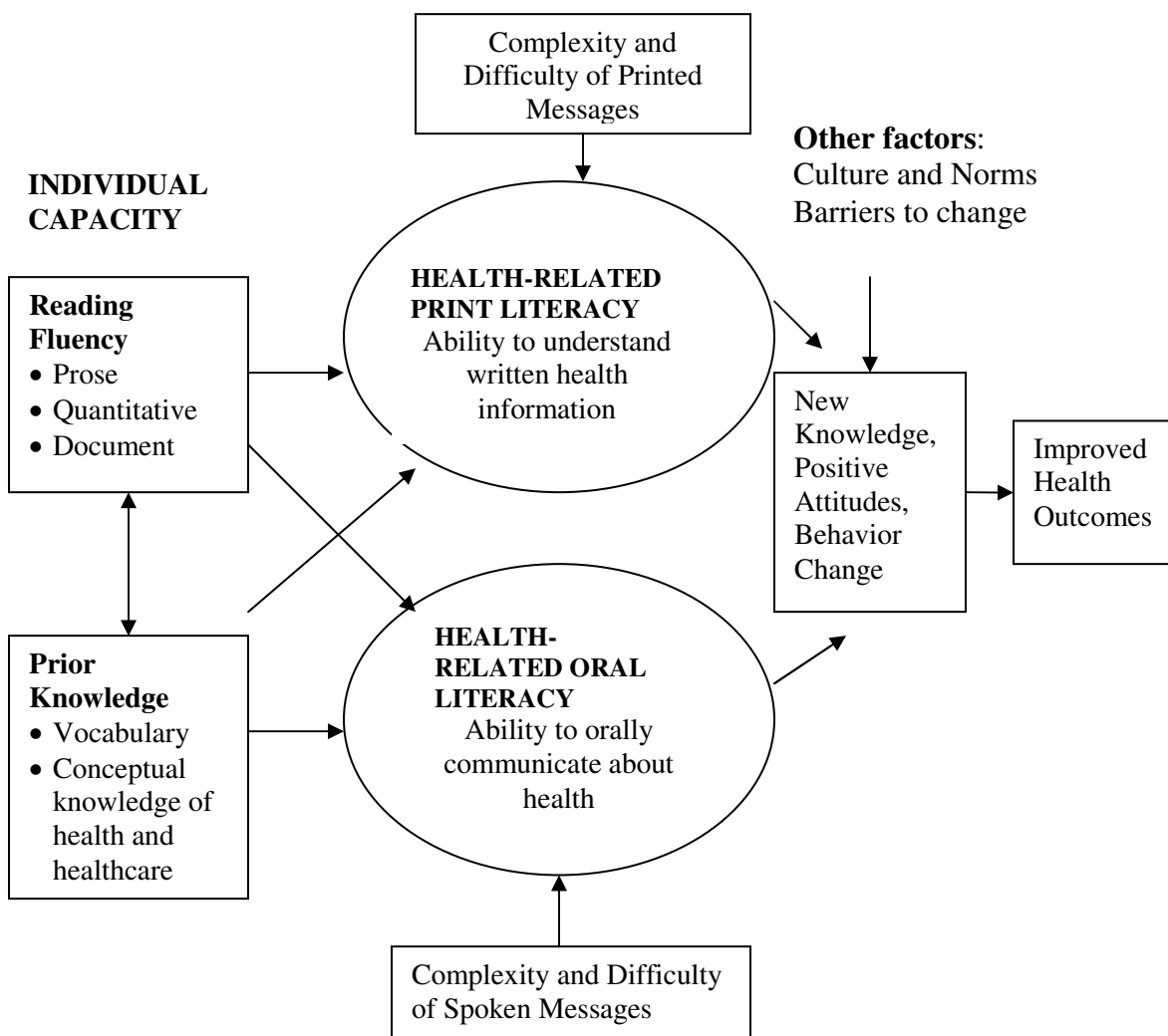
To identify individuals with low health literacy, it is vital to measure health literacy; but the definition of health literacy is not simple. According to the conceptual model presented by Baker (2006), the 2 sub domains of individual capacity of literacy are *reading fluency* and *prior knowledge* (Figure 2.3). The NALS separated reading fluency into 3 skill sets: (1) prose literacy, (2) document literacy, and (3) quantitative literacy (Kutner, Greenberg, and Baer, 2006). Prior knowledge includes vocabulary and conceptual knowledge of health and healthcare. Reading fluency and prior knowledge are highly

correlated because people acquire their vocabulary through reading (Baker, 2006).

The IOM expert panel divided the domain of health literacy into (1) cultural and conceptual knowledge; (2) oral literacy, including speaking and listening skills; (3) print literacy, including writing and reading skills; and (4) numeracy (IOM Report Health Literacy: A Prescription to End Confusion, 2004). The second domain in Baker's conceptual model (2006) is *health literacy* which is divided into *health-related print literacy* and *health-related oral literacy*, as was done in the IOM report mentioned above (IOM Report Literacy: A Prescription to End Confusion, 2004). Though health-related print literacy and health-related oral literacy may not be truly different, they both depend on the individual's health-related reading fluency and prior knowledge, taking into consideration the complexity of printed material and spoken messages encountered in the health care system. Besides culture, social norms, health care access and other factors, health literacy is yet another factor that leads to new knowledge, positive attitude and behavior change resulting in better health outcomes.

An ideal comprehensive measurement of health literacy would include characteristics of the individual and the uniqueness of the individual's health care system. This is relatively easy to conceptualize, but impractical and difficult to directly measure (Baker, 2006).

Figure 2.3: Conceptual model describing the relationship between individual capacities, health-related print and oral literacy, and health outcomes (Baker, 2006).



2.4 How do we measure literacy?

Despite the challenges in measuring literacy, several well-tested measures of individual capacity have been developed. The most widely used measures are Rapid Estimate of Adult Literacy in Medicine (REALM) (Davis et al., 1993) and the Test of Functional Health Literacy in Adults (TOFHLA) (Baker et al., 1999; Parker et al., 1995). Neither test comprehensively

measures an individual's capacity of reading fluency and prior knowledge, but measure different domains of individual capacity. REALM is a word recognition and pronunciation test that measures vocabulary, while TOFHLA measures reading fluency, i.e., prose literacy and numeracy. Both the tests are highly correlated (correlation coefficient 0.84) (Davis et al., 1998). REALM and TOFHLA are both valid and reliable indicators of patient's ability to read health-related material (Davis et al., 1993; Parker et al., 1995).

The health-related questions from NALS were compiled to construct The Health Activities Literacy Scale (HALS) (Education Testing Service), which includes prose, quantitative and document items. The HALS considered a number of health-related activities, which included: health promotion, health protection, disease prevention, health care and maintenance, and systems navigation. The full length test takes approximately an hour to complete, and for the locator test 30-40 minutes are required. The test is new, and its psychometric properties are not known. Though comprehensive, the length of the HALS may prohibit its use in future research.

Recently Weiss and colleagues (2005) developed the Newest Vital Sign (NVS), which purports to measure document and quantitative skills. The 6 questions query about a nutrition label for ice cream. The test requires 3 minutes to complete, and may be more acceptable to patients than word lists.

In another study by Wallace and colleagues (2006), the question "How confident are you filling out medical forms by yourself" had the best

extrapolative value for identifying individuals with a REALM score of $\leq 6^{\text{th}}$ grade. Similar screening questions could be practical tools to measure literacy in clinical settings.

In conclusion, although REALM and TOFHLA measure different domains of the individual capacity of the Baker's conceptual model (Figure 2.3); they measure literacy and that is the best that is available at present.

2. 5 Literacy and self management

Inadequate literacy contributes to uncontrolled chronic disease and rising health care costs (Williams et al., 1998). A recent report by the Agency for Healthcare Research and Quality on literacy and health outcomes (2004) concluded that "low reading skills and poor health are clearly related." Most healthcare materials are written at a 10th grade level or higher. However, 47-51% American adults have difficulty using print materials with precision and consistency (Kirsh et al., 1993). In a study conducted among low-income, community-dwelling older adults, the mean reading skill was found to be at the fifth grade level, and 25% of respondents reported difficulty understanding written information from clinicians (Weiss et al., 1992). Patients with low literacy skills and chronic diseases had less knowledge about their disease and its treatment and poorer self-management skills than those with higher literacy (Williams et al., 1998; Williams et al., 1998). For example, low literate asthma patients were less able to correctly use their metered-dose inhaler than more literate patients. Further, among patients participating in

standardized educational programs for diabetes or asthma, those with lower literacy had worse knowledge and self-management skills than patients with higher literacy levels. Among managed care enrollees, those with inadequate literacy were more likely to be hospitalized, even after controlling for differences in demographics and health status (Baker et al., 2002). Thus, care must be taken when designing and communicating self-management interventions for low literacy individuals with chronic disease. Notably, literacy is recognized as one of the nation's Healthy People 2010 objectives (US Department of Health and Human Services, 2000).

2.6 Literacy and racial/ethnic disparities: are we missing an important link?

Healthy People 2010 states that “Equitably distributed health communication resources and skills, and a robust communication infrastructure can contribute to the closing of the digital divide and the overarching goal of Healthy People 2010 to eliminate health disparities” (US Department of Health and Human Services, 2000). Literacy may be a vital yet ignored issue in understanding health disparities. A study by Bennett and colleagues (1998) was the first to demonstrate that after adjusting for literacy, race was not a statistically significant predictor of advanced stage of prostate cancer at presentation. A number of studies show that education or number of years of school completed was attenuated, and in some cases eliminated, after accounting for literacy (Williams et al., 1998; Williams et al., 1998; Howard, Sentell, and Gazmararian, 2006; Sentell & Halpin, 2006). This is not

surprising because the number of years of school completed represents *education attempted*, whereas literacy is a more valid indicator of *educational attainment* (i.e., what was actually learned during the years of schooling). In addition to being a more precise measure of educational attainment, literacy may be a marker of one's ability to obtain new information and accomplish complex tasks, and this may not be captured by years of schooling (Baker et al., 1998). In sum, literacy has been a more robust predictor of health status, health-related knowledge, and health-related behaviors than education and race (Williams et al., 1998; Williams et al.; Bennett et al., 1998).

Howard, Sentell, and Gazmararian (2006) found that literacy explained a small fraction of the differences in health status, and to a lesser degree, receipt of vaccinations that would normally be attributed to education or race if literacy was not considered. Sentell and Halpin (2006) showed that including literacy in predictive health status models removed the predictive power of both education and African American race by 32% to a point these variables were no longer significant predictors of health status. However, among adults >65 years of age, African-American race remained an important predictor of health status along with literacy, indicating in this sample that race and literacy independently affect health in the elderly (Sentell & Halpin, 2006). We can generally conclude that literacy is a better predictor of health than education, although in the case of race, literacy is a more equivalent statistical control for educational attainment. Beyond doubt there are other reasons beyond literacy imbalances that account for race-based health

inequities (Sentell & Halpin, 2006). Nevertheless, the inclusion of literacy reduces the explanatory power of fundamental variables in health disparities research, which should motivate researchers to include literacy as a key factor in health disparities research.

2.7 Do interventions improve health outcomes for low literacy patients?

Over the past few years, researchers have studied an array of interventions to improve the health of patients with low literacy. Some interventions have made simplified educational materials, in an effort to improve knowledge outcomes. Interventions of this type include brochures, videotapes, computerized tools, and oral presentations. It is important to measure whether an intervention had different effects in persons with low versus high literacy. Such information would help us to design and implement interventions which benefit low literacy individuals, thereby improving their outcomes. However, only 5 studies stratified the effect of the intervention by literacy status (Pignone et al., 2005). Davis and colleagues (1998) performed a controlled trial comparing the impact of an easy-to-read locally designed pamphlet with instructional graphics which they developed, with materials designed by the Centers for Disease Control. Both were written at or below a 6th grade level. The easy-to-read intervention pamphlet with instructional graphics was better understood by patients with reading levels below 9th grade but this was not insulting to others with higher levels of literacy. Only

2% of parents given the easy-to-read pamphlet; said they were insulted by the simplified message.

Similarly, Meade and colleagues (1994) found patients' knowledge of colon cancer increased 23% after reading a booklet written on a fifth-sixth grade reading level and 26% after seeing a videotape. These materials were effective because they targeted specific groups. Michielutte and colleagues (1992) found that poor readers' comprehension of information improved when they were given a pamphlet with illustrated materials rather than a bulleted text version. There were no differences in comprehension level among patients with higher literacy. However a randomized trial to improve knowledge of self-care for cancer fatigue symptoms showed greater self-care knowledge in the intervention group, but this was not related to literacy level (Wydra, 2001). Also, Murphy and colleagues (2000) compared patients watching an instructional videotape about sleep apnea and patients reading a newly designed brochure written at 12th grade level (which was similar to the grade level of the video script) and then responding to a written 11-item questionnaire. No net benefit on knowledge was observed for patients with low or high literacy. Based on patient literacy level, interventions to improve health knowledge have thus produced mixed results (Pignone et al., 2005).

However, an arthritis self-care intervention with 12 months follow up in a pretest-posttest study design had a positive impact despite different levels of formal education among the groups. Goepfinger and colleagues (1989) examined the effectiveness of the 'Bone up on Arthritis'. The intervention

model had a statistically significant positive impact on arthritis knowledge, self-care behavior, perceived helplessness, and pain. The booklets for the lessons were written at a sixth-grade reading level. Despite pretest differences in knowledge and pain among groups with different levels of formal education, both the direction and magnitude of changes over time were similar.

However, few studies have looked at interventions to moderate the impact of low literacy on intermediate markers, measures of disease incidence, or use of health services (Pignone et al., 2005).

2.8 Role of helplessness and exercise outcome expectation

Helplessness refers to an attributional style, explaining negative events and its consequences as uncontrollable, unpredictable, and unchangeable (Abramson, Seligman and Teasdale, 1978; Evers et al., 2001). Cross-sectional chronic pain studies showed that helplessness accounts considerably for the level of pain, disability, and depression (Keefe et al., 1990; Hill, 1993). Helplessness in some children with asthma promotes negative self-focus, which contributes to poor asthma management (Miller and Wood, 1997). Prospective studies of rheumatoid arthritis patients support the central role of helplessness as a predictor for level of pain, disability, and depression over time (Evers et al., 2001; DeVellis and Blalock, 1992; Smith et al., 1994). Callahan and colleagues (1996) showed that higher mortality in rheumatoid arthritis patients was associated with both higher helplessness

scores and lower levels of formal education. However, there are no published studies examining the relationship between low literacy and helplessness.

Social cognitive theory is useful for understanding health behavior because it combines two ideas: cognitive processes are central to behavior change and the idea that performance-based procedures are powerful factors in changing behavior (Bandura, 1977). Most of the research using Bandura's social cognitive model has emphasized the cognitive internal factors, self-efficacy and outcome expectations. Self-efficacy expectation is a central pervasive belief regarding one's capability to be able to exert control over one's own behavior. Outcome expectations are beliefs that benefits will follow particular behaviors (Bandura, 1991). The ultimate choices that people make about performing specific behaviors is strongly determined by beliefs about their ability to perform the behavior (self-efficacy), and by beliefs about the probable consequences of performing that behavior (outcome expectation) (Bandura, 1986). Hence, outcome expectations influence behavior by serving as incentives (positive outcomes) or disincentives (negative outcomes) (Bandura, 1977; Bandura, 1986; Bandura, 1997).

In older adults, both self-efficacy and outcome expectations are crucial to motivating exercise behavior. However, despite one's sense of self-efficacy for exercise (i.e., a belief that one is able to exercise), if an older adult does not believe exercise will improve health or function, it is unlikely that regular exercise will be practiced (Resnick, 2003). The literature has shown a consistently positive relationship between outcome expectations and related

behavior (Resnick et al., 2000; Brassington et al., 2002). Although, outcome expectations have received less attention than self-efficacy in the literature, there is strong support for the relationship between outcome expectations and physical activity (Conn, 1998; Jette et al., 1998; Resnick et al., 2001).

2.9 Unanswered questions to be addressed

Literacy has attracted much attention over the past 15 years, but important gaps in our knowledge persist. First, studies have generally focused on understanding the impact of literacy on health knowledge and behaviors rather than on health outcomes (Kalichman & Rompa, 2000; Kalichman et al., 2000; Williams et al., 1998; Williams et al., 1998). Most important, is the ultimate impact of literacy on measurable health outcomes. Second, most studies have been cross-sectional, which limit our ability to understand the causal pathway (including mediators) through which literacy influences health (DeWalt et al., 2004).

To date, there are only five longitudinal published studies that have examined whether interventions improve health outcomes (Rothman et al., 2004 a; Rothman et al., 2004 b; Weiss et al., 2006; DeWalt et al., 2006; Sisk et al., 2006). In one study, low literacy oriented medication management interventions were offered to type 2 diabetes patients with poor glycemic control. Glycosylated hemoglobin (HbA1c) values were collected prior to enrollment, and 6 months after enrollment. The diabetes program significantly improved HbA1c values independent of literacy level (Rothman et al., 2004

a). Rothman and colleagues (2004 b) showed that a diabetes disease management program that addresses literacy level may be particularly beneficial for patients with low literacy. A recent longitudinal randomized controlled trial with one-year follow up showed that depression severity was lower among participants receiving a targeted literacy training intervention in addition to standard treatment than depression severity among participants receiving only standard depression treatment (Weiss et al., 2006). A primary care-based heart failure self-management program designed for patients with low literacy reduced the risk of hospitalizations or death. This difference was larger for patients with low literacy than for those with higher literacy (DeWalt, 2006). The interventions in the above 4 studies were specifically designed to accommodate low literacy patients (Rothman et al., 2004; Rothman et al., 2004; Weiss et al., 2006; DeWalt et al., 2006).

Prospective cohort studies that measure changes in outcome over time will increase our understanding of the relationships between literacy and health outcomes (Literacy and health outcomes, 2004). The evidence report on “Literacy and Health Outcomes” (2004) found poor descriptions of interventions, and lacked information on how health outcomes were assessed and lack of use of appropriate statistical measures.

Literature in literacy in arthritis examining health outcomes is sparse. As mentioned earlier in the purpose of this dissertation, only one cross-sectional study of 127 patients in a UK tertiary referral center (Gordon et al., 2002) and one abstract by Pincus and colleagues (2000) have addressed the

level of literacy in arthritis patients and its impact on disease severity and function. The study conducted by Gordon and colleagues (2002) reported that low literacy compared to adequate literacy, led to more anxiety and hospital visits, but equal function. The abstract by Pincus and colleagues (2000) estimated literacy in 88 patients attending an academic rheumatology unit and reported that patients with low Rapid Estimate of Adult Literacy in Medicine (REALM) score had poor modified health assessment questionnaire (MHAQ), pain, and global status scores which indicated poorer status. No published studies in arthritis have examined whether an intervention can mitigate literacy related disparities in arthritis, and if so, which mediating factors will be critical in designing such interventions.

Chapter 3 Experimental Design and Methods

3.1 Conceptual Model

The conceptual model for this study illustrates the elements used to evaluate the following specific aims (Figure 3.1):

1. Evaluate the associations between literacy and arthritis outcomes, specifically (a) arthritis symptoms, and (b) self-reported functional status. The hypothesis underlying this specific aim is that literacy will have a positive association with arthritis outcomes as measured by functional status and symptoms.

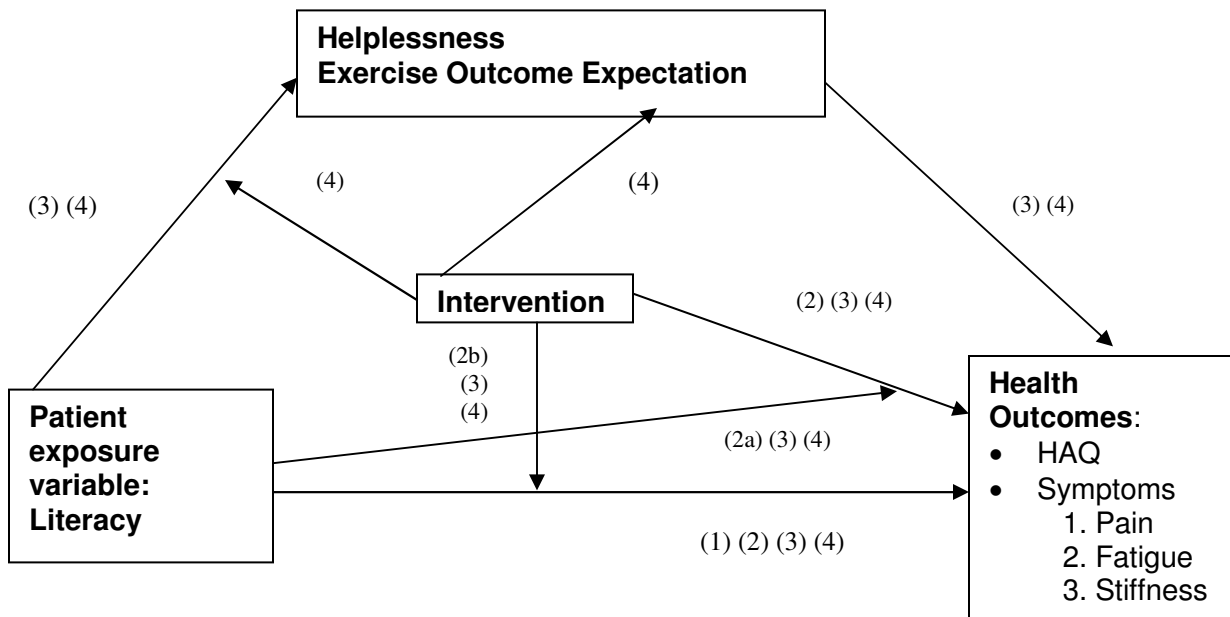
2. Determine whether (a) life style interventions have a differential short-term impact on arthritis outcomes for individuals with low and adequate literacy, and (b) literacy has a differential impact on arthritis outcomes for those exposed and those not exposed to the intervention. The hypotheses here are that: (a) the interventions will improve short-term arthritis outcomes differently for individuals with low and adequate literacy, and (b) For those who receive the intervention, literacy will have a weaker positive effect on the arthritis outcomes. Conversely, for those who do not receive intervention, literacy will have a stronger positive effect on arthritis outcomes.

3. Assess the impact of helplessness and exercise outcome expectation on the relationship between literacy and health outcomes, by mediation. The hypothesis is that helplessness and exercise outcome expectation mediate the effect of low literacy on health outcomes.

4. Assess the impact of helplessness and exercise outcome expectation as mediators on the relationship between the intervention and health outcomes. Also, to determine if literacy has differential impact on helplessness and exercise outcome expectation for those exposed to the intervention and those who are not exposed to the intervention. The hypotheses here are that: (i) helplessness and exercise outcome expectation mediate the effect of the intervention on health outcomes, and (ii) literacy affects helplessness and exercise outcome expectation differently for individuals exposed to and not exposed to life style interventions.

By using data from two randomized trials of life style interventions designed for sedentary adults with arthritis, the specific aims will examine these relationships using both cross-sectional and longitudinal analyses. The model controls for age, gender, race/ethnicity, BMI, marital status and co-morbid conditions. Literacy and education probably have bidirectional causal relationships (Wolf, Gazmararian, & Baker, 2005), and both may operate in the same causal pathway for arthritis outcomes. Therefore, models will be run with and without educational level to estimate the association.

Figure 3.1: Conceptual model for People with Arthritis Can Exercise (PACE) and Active Living Every Day (ALED)



Controlling for:

- Age
- Gender
- Race/Ethnicity
- Co morbid conditions (non-MSK conditions)

Note: The numbers in the parenthesis denote the paths involved in specific aims 1 to 4.

3.2 Overview and Study Design

This study was approved by the Medical Institutional Review Board at the University of North Carolina. All participants gave informed consent. To test the hypotheses in the Specific Aims (above), secondary analysis of two completed randomized controlled trials (RCT) of life style interventions was conducted. These two RCT’s were conducted by Callahan and colleagues and were designed to improve health outcomes for sedentary adults with

arthritis. People with Arthritis Can Exercise (PACE) evaluated an 8-week exercise program, and Active Living Every Day (ALED) evaluated a 20-week physical activity behavioral modification intervention. The PACE participants met twice a week, resulting in 16 sessions of an hour each, while the ALED participants met once a week, ensuing 20 hourly sessions. A schematic of the PACE and ALED study designs is illustrated in Figure 3.2. Although there are some differences in research design (Table 3.1) and measures (Table 3.2), the studies were sufficiently similar to allow us to combine the two data sets to test the hypotheses (Table 3.3). Continuous variables for the two studies PACE and ALED were compared by t tests, and the categorical variables were compared by chi square tests. Except for pain and fatigue, all other variables were not significantly different by study group. The comparison before and after sample attrition was not different by study group; hence the baseline characteristics of the two groups after sample attrition have been shown in Table 3.3. In PACE and ALED, both groups completed the first assessment at baseline and the 2nd assessment at the completion of the intervention which included in both studies' self-report questionnaires. Only the intervention group completed the self report questionnaires at follow up assessment at 6 months. Manuscript examining the primary trial results of PACE are published (Callahan et al. 2008), while that of ALED are in preparation. Detailed descriptions of PACE and ALED have been published (Schoster et al., 2005; Dunn et al., 1998).

Figure 3.2: Schematic of PACE and ALED study design

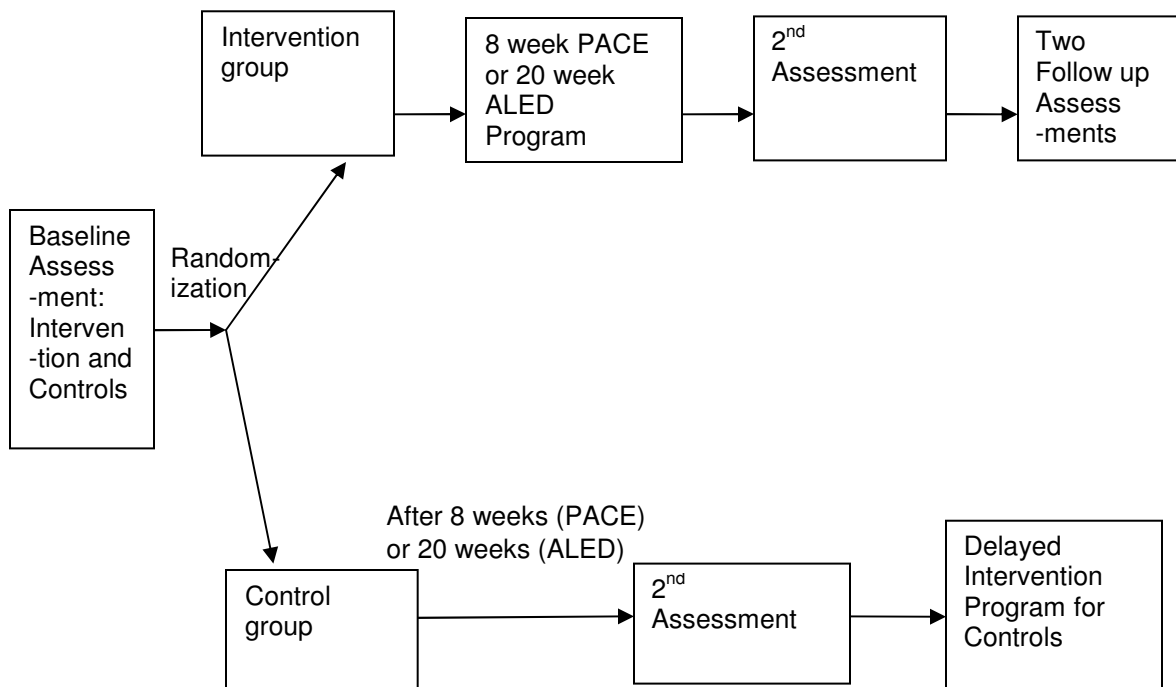


Table 3.1: PACE versus ALED- Research design

	PACE	ALED
Study Design	Randomized Controlled Trial	Randomized Controlled Trial
Number of subjects	347	339
Musculoskeletal condition	Arthritis or joint pain	Arthritis or joint pain
Community sites	18 urban and rural sites across North Carolina	17 urban and rural sites across North Carolina
Duration of intervention	8 weeks	20 weeks
1st assessment (Self report and functional)	Baseline	Baseline
2nd assessment (Self report and functional)	At end of intervention	At end of intervention
Follow up assessments	Self report assessments at 3 and 6-months after intervention	Self report assessments at 6 and 12-months after intervention
Follow up assessments	Only of intervention group	Only of intervention group
Goal	To evaluate effectiveness of exercise program (PACE) in changing arthritis related health outcomes of potential importance	To evaluate the effectiveness of cognitive and behavioral program (ALED) in changing arthritis related health outcomes of potential importance.

Table 3.2: PACE versus ALED- Measures

	PACE	ALED
Literacy	REALM	REALM
Functional Status (Self Report)	HAQ	HAQ
Pain	VAS	VAS
Stiffness	VAS	VAS
Fatigue	VAS	VAS
Helplessness	Helplessness subscale of RAI	Helplessness subscale of RAI
Outcomes expectations for exercise	OEE	OEE
Co-morbidity	MODEMS	MODEMS

REALM = Rapid Estimate of Adult Literacy in Medicine

HAQ = Health Assessment Questionnaire

VAS = Visual Analogue Score

RAI = Rheumatology Attitudes Index

OEE = Outcome expectation for exercise

MODEMS = Musculoskeletal Outcomes Data Evaluation and Management System

Table 3.3: PACE versus ALED- Baseline characteristics (after sample attrition)

	PACE	ALED
REALM	61.3	62.7
REALM < 9 th grade	43 (22.5%)	30 (15%)
Age (years)	69.6	68.0
Female	172 (90.1%)	168 (84%)
White	151 (79.1%)	159 (79.5%)
African American	34 (17.8%)	35 (17.5%)
Less than high school	22 (11.5%)	15 (7.5%)
Retired	104 (54.5%)	103 (51.5%)
Married	93 (48.7%)	117 (58.5%)
BMI	28.6	29.9
Co-morbidity	1.6	1.6
Intervention group	92 (48.2%)	104 (52%)
HAQ	1.1	0.95
Pain*	48.8	42.8
Fatigue*	46.9	39.6
Stiffness	43.6	45.9
Helplessness	2.4	2.5
Outcome expectation for exercise	4.0	4.0

* p< 0.05. There are 391 observations.

REALM = Rapid Estimate of Adult Literacy in Medicine

BMI = Body Mass Index

HAQ = Health Assessment Questionnaire

3.2.1 Research participants

Sedentary adults were recruited from 18 (PACE) and 17 (ALED) urban and rural areas across North Carolina, which included family practice offices, community centers, senior centers, health departments, healthcare systems, and fitness centers. Participants were also recruited from advertisements in local newspapers. Some of the reasons to not participate were: too active, change of mind, lack of transportation etc.; however participation rate was not estimated. In both PACE and ALED (N=700), participants were eligible if they: (1) reported moderate to severe limitation in joint motion and/or strength

resulting from arthritis or joint pain; (2) were currently exercising less than 3 times a week for less than 20 minutes; and (3) were mentally competent. No tests for detecting poor vision or cognitive impairment were performed.

3.2.2 Intervention

PACE evaluated the effectiveness of an 8-week exercise program and ALED studied a 20-week physical activity behavioral modification intervention. Both studies used similar approaches to encouraging behavioral change, although ALED was a non-exercise program. However, both studies were not exclusively designed for low literacy participants.

In the PACE program, participants were offered a basic level program, the group met for 1-hour sessions twice a week. Hence it was a 16-lesson course. The PACE program, designed by the National Arthritis Foundation, consists of gentle strengthening, balance, range-of-motion, and endurance exercises at a basic level appropriate for individuals with functional limitations, plus education in proper body mechanics, relaxation techniques, and behavioral strategies to build self-esteem.

The ALED program was developed jointly by the Cooper Institute, Brown University, and Human Kinetic for the general population (Dunn et al., 1998). The group met for 1-hour sessions once a week for 20 weeks, resulting in a 20-lesson course. ALED included small group sessions around the ALED textbook which reviews main points covered in the classes (E.g., setting goals, enlisting support, and managing time). The ALED textbook also

contains worksheets and assignments. Besides the textbook, participants received a pedometer to be used outside of class for motivation and monitoring of steps. Participants discussed ways to identify and overcome barriers to physical activity. The textbook provided to the participants in ALED was seventh grade. The information in the book was repeated by the instructors when the class met. Anecdotally, research personnel reported that higher socioeconomic status individuals complained that the material they read in the books was repetitive in the class. This way it was ensured that the low literacy individuals benefited from the intervention, even if they were unable to comprehend everything in the book.

In both programs, participants received considerable social support from other adults, and their instructors. The main factors that motivated the participants was the ability to work at their own pace, exercising “bit by bit”; and being able to share and derive support from other participants, as the entire group had arthritis related limitations. All this support and the behavioral strategies increased their confidence that they could do different kinds of exercise safely.

3.2.3 Procedures

Random assignment tickets were placed in a sealed envelope with colored paper to prevent any bias in the randomization process to intervention and control group (delayed intervention). Baseline and end of intervention assessments were conducted by self-report questionnaires and functional

tests in both studies. The intervention group took the course immediately and the control group started the course after completion of an assessment in eight weeks (PACE) or 20 weeks (ALED). In ALED, some participants from the intervention moved to the control group, citing disappointment that the intervention was not a physical exercise program. Hence, the final grouping in ALED was a modified intention to treat (MITT).

3.2.4 Instrumentation

Both groups completed the Rapid Estimate of Adult Literacy in Medicine (REALM) questionnaire.

Self-Report Questionnaire: Self-report questionnaire included demographics, health-related quality of life, functional status and co morbid conditions.

Demographic measures were age, race/ethnicity, marital status, educational level, gender, body mass index (BMI) and current work status. After demographic measures, information was taken on health-related quality of life, functional status and co morbid conditions, all described below in the measures section. Further, self report measures of helplessness (subscale of rheumatology attitude index) and outcome expectation for exercise was collected.

3.2.5 Measures

Table 3.2 summarizes the measures used in PACE and ALED. Although there are minor differences in some of the measures used in these

two studies, most measures central to the conceptual model and research goals were identical. Literacy was assessed with the Rapid Estimate of Adult Literacy in Medicine (REALM), a validated and widely-used measure of reading ability (Davis et al., 1993; Davis et al., 1998). This is a word recognition test, in which subjects read from a list of 66 routinely used lay medical items arranged in order of complexity and pronunciation difficulty. Most people with a normal level of literacy will complete the test in 2-3 minutes. It has high criterion validity, correlating 0.88 with the Wide Range Achievement Test-Revised, 0.97 with the Peabody Individual Achievement Test-Revised, and 0.84 with the Test of Functional Health Literacy in Adults (Davis et al., 1998).

REALM scores between 0 to 18 indicate a third-grade reading level or lower, 19 to 44 a fourth to sixth-grade reading level, 45 to 60 a seventh to eighth-grade level, and 61 to 66 indicate a high school reading level or above. However, in this study REALM will be dichotomized because of the small sample size of low literacy individuals (<9th grade vs. ≥9th grade; a common cut-point (Gordon et al., 2002)).

Primary dependent variables:

Tables 3.3 and 3.4 list the primary dependent variables: self-report functional status and arthritis symptoms (pain, stiffness, fatigue). The Health Assessment Questionnaire (HAQ) Disability Index, a well-validated measure of self-reported functional status (Fries et al., 1980); was used to measure

difficulty in performing activities of daily living and disease progression. It queries 20 specific functions, grouped into 8 categories: dressing, grooming, arising, eating, walking, personal hygiene, reaching and gripping. The HAQ is scored from 0 to 3, with 0 = no difficulty and 3 = unable to do (Ramey, Raynauld, and Fries, 1992; Wolfe, 2001; Fries et al., 1980). Performance based measures included timed chair stands, timed 360 degree turns, and walking speed at normal and fast paces (Steffen, Hacker, and Mollinger, 2002; Guralnik et al., 2000). However these outcomes could not be included as they had a large number of missing values at 2nd assessment. Hence data including missing values of performance based tests were deleted, and have not been described.

To assess arthritis symptoms, patients completed visual analog scales (VAS) for pain (Burckhardt and Jones, 2003), stiffness and fatigue (Wolfe, 2004). *Pain* experienced over the past week was assessed using a 100-millimeter (mm) VAS, with 0 indicating “No pain” and 100 indicating “Pain as bad as it could be.” A study of literate and low literate patients with rheumatoid arthritis showed high reliability of the VAS coefficient (Ferraz et al., 1990). *VAS fatigue* is a single item scale. It measures severity of fatigue over the past week with the single question: “How much of a problem has fatigue or tiredness been for you in the past one week?” (Wolfe, 2004) Fatigue was assessed using a 100-millimeter (mm) VAS anchored with “No fatigue” and “Fatigue as bad as it could be.” A similar method was used to assess stiffness.

Table 3.4: Description of dependent variables for specific aim 1a

Variable	Description	Type	Notes
Baseline Health Assessment Questionnaire (HAQ)	Ability to do everyday activities (low=no problem; high=unable) measured at baseline	Continuous	This variable will be an independent variable for specific aim 1b, 2, 3, and 4(i); for the dependent variable final HAQ
Baseline pain	Pain experienced over the past week measured in millimeter (0-100) by Visual Analogue Scale (VAS) at baseline	Continuous	This variable will be an independent variable for specific aim 1b, 2, 3, and 4(i); for the dependent variable final pain
Baseline fatigue	Fatigue experienced over the past week measured in millimeter (0-100) by VAS at baseline	Continuous	This variable will be an independent variable for specific aim 1b, 2, 3, and 4(i); for the dependent variable final fatigue
Baseline stiffness	Fatigue experienced over the past week measured in millimeter (0-100) by VAS at baseline	Continuous	This variable will be an independent variable for specific aim 1b, 2, 3, and 4(i); for the dependent variable final stiffness

Table 3.5: Description of dependent variables for specific aim1b, 2, 3 and 4(i)

Variable	Description	Type
Final HAQ	Ability to do everyday activities (low=no problem; high=unable) measured at end of intervention	Continuous
Final Pain	Pain experienced over the past week measured in millimeter (0-100) by VAS at end of intervention	Continuous
Final Fatigue	Fatigue experienced over the past week measured in millimeter (0-100) by VAS at end of intervention	Continuous
Final Stiffness	Fatigue experienced over the past week measured in millimeter (0-100) by VAS at end of intervention	Continuous

HAQ = Health Assessment Questionnaire
VAS = Visual Analogue Score

Mediating variables

Two variables are hypothesized to mediate the relationship between literacy and health outcomes: helplessness, and outcome expectations for exercise (Table 3.5). *Helplessness* was measured using the five-item subscale of Rheumatology Attitudes Index (RAI) (Brady, 2003; Callahan, Brooks, and Pincus, 1988; DeVellis, and Callahan, 1993) (e.g., “Arthritis is controlling my life.”) Responses are measured using a 5-point Likert scale, with 1= strongly disagree to 5= strongly agree. Total score is a summation of all items. Internal consistency is 0.67-0.70. There is a correlation of 0.79 between full RAI and RAI helplessness scale (Brady, 2003).

Outcome expectations for exercise consist of nine items with five-point Likert response that focuses on perceived consequences of exercise for older adults. The scale was scored by summing the numerical ratings for each

response and dividing by the number of responses, yielding a range from one to five points. One item, “exercise gives me a sense of personal accomplishment” was inadvertently omitted from the scale employed in the studies. One indicates low outcome expectation for exercise and 5 is an indication for strong outcome expectations for exercise. There is sufficient evidence for internal consistency of the OEE scale with an alpha coefficient of 0.89-0.93. The test-retest reliability measured at 2-week interval is 0.76 (Resnick, 2001). There is evidence for criterion and construct validity, which is supported by significant associations with exercise behavior and self-efficacy (Resnick et al., 2001).

Table 3.6: Description of independent and other study variables

Variable	Description/Categories	Type
Primary independent variable		
REALM	Rapid Estimate of Adult Literacy in Medicine measured at baseline: Low literacy < 9 th grade Adequate literacy ≥ 9 th grade	Dichotomous
Other explanatory/control variables		
Age	Age in years calculated by date of birth (34 -95)	Continuous
Sex		Dichotomous
Race	White, African American, Other Race	Dummy variables
Highest degree or level of school	Less than high school, high school, some college, college degree	Dummy variables
Current work	Working, homemaker, disabled, retired, other	Dummy variables
Marital status	Married/living with significant other, separated/divorced, widowed, single	Dummy variables
Body mass index (BMI)	BMI calculated as (weight*0.454)/(height in feet*12+height in inches)/39.37)^2	Dummy variables
Co-morbid	Normal weight, overweight, obese Other non-arthritis conditions scored as a count of other conditions	Count
Intervention	Intervention group or control group	Dummy variable
Mediating variables		
Helplessness	Feeling of helplessness (high=helpless)	Continuous
Outcome expectation of exercise	Expected benefits of exercise (high =strong belief)	Continuous

Demographic measures

Several demographic variables are utilized as controls and include age (computed by date of birth), race, marital status, educational level, gender, current employment status and body mass index (BMI) in both studies (Table 3.5). BMI was measured in kg/m² and was computed by height and weight information obtained during the study. Modification of the American Academy of Orthopedic Surgeons (AAOS) Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS) co-morbidity list was used to assess

the chronic conditions (Evaluating Outcomes of Total Hip & Total Knee Replacements). Co-morbidity scores range from 0 to 11, which is a non-weighted count of such non-musculoskeletal conditions as heart disease, lung disease, hypertension, kidney disease, ulcer/stomach disease, stroke or mini-stroke, diabetes, and cancer.

3.3 Human subjects review

The research projects from which these data come were originally submitted and approved by the Institutional Review Board (IRB) at the University of North Carolina, School of Medicine and East Carolina University in 2002 and 2003. The secondary analysis research project was submitted and approved by the IRB at the School of Public Health, University of North Carolina in 2006.

3.4 Data analysis

The specific aims will involve control and intervention groups at baseline, and at intervention completion, specifically:

- To evaluate the association between literacy and arthritis symptoms and self-reported functional status (Specific Aim 1), cross-sectional studies will be conducted using the baseline data and a longitudinal study using the intervention completion data.
- To determine if life style interventions have a different short-term impact on arthritis outcomes for low and adequate literacy adults and to

determine whether literacy has a different impact on arthritis outcomes for those exposed and those not exposed to the intervention (Specific Aim 2); differences between control and intervention groups will be examined (both overall and for individuals with low and adequate literacy) using data gathered at baseline and at intervention completion.

- To assess the impact of mediators (helplessness and exercise outcome expectation) on the relationship between literacy and health outcomes (Specific Aim 3), data collected at baseline and at intervention completion will be used.
- To assess the impact of mediators (helplessness and exercise outcome expectation) on the relationship between intervention and health outcomes and to determine if literacy has differential impact on mediators (helplessness and exercise outcome expectation) for those exposed to the intervention and those who are not exposed to the intervention (Specific Aim 4), data collected at baseline and at intervention completion will be used.

The **overall goal of data analysis** is to examine if life style interventions, especially in individuals with low literacy and arthritis, will result in better health outcomes and to study the contribution of factors which will mitigate the impact of low literacy on health outcomes of individuals with arthritis. After appending the two datasets, examining the distribution of the variables, and addressing any missing values, the analyses were conducted consistent with the specific aims:

Aim 1 involves cross-sectional (1a) and longitudinal (1b) analyses of the appended data to identify associations between literacy and arthritis outcomes in this sedentary population. The literacy variable, REALM, will be dichotomized (<9th grade vs. ≥9th grade; a common cut-point (Gordon et al., 2002; Davis et al., 1993)), and will serve as the primary independent variable in the linear regression models. Models will be run with each primary dependent variable (HAQ and arthritis symptoms) at baseline and at intervention completion. Linear regression models in the 4 specific aims will be controlled for age, gender, race, BMI, marital status, current work status and co-morbid conditions. Literacy and education probably have bidirectional causal relationships (Wolf, Gazmararian, & Baker, 2005), and both may operate in the same causal pathway for arthritis outcomes. Therefore, models will be run with and without educational level to estimate the association.

The linear regression models for this aim are:

Aim 1a

$$\text{Arthritis Health Status at baseline}^*, \text{bHAQ} = \beta_0 + \beta_1 \text{literacy} + \beta_2 \text{age} + \beta_3 \text{gender} + \beta_4 \text{race} + \beta_5 \text{BMI} + \beta_6 \text{work_status} + \beta_7 \text{marital_status} + \beta_8 \text{education} + \beta_9 \text{comorbid}$$

Aim 1b

$$\text{Arthritis Outcome, fHAQ} = \beta_0 + \beta_1 \text{bHAQ} + \beta_2 \text{literacy} + \beta_3 \text{age} + \beta_4 \text{gender} + \beta_5 \text{race} + \beta_6 \text{BMI} + \beta_7 \text{work_status} + \beta_8 \text{marital_status} + \beta_9 \text{education} + \beta_{10} \text{comorbid}$$

The description of the variables in the above equation is given in Table 3.7.

Table 3.7: Description of variables

Variable Name	Measurement/Description
Literacy (primary independent variable)	Dichotomized <9 th grade vs. ≥ 9 th grade
bHAQ	Baseline HAQ
fHAQ	Final HAQ
Intervention	Dichotomized as control vs. intervention

HAQ = Health Assessment Questionnaire

*Arthritis health status variables are measured at baseline: HAQ and arthritis symptoms of pain, fatigue and stiffness. Linear regression models will be run on each baseline arthritis health status variable.

Then models will be run on each final arthritis outcome as in the case of HAQ, now the dependent variable, with the respective baseline health status (bHAQ) in the equation for adjustment.

For **Aim 2**, adjusted linear regression models will be run for each primary dependent variable measured at intervention completion after adjusting for its baseline value. The intervention variable, dichotomized as control vs. intervention, will be an independent variable along with the literacy variable. These models will include literacy*intervention interactions if literacy or intervention or both are found to have significant effects. The model for this aim is:

$$\underline{\text{Arthritis Outcome}^*}, \text{fHAQ} = \beta_0 + \beta_1 \text{bHAQ} + \beta_2 \text{literacy} + \beta_3 \text{intervention} + \beta_4 \text{literacy} * \text{intervention}^\dagger + \beta_5 \text{gender} + \beta_6 \text{race} + \beta_7 \text{age} + \beta_8 \text{work_status} + \beta_9 \text{marital_status} + \beta_{10} \text{education} + \beta_{11} \text{BMI} + \beta_{12} \text{comorbid}$$

The description of the variables in the above equation is given in Table 3.7.

*Models will be run on each arthritis outcome as in the case of HAQ, with the final outcome being the dependent variable, and the respective baseline health status in the equation for adjustment.

† The interaction term **literacy*intervention** will be included if literacy or intervention or both have significant effects.

To achieve **Aim 3**, a linear regression model (I) will be estimated where *helplessness* is the dependent variable and literacy is the independent variable. Then a linear regression model (II) will be estimated where *helplessness* and literacy are independent variables, and arthritis outcome is the dependent variable. The intervention and literacy*intervention interaction (given that either one or both have significant effects) will also be included in the regression. As in Aim 2, adjusted models with each primary dependent variable measured at end of intervention will be run after adjusting for its baseline value.

Similarly, two linear regression models (III and IV) will be estimated with *exercise outcome expectation*. This will help us to assess the extent to which mediating factors, helplessness and outcome expectation mitigate the relationship between literacy and each arthritis outcome. The equations for Aim 3 are:

- I. **Helplessness** = $\beta_0 + \beta_1 \text{literacy} + \beta_2 \text{gender} + \beta_3 \text{race} + \beta_4 \text{age} + \beta_5 \text{work_status} + \beta_6 \text{marital_status} + \beta_7 \text{education} + \beta_8 \text{BMI} + \beta_9 \text{comorbid}$

- II. **Arthritis Outcome***, **fHAQ** = $\beta_0 + \beta_1 \text{bHAQ} + \beta_2 \text{literacy} + \beta_3 \text{intervention} + \beta_4 \text{literacy} * \text{intervention} + \beta_5 \text{helplessness} + \beta_6 \text{gender} + \beta_7 \text{race} + \beta_8 \text{age} + \beta_9 \text{work_status} + \beta_{10} \text{marital_status} + \beta_{11} \text{education} + \beta_{12} \text{BMI} + \beta_{13} \text{comorbid}$

- III. **Exercise Outcome Expectation** = $\beta_0 + \beta_1 \text{literacy} + \beta_2 \text{gender} + \beta_3 \text{race} + \beta_4 \text{age} + \beta_5 \text{work_status} + \beta_6 \text{marital_status} + \beta_7 \text{education} + \beta_8 \text{BMI} + \beta_9 \text{comorbid}$

- IV. **Arthritis Outcome***, **fHAQ** = $\beta_0 + \beta_1 \text{bHAQ} + \beta_2 \text{literacy} + \beta_3 \text{intervention} + \beta_4 \text{literacy} * \text{intervention} + \beta_5 \text{exercise_outcome_expectation} + \beta_6 \text{gender} + \beta_7 \text{race} + \beta_8 \text{age} + \beta_9 \text{work_status} + \beta_{10} \text{marital_status} + \beta_{11} \text{education} + \beta_{12} \text{BMI} + \beta_{13} \text{comorbid}$

The description of the variables in the above equation is given in Table 3.7.

*Models will be run on each arthritis outcome as in the case of HAQ, with the final outcome being the dependent variable, and the respective baseline health status variable in the equation for adjustment.

† The interaction term **literacy*intervention** will be included if literacy or intervention or both have significant effects.

For **Aim 4(i)**, a linear regression model (V) will be estimated where *helplessness* is the dependent variable and the intervention is the independent variable. Then a linear regression model (VI) will be estimated

where *helplessness* and the intervention are independent variables, and arthritis outcome is the dependent variable. As in Aim 2, adjusted models with each primary dependent variable measured at end of the intervention will be run after adjusting for its baseline value.

Similarly, two linear regression models (VII and VIII) will be computed with *exercise outcome expectation*. This will help to assess the extent to which mediating factors, helplessness and outcome expectation, affect the relationship between intervention and each arthritis outcome. The equations for aim 4(i) are:

$$\text{V. } \underline{\text{Helplessness}} = \beta_0 + \beta_1 \text{literacy} + \beta_2 \text{intervention} + \beta_3 \text{gender} + \beta_4 \text{race} + \beta_5 \text{age} + \beta_6 \text{work_status} + \beta_7 \text{marital_status} + \beta_8 \text{education} + \beta_9 \text{BMI} + \beta_{10} \text{comorbid}$$

$$\text{VI. } \underline{\text{Arthritis Outcome}^*}, \text{fHAQ} = \beta_0 + \beta_1 \text{bHAQ} + \beta_2 \text{literacy} + \beta_3 \text{intervention} + \beta_4 \text{literacy}^* \text{intervention} + \beta_5 \text{helplessness} + \beta_6 \text{gender} + \beta_7 \text{race} + \beta_8 \text{age} + \beta_9 \text{work_status} + \beta_{10} \text{marital_status} + \beta_{11} \text{education} + \beta_{12} \text{BMI} + \beta_{13} \text{comorbid}$$

(Same as equation II)

$$\text{VII. } \underline{\text{Exercise Outcome Expectation}} = \beta_0 + \beta_1 \text{literacy} + \beta_2 \text{intervention} + \beta_3 \text{gender} + \beta_4 \text{race} + \beta_5 \text{age} + \beta_6 \text{work_status} + \beta_7 \text{marital_status} + \beta_8 \text{education} + \beta_9 \text{BMI} + \beta_{10} \text{comorbid}$$

$$\text{VIII. } \underline{\text{Arthritis Outcome}^*}, \text{fHAQ} = \beta_0 + \beta_1 \text{bHAQ} + \beta_2 \text{literacy} + \beta_3 \text{intervention} + \beta_4 \text{literacy}^* \text{intervention} + \beta_5 \text{exercise_outcome_expectation} + \beta_6 \text{gender} + \beta_7 \text{race} + \beta_8 \text{age} +$$

$$\beta_9 \text{work_status} + \beta_{10} \text{marital_status} + \beta_{11} \text{education} + \beta_{12} \text{BMI} + \beta_{13} \text{comorbid}$$

(Same as equation IV)

The description of the variables in the above equation is given in Table 3.7.

*Models will be run on each arthritis outcome as in the case of HAQ, with the final outcome being the dependent variable, and the respective baseline health status variable in the equation for adjustment.

† The interaction term **literacy*intervention** will be included if literacy or intervention or both have significant effects.

For **Aim 4(ii)**, a linear regression model (IX and X) will be estimated for each dependent variable, helplessness and exercise outcome expectation. The intervention variable, dichotomized as control vs. intervention, will be an independent variable along with the literacy variable. These models will include literacy*intervention interactions (provided either literacy or intervention or both have significant coefficients) to determine if significant coefficients can be obtained for the interaction terms. The models for this aim are:

$$\text{IX. } \underline{\text{Helplessness}} = \beta_0 + \beta_1 \text{literacy} + \beta_2 \text{intervention} + \beta_3 \text{literacy*intervention} + \beta_4 \text{gender} + \beta_5 \text{race} + \beta_6 \text{age} + \beta_7 \text{work_status} + \beta_8 \text{marital_status} + \beta_9 \text{education} + \beta_{10} \text{BMI} + \beta_{11} \text{comorbid}$$

$$\begin{aligned}
 \text{X. } \underline{\text{Exercise Outcome Expectation}} &= \beta_0 + \beta_1 \text{literacy} + \beta_2 \text{intervention} \\
 &+ \beta_3 \text{literacy} * \text{intervention} + \beta_4 \text{gender} + \beta_5 \text{race} + \beta_6 \text{age} + \\
 &\beta_7 \text{work_status} + \beta_8 \text{marital_status} + \beta_9 \text{education} + \beta_{10} \text{BMI} + \\
 &\beta_{11} \text{comorbid}
 \end{aligned}$$

The description of the variables in the above equation is given in Table 3.7.

† The interaction term **literacy*intervention** will be included if literacy or intervention or both have significant effects. All analyses were done using STATA Statistical Software for Personal Computer version 9.

3.5 Sample Attrition

Once the two datasets of ALED and PACE were appended, the total sample size was 700 (PACE, n= 346; ALED, n=354). Out of the participants assigned to intervention or control, 564 were truly randomized, 94 were in a group because of a friend, and 34 were self-selected. The actual groups formed as intervention and control (delayed intervention) had equal distributions from each of the categories: true, with friend, and self-selected. Eight values had to be deleted because of unidentified grouping in randomization, and unequal distribution in the actual group attended resulting in a sample size of 692. Table 3.8 shows the distribution of participants after deletion, based on randomization and the actual group which participated in the intervention and control group (delayed intervention).

Next missing values for the dependent, independent, and mediating variables were identified. The functional performance tests (one of the arthritis

health outcomes) had more than one third of their values missing at final assessment. For the functional performance tests, the participants had to show up at a scheduled slot of time (only one option was available for four hours). The various reasons why people could not show up were: worsening of symptoms, bad weather, lack of transport, change of mind, out of town, assessments close to holidays or vacation, elderly going to summer homes etc. The other final dependent variables, HAQ, pain, fatigue and stiffness, were assessed by mail, hence did not have large missing values. Around 17% of the data had missing values for REALM, the primary independent variable of interest. Multiple imputation for REALM was considered as a possibility to maintain the sample size, however it was not beneficial since everyone who had a missing value for REALM also had a missing value for the final functional performance tests. Hence, list-wise deletion was the option chosen.

For cross-sectional analysis

HAQ was moderately correlated with each individual functional performance test (Range: 0.37-0.46, $p < 0.01$). To preserve the sample size, we decided not to include functional performance tests as dependent variables in our analysis. Next 121 missing values of REALM, the primary independent variable were dropped, resulting in a sample size of 571.

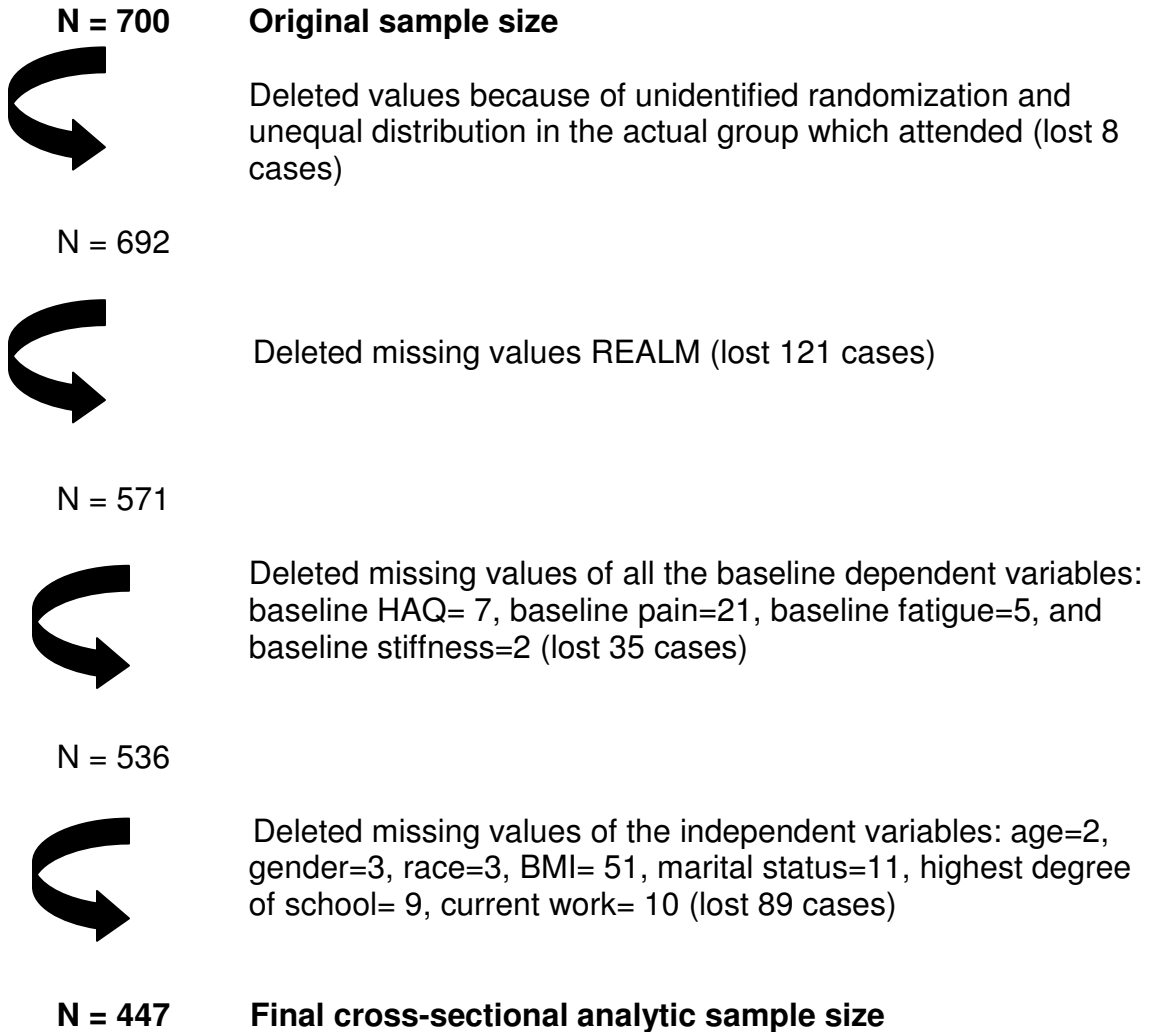
All the missing values of the baseline dependent variables (HAQ, pain, fatigue and stiffness) and the independent variable were identified and

dropped (Figure 3.2) and the final sample size for the cross sectional analysis was 447.

Table 3.8: Distribution of participants based on randomization and the actual group attended (n=692)

Actual Group attended (%)	Randomization (%)			Total
	True	With friend	Self-selected	
Control	311 (55.14%)	47 (50%)	18 (52.94%)	376 (54.34%)
Intervention	253 (44.86%)	47 (50%)	16 (47.06%)	316 (45.66%)
Total	564 (100%)	94 (100%)	34 (100%)	692 (100%)

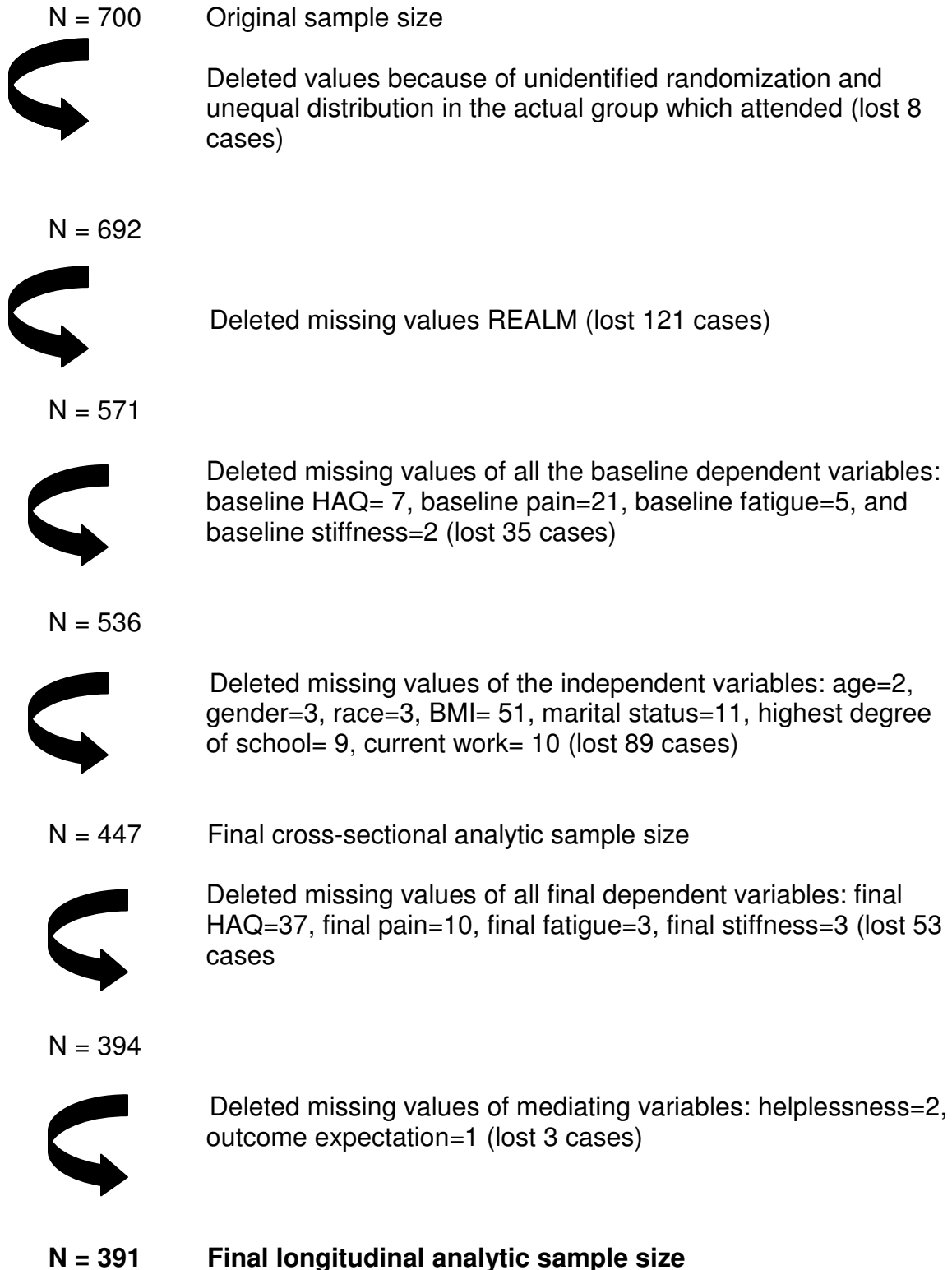
Figure 3.3: Sample attrition for cross sectional analysis



For longitudinal analysis

Starting with the sample size of 447 from the cross-sectional analysis, the missing values of final dependent variables were deleted (final HAQ, final pain, final fatigue and final stiffness). Since the missing values of independent variables were already addressed, the missing mediating variables were dropped resulting in a final sample size of 391 for the longitudinal analysis (Figure 3.3).

Figure 3.4: Sample attrition for longitudinal analysis



3.6 Statistical power

In the fixed sample of 391 participants after sample attrition, there were 196 individuals in the intervention group, and 195 individuals in the control group at baseline. We first confirmed an adequate sample size to detect important differences in HAQ scores between the control and intervention groups. In randomized controlled trials, an average change in HAQ scores of 0.24 corresponds with clinically detectable improvement (Kosinski et al, 2000). Given the number of participants in the intervention and control groups, there will be more than 90% power available to detect a difference of 0.24, based on a 0.05 significance level and an observed standard deviation of 0.64 in the HAQ data. In addition to the HAQ calculations, power was estimated for the pain score for which a difference of 30% is considered to be clinically meaningful. Here, a mean intervention difference of 10 was used, based on previous clinical trials (Bolnot-Delmas et al, 1996; Peloso et al, 2000). A 10-point difference in treatment represents a difference of 38% (McQuay, Barden, and Moore, 2003). The pain variable was scored on a 0-100 scale in both studies. There will be more than 90% power available to detect a mean intervention difference of 10 in the VAS score from baseline between the control and intervention group, based on a 0.05 significance level and an observed standard deviation of 26 in the pain VAS data. Power calculations of fatigue and stiffness were not undertaken due to inadequate literature on average changes in their VAS scores.

Besides doing the power calculation for the original study which was adequate, power calculation was attempted for each aim. In a fixed sample of 391 participants after sample attrition, there were 318 adequate literacy individuals and 73 low literacy individuals. To ensure that the sample size was adequate for Aim 1, power calculations of HAQ and VAS pain score were undertaken. In randomized controlled trials, an average change in HAQ scores of 0.24 corresponds with clinically detectable improvement (Kosinski et al, 2000). Given the number of participants in the low literacy and adequate literacy groups, there will be 81% power available to detect a difference of 0.24, based on a 0.05 significance level and an observed standard deviation of 0.64 in the HAQ data. For the VAS pain score a mean intervention difference of 10 was used, based on previous clinical trials (Bolnot-Delmas et al, 1996; Peloso et al, 2000) as mentioned above. There will be 84% power available to detect a mean difference of 10 in the VAS pain score from baseline between the low literacy and adequate literacy group, based on a 0.05 significance level and an observed standard deviation of 26 in the VAS pain data. As for the original study, power calculations of fatigue and stiffness were not undertaken due to inadequate literature on average changes in their VAS scores.

Power calculations were conducted for aim 2, after establishing adequate power for aim 1. As mentioned above, the meaningful effect size for HAQ is 0.24. The standard error of 0.10 of the interaction term literacy*intervention was estimated from the regression analysis of aim 2 for

HAQ. The degrees of freedom were estimated as 369. From this data, power was calculated as 76% based on a 0.05 significance level. Similarly, power was calculated for pain. As stated above, the meaningful effect size for pain is 10. The standard error of 6.2 of the interaction term literacy*intervention was estimated from the regression analysis of aim 2 for pain. The degrees of freedom estimated were 369. From this data, power was calculated as 48% based on a 0.05 significance level. Again, power calculations of fatigue and stiffness were not undertaken due to unavailable meaningful effect size. Power calculations were adequate for HAQ, but not for pain.

For aim 3 and 4 it was difficult to obtain values of meaningful effect size for helplessness and exercise outcome expectation. Further it is difficult to estimate standard errors of mediating variables. Hence power calculation was intractable for aims 3 and 4.

Chapter 4 Results

4.1 Descriptive statistics for cross-sectional model

This sample was only used for Aim 1a. As shown in Figure 3.3, a total of 700 participants were enrolled in the 2 RCTs. After sample attrition, 447 participants were available for cross-sectional analysis. As shown in Table 4.1, the mean age of the sample was 69 years (range 42-90) and 386 (86%) were female, 357 (80%) Caucasian, and 76 (17%) African American (AA). A total of 323 (72%) were either overweight or obese, and participants had a mean (SD) of 1.5 (1.3) non-musculoskeletal co-morbid conditions. Fifty (11%) participants had less than high school education. Two hundred and thirty two adults (52%) were retired and 236 (53%) were married. The population had a mean (SD) HAQ of 0.99 (0.64), mean (SD) pain of 45 (27), mean (SD) fatigue of 43 (30), and mean (SD) stiffness of 45 (27) at baseline. (Table 4.1)

Of all patients, 89 (20%) had low literacy, as seen in Table 4.2. Of the patients with adequate literacy (>8th grade), 16 (5%) had not completed high school. Conversely, of the patients with low literacy, 55 (62%) had completed high school or above. Furthermore, 24 (27%) patients with low literacy had some college, associate, bachelors or even postgraduate degree (Table 4.2). More males (25%) than females (19%) had low literacy levels ($p=0.33$). Significantly more African Americans (54%) than Caucasians (12%) had low literacy levels ($p<0.001$).

Table 4.1: Cross-sectional sample characteristics (N=447)

	N	%
Race		
Caucasian	357	80%
African American	76	17%
Gender		
Female	386	86%
Body Mass Index		
Overweight	152	34%
Obese	171	38%
Education		
Less than high school	50	11%
Literacy		
REALM < 9 th grade	89	20%
Work status		
Retired	232	52%
Marital status		
Married	236	53%
	Mean	SD
Age (42-90)	69	10
Number of co-morbid conditions (0-7)	1.5	1.3
Functional Disability		
HAQ (0-2.75)	0.99	0.64
Arthritis symptoms (mm on VAS)		
Pain (0-100)	45	27
Fatigue (0-100)	43	30
Stiffness (0-100)	45	27
REALM = Rapid Estimate of Adult Literacy in Medicine		
HAQ = Health Assessment Questionnaire		
VAS= Visual Analogue Score		

Table 4.2: Relationship of educational status with literacy in the cross-sectional sample (N=447)

Educational status	Low literacy	Adequate literacy	Total
Less than high school	34 (38%)	16 (5%)	50 (11%)
High school	31 (35%)	91 (25%)	122 (27%)
Some college (including associate)	19 (21%)	133 (37%)	152 (34%)
College degree (including bachelors and postgraduate)	5 (6%)	118 (33%)	123 (28%)
Total	89 (100%)	358 (100%)	447 (100%)

N (%).

4.2 Cross-sectional model

The cross-sectional model was used for the first specific aim (Aim 1a), which was to evaluate the associations between literacy and arthritis health status at baseline. Bivariate and multivariate models were estimated.

4.2.1 Bivariate analysis

Individuals with low literacy did not have significantly worse disability (HAQ) or arthritis symptoms than individuals with adequate literacy in the bivariate analysis. However, there were other bivariate associations which were significant (Table 4.3).

Baseline HAQ

Bivariate analysis showed that males had less functional disability than females ($p=0.005$), the obese had more functional disability than normal weight individuals ($p<0.001$), and the disabled had more functional disability compared to retired participants ($p<0.001$). Increase in one non-musculoskeletal condition was associated with 0.17 unit (95% CI= 0.12 - 0.21) increase in HAQ.

Baseline pain

Bivariate analysis showed that one year increase in age, was associated with a 0.35 unit (95% CI = -.58 to -.12) lower pain. Obese individuals had 7.1 units (95% CI= .93 - 13) increase in pain compared to normal weight individuals. Individuals who had college degree had 11 units (95% CI= -20 to -2.2) decrease in pain compared to individuals with less than

high school education. Disabled individuals had 16 units (95% CI= 9.4 - 22) more pain than retired individuals. Increase in one non-musculoskeletal condition was associated with 3.5 units (95% CI= 1.5 - 5.4) more pain.

Baseline fatigue

One year increase in age was associated with a 0.4 unit (95% CI= -0.66 to -0.14) decrease in fatigue. Also males had 9.2 units (95% CI = -17 to -0.96) less fatigue than females. Obese individuals had 7.4 units (95% CI =0.41 - 14) more fatigue than normal weight individuals. Disabled individuals compared to retired individuals had 23 units (95% CI= 16 - 30) more fatigue. Increase in one non-musculoskeletal condition was associated with 5.5 units (95% CI =3.3 - 7.7) more fatigue.

Baseline stiffness

Similarly for stiffness, as age increases by one year baseline stiffness decreases by 0.38 unit (95% CI = -0.61 to -0.16). Being obese was associated with 8.8 units (95% CI = 2.7 - 15) more stiffness compared to a normal weight individual. Furthermore, a disabled person has 13 units (95% CI = 6.9 - 20) increase in stiffness than a retired individual. Increase in one co-morbid condition was associated with 4 units (95% CI = 2.1 - 6.0) more stiffness.

Summary

My hypothesis involving the bivariate cross-sectional analysis of Aim 1a, that literacy will have a positive association with baseline arthritis health status, was not supported.

Table 4.3: Cross sectional analysis of the arthritis health status variables (N=447)

Explanatory variables	Dependent variables							
	HAQ (0-2.75)		PAIN (0-100 mm on VAS)		FATIGUE (0-100 mm on VAS)		STIFFNESS (0-100 mm on VAS)	
	Bivariate	Aim 1a (Multivariate)	Bivariate	Aim 1a (Multivariate)	Bivariate	Aim 1a (Multivariate)	Bivariate	Aim 1a (Multivariate)
Low literacy	-.04 (.08)	-.06 (.08)	3.38 (3.17)	1.47 (3.85)	2.29 (3.61)	6.61 (4.23)	1.14 (3.15)	-1.20 (3.82)
Age	-.00 (.00)	.01 (.00)	-.35** (.12)	-.14 (.17)	-.40** (.13)	-.15 (.19)	-.38** (.12)	-.15 (.17)
Male	-.24** (.08)	-.22* (.09)	-2.36 (3.69)	-.15 (3.91)	-9.17* (4.17)	-8.62* (4.30)	-2.78 (3.67)	-.46 (3.88)
Race								
Black	.01 (.08)	-.03 (.09)	2.72 (3.38)	-.09 (3.91)	-4.49 (3.85)	-9.46* (4.30)	4.81 (3.36)	3.17 (3.88)
Other Race	.03 (.17)	.07 (.16)	-3.12 (7.30)	-4.02 (7.45)	-1.72 (8.29)	-4.80 (8.20)	6.58 (7.23)	6.27 (7.40)
White (R)								
BMI								
Overweight	.08 (.08)	.04 (.07)	-.52 (3.22)	-3.10 (3.25)	.84 (3.67)	-1.58 (3.57)	.88 (3.19)	-1.50 (3.22)
Obese	.26** (.07)	.12 (.08)	7.10* (3.13)	.83 (3.52)	7.44* (3.57)	.83 (3.88)	8.76** (3.11)	1.83 (3.50)
Normal weight (R)								
Education								
High school	-.13 (.11)	-.04 (.10)	-6.49 (4.47)	-2.70 (4.77)	-4.73 (5.11)	-.10 (5.25)	-4.70 (4.46)	-1.75 (4.74)
Some college	-.00 (.10)	.06 (.11)	-4.09 (4.34)	-1.28 (4.81)	-.05 (4.96)	3.81 (5.29)	-1.09 (4.33)	.39 (4.78)
College degree	-.17 (.11)	-.03 (.11)	-11.01* (4.46)	-6.11 (5.15)	-5.63 (5.10)	2.69 (5.67)	-7.30 (4.45)	-4.66 (5.12)
Less than high school (R)								

Explanatory variables	Dependent variables							
	HAQ		PAIN		FATIGUE		STIFFNESS	
	Bivariate	Aim 1a (Multivariate)	Bivariate	Aim 1a (Multivariate)	Bivariate	Aim 1a (Multivariate)	Bivariate	Aim 1a (Multivariate)
Marital status								
Separated	.09	.06	2.89	1.31	4.82	4.98	3.19	1.17
/divorced	(.10)	(.10)	(4.32)	(4.34)	(4.91)	(4.78)	(4.29)	(4.31)
Widowed	.06	.03	-1.92	.17	-1.39	1.53	-2.22	-.18
	(.07)	(.07)	(2.85)	(3.36)	(3.24)	(3.70)	(2.83)	(3.34)
Single	-.16	-.24	.22	-1.14	-2.90	-4.02	-.77	-3.03
	(.14)	(.13)	(5.75)	(5.83)	(6.53)	(6.41)	(5.71)	(5.79)
Married (R)								
Work status								
Working	-.17	-.13	2.97	1.20	-.47	-2.74	4.00	1.23
	(.09)	(.10)	(3.92)	(4.54)	(4.38)	(4.99)	(3.92)	(4.50)
Homemaker	.13	.08	4.92	4.38	7.81	5.75	.56	-.23
	(.09)	(.09)	(3.95)	(4.14)	(4.42)	(4.56)	(3.95)	(4.11)
Disabled	.52**	.48**	15.90**	10.62*	22.74**	16.86**	13.31**	7.30
	(.08)	(.09)	(3.29)	(4.11)	(3.67)	(4.52)	(3.28)	(4.08)
Other	.17	.14	10.13	7.21	4.67	-.28	13.41*	9.38
	(.14)	(.15)	(6.24)	(6.62)	(6.98)	(7.29)	(6.24)	(6.58)
Retired (R)								
Co morbid	.17**	.12**	3.48**	2.55*	5.48**	4.43**	4.01**	3.17**
	(.02)	(.02)	(1.00)	(1.07)	(1.13)	(1.17)	(.99)	(1.06)
R ²		.22		.08		.14		.08

Notes: Standard errors in parentheses.

*Statistically significant at the 5% level.

**Statistically significant at the 1% level.

HAQ = Health Assessment Questionnaire

VAS = Visual Analogue Score

4.2.2 Specific Aim 1a: multivariate analysis

This aim evaluated the associations between literacy and arthritis health status at baseline. Four separate linear regression models were run, each for a baseline arthritis health status, namely: baseline HAQ, baseline pain, baseline fatigue and baseline stiffness. Literacy variable which was dichotomized as low literacy vs. adequate literacy was the primary independent variable of interest. Each model was controlled for age, gender, race, body mass index, marital status, and work status. Each model was run with and without educational status. Literacy was not significant in any of the models, as was the case for the bivariate models.

Baseline HAQ

The adjusted model showed that males had less functional disability than females ($p=0.01$). Though obese participants had more functional disability than normal weight individuals in the bivariate analysis, there was no significant difference in the adjusted model. Disabled compared to retired participants, had 0.48 unit (95% CI = 0.30 - 0.65) more functional disability. Increase in one non-musculoskeletal condition was associated with 0.12 unit (95% CI = 0.08 - 0.17) increase in HAQ. Thus male gender, being disabled, and co-morbidity were significant in bivariate and multivariate analysis (Table 4.3).

Baseline pain

Adjusted model, like the bivariate analysis, showed significant values for being disabled and having a co-morbid condition. However age, obesity and college degree which were significant in bivariate analysis did not continue being

significant in the multivariate model (Table 4.3). Disabled individuals had 10.6 units (95% CI = 2.5 - 18) more pain than retired individuals. Similarly, increase in one non-musculoskeletal condition was associated with 2.6 units (95% CI = 0.45 - 4.6) more pain.

Baseline fatigue

Males had 8.6 units (95% CI = -17 to -0.16) less fatigue than females. African Americans had 9.5 units (95% CI = -18 to -1.0) less fatigue than Caucasian in the multivariate, but not the bivariate analysis (Table 4.3). Disabled had 16.9 units (95% CI = 8.0-25.0) more fatigue than retired individuals. Increase in one musculoskeletal condition was associated with 4.4 unit (95% CI =2.1 - 6.7) more fatigue. Obesity which was significant in the bivariate analysis lost its significance in the multivariate analysis (Table 4.3).

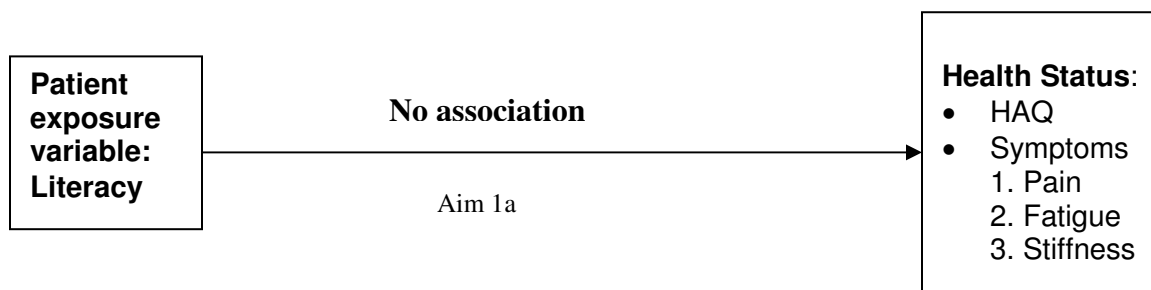
Baseline stiffness

In the adjusted model, increase in one non-musculoskeletal condition was associated with 3.2 unit (95% CI = 1.1 - 5.3) more stiffness. Obesity and being disabled, which were significant on bivariate model, lost their significance after adjustment (Table 4.3).

Summary

My hypothesis involving the multivariate cross-sectional analysis of Aim 1a, that literacy will have a positive association with baseline arthritis outcomes, was not supported (Figure 4.1).

Figure 4.1: Result for Aim 1a



4.2.3 Correlation between literacy and educational status

Correlation between low literacy and less than high school was 0.43 ($p < 0.001$). When adjusted models were run with the dichotomized literacy variable, excluding educational status, literacy remained not significant. In short, there was no difference in either the significant variables, or their point estimates in models when including or excluding the educational status. Hence, educational status was included in the final model.

4.3 Descriptive statistics for the longitudinal sample

This sample is used for aims 1b, 2, 3 and 4. As shown in Figure 3.4, a total of 700 participants were enrolled in the 2 RCTs. After listwise deletion of missing data, 391 participants were available for longitudinal analysis. As shown in Table 4.4, the mean age of the sample was 69 years (range 42-89) and 340 (87%) were female, 310 (79%) were Caucasian and 69 (18%) African Americans. A total of 284 (73%) were either overweight or obese, and participants had a mean (SD) of 1.6 (1.2) non-musculoskeletal co-morbid

conditions. Thirty seven (9%) participants had less than high school education. Two hundred and seven (53%) were retired and 212 (55%) were married. The population had a mean (SD) baseline HAQ of 1.0 (0.65), mean (SD) baseline pain of 46 (26) and mean (SD) baseline fatigue of 43 (31), and mean (SD) stiffness of 45 (27). Population had mean (SD) helplessness of 2.4 (0.92) and mean (SD) OEE of 4.0 (0.73) at baseline. At the end of interventions, mean (SD) final HAQ was 0.94 (0.67), mean (SD) final pain was 40 (27), mean (SD) final fatigue was 40 (29), and mean (SD) stiffness was 40 (27) (Table 4.4).

Of all participants, 73 (19%) had low literacy, as seen in Table 4.5. Of the patients with adequate literacy (>8th grade), 13 (4%) had not completed high school. Conversely, of the patients with low literacy, 49 (67%) had completed high school or above. Furthermore, 23 (32%) of patients with low literacy had some college, associate, bachelors or even postgraduate degree (Table 4.5). More African Americans' (49%) than Caucasians, had low literacy levels ($p<0.001$). More males (24%) than females (18%) had low literacy levels ($p=0.34$).

Table 4.4: Longitudinal sample characteristics (N=391)

	N	%
Race		
Caucasian	310	79%
African American	69	18%
Gender		
Female	340	87%
Body Mass Index		
Overweight	137	35%
Obese	147	38%
Education		
Less than high school	37	9%
Literacy		
REALM < 9 th grade	73	19%
Work status		
Retired	207	53%
Marital status		
Married	212	55%
	Mean	SD
Age (42-89)	69	10
Number of co-morbid conditions (0-7)	1.6	1.2
Functional Disability		
Baseline HAQ (0-2.75)	1.0	0.65
Final HAQ (0-2.88)	0.94	0.67
Arthritis symptoms (mm on VAS)		
Baseline Pain (0-100)	46	26
Final Pain (0-100)	40	27
Baseline Fatigue (0-100)	43	31
Final Fatigue (0-100)	40	29
Baseline Stiffness (0-100)	45	27
Final Stiffness (0-100)	40	27
Psychosocial factors		
Helplessness (1-5)	2.4	0.92
Outcome expectation for exercise (1-5)	4.0	0.73

REALM = Rapid Estimate of Adult Literacy in Medicine

HAQ = Health Assessment Questionnaire

VAS= Visual Analogue Score

Table 4.5: Relationship of educational status with literacy in the longitudinal sample (N=391)

Educational status	Low literacy	Adequate literacy	Total
Less than high school	24 (33%)	13 (4%)	37 (9%)
High school	26 (36%)	82 (26%)	108 (28%)
Some college (including associate)	18 (25%)	118 (37%)	136 (35%)
College degree (including bachelors and postgraduate)	5 (7%)	105 (33%)	110 (28%)
Total	73 (101%)	318 (100%)	391 (100%)

Percentages rounded, so total can be above 100%.

4.4 Longitudinal model

This model was used for the remaining specific aims namely aim 1b, 2, 3 and 4, and bivariate and multivariate models were run.

4.4.1 Bivariate analysis

The bivariate analysis looked at variables from aims 1b, 2, 3 and 4. Individuals with low literacy did not have significantly worse disability (HAQ) or arthritis symptoms than individuals with adequate literacy in bivariate analysis. There were other bivariate associations which were significant (Table 4.6 – Table 4.9).

Final HAQ

As shown in Table 4.6, bivariate analysis showed that obese individuals had 0.20 unit (95% CI = 0.03 - 0.37) higher HAQ compared to normal weight individuals and the widowed had 0.22 unit (95% CI = 0.07 - 0.37) higher HAQ compared to married people. Further, the disabled had 0.62 unit (95% CI = 0.45 - 0.78) higher HAQ compared to retired participants. An increase of one non-

musculoskeletal condition was associated with 0.17 unit (95% CI = 0.11-0.22) increase in HAQ. One unit increase in helplessness was associated with 0.26 (95% CI = 0.19 - 0.33) more functional disability. Lastly, one unit increase in exercise outcome expectation was associated with 0.13 unit (95% CI = -0.22 to -0.04) less functional disability.

Final pain

As shown in Table 4.7, bivariate analysis showed that the obese had 8.3 units (95% CI = 1.6 - 14) higher pain compared to normal weight individuals, and the disabled had 15 units (95% CI = 8.4 - 22) more pain than retired individuals. An increase of one non-musculoskeletal condition was associated with 3.3 units (95% CI = 1.2 - 5.5) more pain. Further, one unit increase in helplessness was associated with 12 units (95% CI = 9.2 - 14) more pain. Lastly, one unit increase in exercise outcome expectation was associated with 4.1 units (95% CI = -7.7 to -0.41) less pain.

Final fatigue

Bivariate analysis (Table 4.8) showed that the disabled had 22 units (95% CI = 14 - 29) more fatigue than the retired. An increase of one non-musculoskeletal condition was associated with 5.2 units (95% CI = 3.0 - 7.5) more fatigue. One unit increase in helplessness was associated with 11 units (95% CI = 7.9 - 14) more fatigue. Lastly, one unit increase in exercise outcome expectation was associated with 4.9 units (95% CI = -8.79 to -0.92) less fatigue.

Final stiffness

One year increase in age was associated with 0.35 unit (95% CI = -0.60 to -0.10) less stiffness as shown in Table 4.9. The obese have 11 units (95% CI = 4.4 - 18) more stiffness compared to normal weight individual. Having a college degree was associated with 13 units (95% CI = -23 to -2.8) less stiffness compared to an individual having less than high school education. Furthermore, a disabled person has 15 units (95% CI = 8.1 – 21.90) more stiffness than a retired individual. An increase of one co-morbid condition was associated with 2.5 units (95% CI = 0.37 - 4.7) more stiffness. Lastly, one unit increase in helplessness was associated with 9.3 units (95% CI= 6.6 - 12) more stiffness (Table 4.9).

Summary

My hypotheses involving the bivariate longitudinal analysis of Aim 1b (literacy will have a positive association with arthritis outcomes) and Aim 2 (interventions will improve short-term arthritis outcomes differently for individuals with I and adequate literacy) were not supported. However; my hypotheses involving bivariate longitudinal analysis of Aim 3 and 4 (helplessness and exercise outcome expectation mediate the effect of low literacy on health outcomes) were supported. Increases in helplessness worsened all arthritis outcomes, namely; functional disability, pain, fatigue and stiffness. Also, increases in exercise outcome expectation resulted in a decrease in functional disability, pain and fatigue.

4.4.2 Specific Aim 1b: multivariate analysis

Specific Aim 1b evaluated the association between literacy and health outcomes in the longitudinal sample. Four separate linear regression models were run, each for a final arthritis outcome, namely: final HAQ, final pain, final fatigue and final stiffness (Table 4.6 - Table 4.9). Literacy, which was dichotomized, was the primary independent variable of interest. Each model was controlled for the respective baseline arthritis health status. For example, for the model of final HAQ, baseline HAQ was controlled for. In all models, the baseline values of arthritis health status were significant. The other variables adjusted for were age, gender, race, body mass index, educational status, marital status and work status. Literacy was not significant in any of the models, as was the case for the bivariate models.

Final HAQ

The adjusted model, as mentioned above, showed that the widowed had 0.17 unit (95% CI = 0.07 - 0.27) higher functional disability compared to married people (Table 4.6). Disabled compared to retired participants, had 0.27 unit (95% CI = 0.14 - 0.40) more functional disability. Though obese participants had more functional disability than normal weight individuals in the bivariate analysis, there was no significant difference in the multivariate model. Similarly, co-morbidity had significant functional disability in bivariate analysis, which was not present in the multivariate model.

Final pain

The multivariate model, like the bivariate analysis, showed significant association between pain and disability. However, obesity, and co-morbidity which were significant in bivariate analysis did not continue being significant in multivariate model (Table 4.7). Disabled individuals had 8.1 units (95% CI = 0.34 - 16) more pain than retired individuals.

Final fatigue

Being disabled and co-morbidity were significant in the multivariate model, as in the bivariate model (Table 4.8). Disabled had 13 units (95% CI = 4.4 - 21) more fatigue than retired individuals. An increase of one musculoskeletal condition was associated with 2.3 units (95% CI = 0.21 - 4.5) more fatigue.

Final stiffness

Age, obesity, having a college degree, being disabled and co-morbidity which were significant in the bivariate model lost their significance in the multivariate model (Table 4.9).

Summary

My hypothesis involving the multivariate longitudinal analysis of Aim 1b, that literacy will have a positive association with arthritis outcomes, was not supported (Figure 4.2).

Figure 4.2: Result for Aim 1b

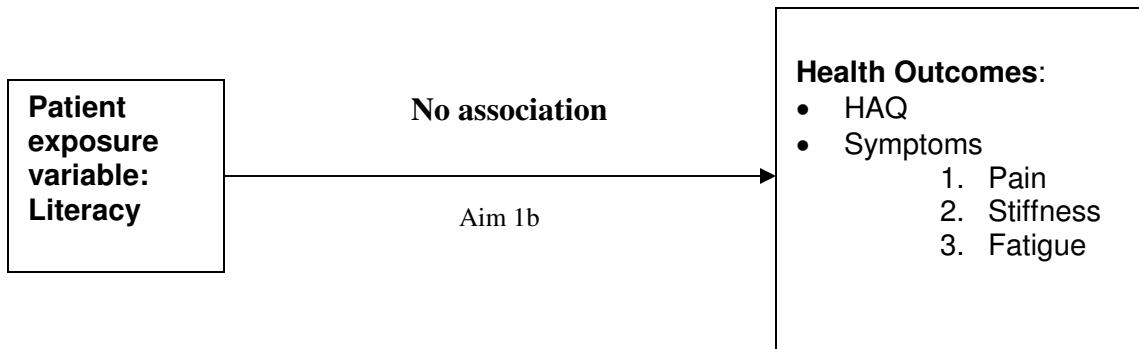


Table 4.6: Longitudinal analysis of final Health Assessment Questionnaire (HAQ) (N=391)

Explanatory variables	Bivariate	Aim 1b (Multivariate)	Aim 2 (Multivariate)	Aim 3 & 4 (helplessness as iv)	Aim 3 & 4 (OEE as iv)
Baseline HAQ		.78** (.03)	.78** (.03)	.78** (.04)	.78** (.03)
<i>Low literacy</i>	-.06 (.09)	-.11 (.06)	-.11 (.06)	-.11 (.06)	-.11 (.06)
<i>Intervention</i>	-.08 (.07)		-.02 (.04)	-.02 (.04)	-.02 (.04)
<i>Helplessness</i>	.26** (.03)			.00	-.01
<i>Outcome Expectation</i>	-.13* (.05)			(.02)	(.03)
Age	-.00 (.00)	.00 (.00)	.00 (.00)	.00 (.00)	.00 (.00)
Male	-.18 (.10)	.11 (.06)	.11 (.06)	.11 (.06)	.11 (.06)
Race					
Black	.03 (.09)	.04 (.06)	.04 (.06)	.04 (.06)	.04 (.06)
Other Race (White)	-.10 (.20)	-.05 (.12)	-.04 (.12)	-.04 (.12)	-.04 (.12)
Body Mass Index					
Overweight	.11 (.09)	.04 (.05)	.04 (.05)	.04 (.05)	.04 (.05)
Obese (Normal weight)	.20* (.08)	-.06 (.06)	-.06 (.06)	-.06 (.06)	-.06 (.06)
Education					
High school	-.19 (.13)	-.02 (.08)	-.03 (.08)	-.03 (.08)	-.03 (.08)
Some college	-.12 (.12)	-.05 (.08)	-.05 (.08)	-.05 (.08)	-.05 (.08)
College degree (Less than high school)	-.22 (.13)	-.01 (.08)	-.02 (.08)	-.02 (.08)	-.02 (.08)
Marital status					
Separated /divorced	.17 (.12)	.10 (.07)	.10 (.07)	.10 (.07)	.10 (.07)
Widowed	.22** (.08)	.17** (.05)	.17** (.05)	.17** (.05)	.17** (.05)
Single (Married)	-.03 (.15)	.12 (.09)	.12 (.09)	.12 (.09)	.12 (.09)
Work status					
Working	-.19 (.10)	.03 (.07)	.03 (.07)	.03 (.07)	.03 (.07)
Homemaker	.05 (.10)	.02 (.06)	.02 (.07)	.02 (.07)	.02 (.07)
Disabled	.62** (.08)	.27** (.07)	.27** (.07)	.27** (.07)	.27** (.07)
Other (Retired)	.44 (.17)	.25 (.11)	.25 (.11)	.25 (.11)	.25 (.11)
Co morbid	.17** (.03)	.01 (.02)	.01 (.02)	.01 (.02)	.01 (.02)
R ²		.69	.69	.69	.69

*p<0.05 **p<0.01

OEE = Outcome expectation for exercise, iv = independent variable

Table 4.7: Longitudinal analysis of final pain (N=391)

Explanatory variables	Bivariate	Aim 1b (Multivariate)	Aim 2 (Multivariate)	Aim 3 & 4 (helplessness as iv)	Aim 3 & 4 (OEE as iv)
Baseline pain		.44** (.05)	.45** (.05)	.37** (.05)	.45** (.05)
<i>Low literacy</i>	1.36 (3.46)	-1.90 (3.71)	-2.29 (3.68)	-3.55 (3.61)	-2.44 (3.69)
<i>Intervention</i>	-5.11 (2.68)		-6.49** (2.42)	-5.96* (2.37)	-6.33* (2.43)
<i>Helplessness Outcome Expectation</i>	11.83** (1.33) -4.05* (1.85)			6.15** (1.47)	-1.02 (1.68)
Age	-.24 (.13)	.02 (.17)	.00 (.17)	.00 (.16)	.00 (.17)
Male	3.73 (4.00)	7.27 (3.78)	7.90* (3.76)	7.75* (3.67)	7.73* (3.77)
Race					
Black	-.62 (3.55)	-1.72 (3.72)	- 1.63 (3.69)	.90 (3.66)	-1.46 (3.71)
Other Race (White)	8.82 (7.84)	10.86 (7.20)	12.40 7.16	10.91 (7.02)	12.32 (7.17)
BMI					
Overweight	3.01 (3.42)	2.10 (3.10)	1.88 (3.08)	1.49 (3.01)	1.84 (3.08)
Obese (Normal weight)	8.25* (3.36)	3.12 (3.43)	3.31 (3.40)	2.00 (3.34)	3.27 (3.41)
Education					
High school	-4.85 (5.08)	1.65 (4.81)	1.33 (4.77)	1.97 (4.67)	1.03 (4.80)
Some college	-5.03 (4.94)	-.96 (4.79)	-1.89 4.76	-2.01 (4.66)	-2.04 (4.76)
College degree (Less than high school)	-7.40 (5.07)	-.05 (5.14)	-.29 (5.09)	-.40 (4.98)	-.56 (5.12)
Marital status					
Separated /divorced	8.20 (4.80)	6.28 (4.35)	6.50 (4.32)	6.77 (4.23)	6.47 (4.32)
Widowed	1.11 (3.04)	3.79 (3.20)	4.14 (3.18)	3.87 (3.11)	4.06 (3.19)
Single (Married)	2.37 (5.85)	1.62 (5.39)	2.12 (5.35)	1.02 (5.24)	2.09 (5.36)
Work status					
Working	-3.12 (4.23)	-4.09 (4.37)	-3.55 (4.34)	-2.86 (4.24)	-3.58 (4.34)
Homemaker	-.32 (4.19)	-1.12 (3.95)	.05 (3.94)	-.04 (3.86)	.15 (3.95)
Disabled	15.21** (3.48)	8.07* (3.93)	7.14 (3.91)	5.30 (3.85)	6.84 (3.94)
Other (Retired)	10.69* (6.94)	6.12 (6.53)	6.17 (6.47)	6.08 (6.33)	6.27 (6.48)
Co morbid	3.33** (1.08)	1.29 (1.04)	1.47 (1.03)	.87 (1.02)	1.45 (1.03)
R ²		.27	.28	.32	.28

*p<0.05 **p<0.01

OEE = Outcome expectation for exercise, iv = independent variable

Table 4.8: Longitudinal analysis of final fatigue (N=391)

Explanatory variables	Bivariate	Aim 1b (Multivariate)	Aim 2 (Multivariate)	Aim 3 & 4 (helplessness as iv)	Aim 3 & 4 (OEE as iv)
Baseline fatigue		.45** (.04)	.45** (.04)	.40** (.05)	.44** (.04)
<i>Low literacy</i>	-1.52 (3.74)	-5.90 (3.86)	-6.06 (3.86)	-6.50 (3.84)	-6.28 (3.87)
<i>Intervention</i>	-3.77 (2.91)		-2.65 (2.51)	-2.43 (2.50)	-2.38 (2.53)
<i>Helplessness Outcome Expectation</i>	10.79** (1.48) -4.86* (2.00)			3.79* (1.53)	-1.67 (1.76)
Age	-.27 (.14)	.28 (.17)	.28 (.17)	.27 (.17)	.27 (.17)
Male	-7.14 (4.32)	.12 (3.93)	.37 (3.93)	.05 (3.91)	.07 (3.95)
Race					
Black	-.70 (3.84)	3.43 (3.88)	3.47 (3.88)	4.70 (3.89)	3.72 (3.89)
Other Race (White)	-6.13 (8.50)	-.91 (7.44)	-.28 (7.46)	-1.25 (7.42)	-.42 (7.46)
BMI					
Overweight	4.32 (3.71)	1.70 (3.20)	1.60 (3.20)	1.45 (3.18)	1.54 (3.20)
Obese (Normal weight)	5.95 (3.66)	-1.53 (3.54)	-1.45 (3.54)	-2.27 (3.54)	-1.51 (3.55)
Education					
High school	-2.27 (5.45)	.54 (4.96)	.39 (4.97)	1.24 (4.94)	-.07 4.99
Some college	4.82 (5.31)	5.14 (4.96)	4.75 (4.97)	5.13 (4.94)	4.53 (4.98)
College degree (Less than high school)	-5.27 (5.44)	-2.43 (5.30)	-2.55 (5.31)	-1.94 (5.27)	-2.94 (5.32)
Marital status					
Separated /divorced	8.49 (5.20)	4.39 (4.50)	4.48 (4.50)	4.73 (4.47)	4.45 (4.50)
Widowed	1.65 (3.29)	.02 (3.31)	.17 (3.32)	.07 (3.29)	.04 (3.32)
Single (Married)	2.23 (6.33)	.76 (5.58)	.97 (5.58)	.14 (5.55)	.91 (5.58)
Work status					
Working	4.86 (4.50)	7.19 (4.51)	7.42 (4.52)	7.75 (4.49)	7.36 (4.52)
Homemaker	3.06 (4.46)	-1.04 (4.10)	-.56 (4.13)	-.34 (4.10)	-.39 (4.13)
Disabled	21.60** (3.71)	12.53** (4.13)	12.17** (4.14)	11.38** (4.12)	11.71** (4.17)
Other (Retired)	19.14 (7.39)	15.53 (6.74)	15.58 (6.74)	15.43 (6.70)	15.73 (6.74)
Co morbid	5.24** (1.15)	2.33* (1.08)	2.41* (1.08)	2.11* (1.08)	2.38 (1.08)
R ²		.33	.34	.35	.34

*p<0.05 **p<0.01

OEE = Outcome expectation for exercise, iv = independent variable

Table 4.9: Longitudinal analysis of final stiffness (N=391)

Explanatory variables	Bivariate	Aim 1b (Multivariate)	Aim 2 (Multivariate)	Aim 3 & 4 (helplessness as iv)	Aim 3 & 4 (OEE as iv)
Baseline stiffness		.46** (.05)	.45** (.05)	.41** (.05)	.45** (.05)
<i>Low literacy</i>	2.80 (3.48)	-3.31 (3.73)	-3.51 (3.72)	-4.34 (3.72)	-3.73 (3.73)
<i>Intervention</i>	-3.93 (2.71)		-3.46 (2.44)	-3.29 (2.43)	-3.23 (2.46)
<i>Helplessness Outcome Expectation</i>	9.30** (1.39) -3.06 (1.87)			3.60* (1.50)	-1.45 (1.70)
Age	-.35** (.13)	.04 (.17)	.03 (.17)	.02 (.17)	.03 (.17)
Male	.62 (4.03)	4.30 (3.80)	4.62 (3.80)	4.58 (3.77)	4.38 (3.81)
Race					
Black	6.39 (3.56)	3.44 (3.74)	3.47 (3.73)	5.21 (3.78)	3.73 (3.75)
Other Race (White)	2.43 (7.87)	-.07 (7.24)	.75 (7.26)	.36 (7.21)	.65 (7.26)
BMI					
Overweight	4.31 (3.42)	2.63 (3.11)	2.50 (3.11)	2.36 (3.09)	2.45 (3.11)
Obese (Normal weight)	10.98** (3.37)	4.15 (3.45)	4.25 (3.44)	3.55 (3.43)	4.20 (3.45)
Education					
High school	-9.44 (5.08)	-3.32 (4.83)	-3.52 (4.82)	-3.00 (4.80)	-3.93 (4.85)
Some college	-8.13 (4.95)	-4.82 (4.81)	-5.33 (4.82)	-5.31 (4.80)	-5.54 (4.83)
College degree (Less than high school)	-12.79* (5.07)	-6.00 (5.16)	-6.16 (5.15)	-6.14 (5.12)	-6.53 (5.17)
Marital status					
Separated /divorced	7.10 (4.84)	2.65 (4.37)	2.78 (4.37)	2.88 (4.34)	2.74 (4.37)
Widowed	-.19 (3.06)	.68 (3.22)	.87 (3.22)	.75 (3.20)	.75 (3.22)
Single (Married)	.54 (5.89)	-1.63 (5.42)	-1.36 (5.42)	-2.08 (5.39)	-1.40 (5.42)
Work status					
Working	1.97 (4.27)	.02 (4.39)	.32 (4.39)	.60 (4.36)	.27 (4.39)
Homemaker	-2.27 (4.23)	-2.93 (3.97)	-2.30 (3.99)	-2.44 (3.96)	-2.17 (4.00)
Disabled	15.00** (3.51)	7.31 (3.93)	6.86 (3.94)	5.62 (3.95)	6.40 (3.98)
Other (Retired)	13.78 (7.00)	6.84 (6.57)	6.90 (6.56)	7.03 (6.52)	7.03 (6.57)
Co morbid	2.51* (1.09)	-.15 (1.05)	.04 (1.04)	-.35 (1.05)	.08 (1.05)
R ²		.33	.28	.29	.28

* p<0.05 **p<0.01

OEE = Outcome expectation for exercise, iv = independent variable

4.4.3 Specific Aim 2- multivariate analysis

Aim 2 determined whether (a) life style interventions have a differential short-term impact on arthritis outcomes for individuals with low and adequate literacy, and (b) literacy has a differential impact on arthritis outcomes for those exposed and those not exposed to the intervention.

As in Aim 1, four separate linear regression models were run, each for a final arthritis outcome measured at intervention completion after adjusting for its baseline value, namely: final HAQ, final pain, final fatigue, and final stiffness. The intervention variable, dichotomized as control vs. intervention was an independent variable along with the literacy variable. The literacy variable was dichotomized as low literacy vs. adequate literacy. Both these variables are of primary interest in this model. The literacy*intervention interaction was not included in the final HAQ, final pain, final fatigue and final stiffness models as literacy or intervention, or both did not have significant effects. For the arthritis outcome final pain, the intervention had a significant effect, but the interaction of literacy and the intervention did not have a significant effect, hence it is not shown in Table 4.7. Each model was controlled for the respective baseline arthritis health status, age, gender, race, body mass index, educational status, marital status, and work status. Literacy was not significant in any of the models, as was the case in bivariate and multivariate analysis (Specific aim 1). Intervention was not significant in these models, only in the case of final pain (Table 4.7).

Final HAQ

As shown in Table 4.6, the multivariate model showed that the widowed had 0.17 unit (95% CI = 0.07-0.27) more functional disability than the married. The widowed have consistently shown a significant effect in bivariate and multivariate models of specific aim 1 and 2. Disabled compared to retired participants, had 0.27 unit (95% CI = 0.14 -0.40) more functional disability.

Final pain

As shown in Table 4.7, the multivariate model showed that the intervention group had 6.5 units (95% CI = -11 to -1.7) less pain than the control group. Since intervention was significant, the literacy*intervention interaction was included in the model, but was not significant. Males had 7.9 units (95% CI = 0.51- 15) more pain than females. However, obesity, being disabled and co-morbidity which were significant in bivariate analysis did not continue being significant in the multivariate model.

Final fatigue

Being disabled and co-morbidity were significant in the multivariate model, as in the bivariate model and multivariate model of Specific aim1 (Table 4.8). Disabled had 12 units (95% CI = 4.0 - 20) more fatigue than retired individuals. An increase of one non-musculoskeletal condition was associated with 2.4 units (95% CI = 0.28 - 4.5) more fatigue.

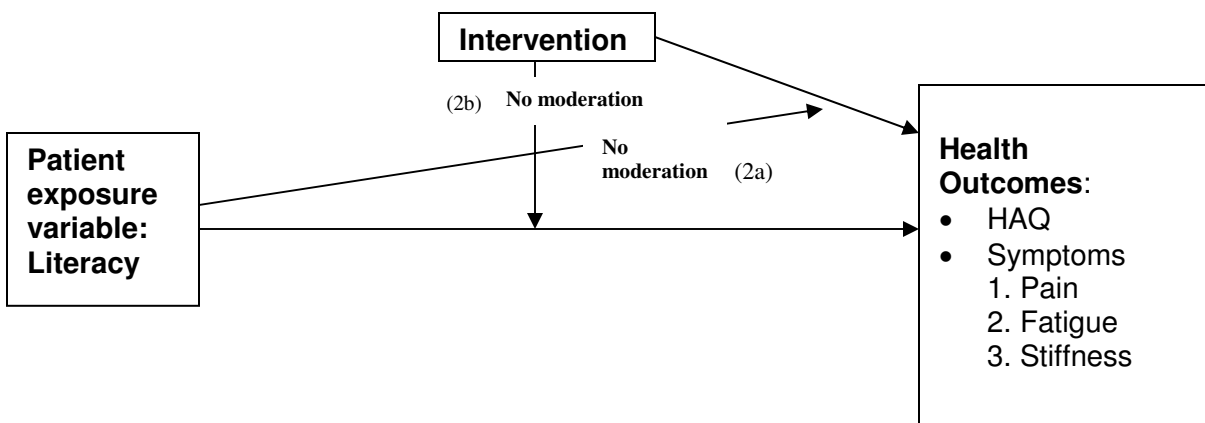
Final stiffness

Age, obesity, having a college degree, being disabled and co-morbidity which were significant on bivariate model lost their significance in the multivariate model of Specific aim 1 and 2 (Table 4.9).

Summary

Literacy was not significant in these models. Intervention was not significant in most models, only in the case of final pain (Table 4.7). My hypothesis involving the multivariate longitudinal analysis of Aim 2 (namely, that intervention will improve short-term arthritis outcomes differently for individuals with low and adequate literacy, and that those who receive the intervention, literacy will have a weaker positive effect on arthritis outcomes and vice versa) was not supported (Figure 4.3).

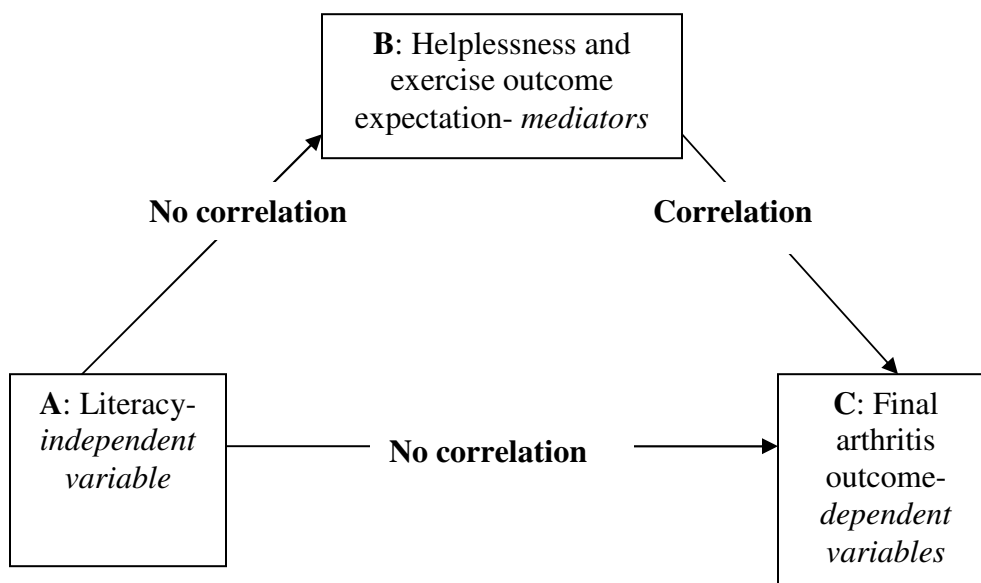
Figure 4.3: Result for Aim 2



4.4.4 Specific Aim 3- correlation

Specific Aim 3 assesses' the impact of mediators, helplessness and exercise outcome expectation, on the relationship between the independent variable literacy and the dependent variables of final health outcomes as shown in Figure 4.4. Helplessness and exercise outcome expectation may explain the entire route, in other words, everyone who has low literacy feels more helpless and has less exercise outcome expectation, and thus has a worse arthritis outcome. Or more likely, some participants who have low literacy, feel helpless, and have less outcome expectation, and hence have worse arthritis outcomes. Hence identification of the mediator is very helpful because it explains the mechanism by which we get from point A to C. There is a precondition that must be met: all three correlations among the three variables in question must be statistically significant.

Figure 4.4: Role of helplessness and exercise outcome expectation as a mediator in the relationship between literacy and final health outcomes



Note: All three correlations among the three variables in the figure must be statistically significant to prove mediation.

Correlation between helplessness, low literacy, and final arthritis outcomes

As shown in Table 4.10, correlations between low literacy, helplessness and final arthritis outcomes, namely, final HAQ, final pain, final fatigue, and final stiffness were examined. Helplessness was moderately and significantly correlated with functional disability (0.36, $p < 0.0001$). Similarly, helplessness was moderately and significantly correlated with final pain (0.41, $p < 0.0001$). There were no significant correlations among the other variables of interest, namely low literacy and functional disability, low literacy and final pain and low literacy and helplessness. Helplessness had a moderate and significant correlation with final

fatigue (0.35, $p < 0.0001$) and helplessness had a moderate and significant correlation with final stiffness (0.32, $p < 0.0001$) respectively.

Table 4.10: Correlation between low literacy, helplessness, outcome expectation and final HAQ, final pain, final fatigue and final stiffness (N=391)

	Low literacy	Helplessness	Outcome expectation	Final HAQ	Final pain	Final fatigue	Final stiffness
Low literacy	1.00						
Helplessness	0.06	1.00					
Outcome expectation	-0.05	--	1.00				
Final HAQ	-0.04	0.36***	-0.14**	1.00			
Final pain	0.02	0.41***	-0.11*	--	1.00		
Final fatigue	-0.02	0.35***	-0.12*	--	--	1.00	
Final stiffness	0.04	0.32***	-0.08 [†]	--	--	--	1.00

* $p < 0.05$

** $p < 0.01$

*** $p < 0.0001$

[†] $p > 0.05$

--Not relevant

HAQ = Health Assessment Questionnaire

Correlation between exercise outcome expectation, low literacy, and final arthritis outcomes

As shown in Table 4.10, correlations between low literacy, exercise outcome expectation and final arthritis outcomes, namely, final HAQ, final pain, final fatigue, and final stiffness were examined. Exercise outcome expectation was mildly and significantly correlated with functional disability (-0.14, $p = 0.005$). Similarly, exercise outcome expectation was mildly and significantly correlated with final pain (-0.11, $p = 0.03$). There were no significant correlations among the other variables of interest, namely low literacy and functional disability or low literacy and final pain and low literacy and exercise outcome expectation.

Exercise outcome expectation had a mild and significant correlation with final fatigue (-0.12, $p=0.02$) and exercise outcome expectation had a mild and not significant correlation with final stiffness (-0.08, $p=0.10$) respectively.

Summary

As seen in Figure 4.4, there were significant correlations only between the mediators and final arthritis outcomes. However, there was no significant correlation between literacy and final arthritis outcomes, or between literacy and the mediators. Hence, there was no significant mediation.

4.4.5 Specific Aim 3- bivariate and multivariate analysis

To show significant mediation, besides correlation, multivariate analysis was computed where the mediators were the dependent variables and literacy was the independent variable. If needed, a simultaneous inclusion multiple regression will be estimated with literacy, intervention and mediators as the independent variables and final arthritis outcomes as the dependent variables.

Helplessness as a dependent variable

Bivariate and multivariate models were run.

Bivariate analysis

Individuals with low literacy did not have more helplessness than individuals with adequate literacy in bivariate analysis. There were other bivariate associations which were significant (Table 4.11). One unit increase in age was associated with 0.01 unit (95% CI = -0.02 to -0.00) less helplessness. The obese had 0.37 unit (95% CI = 0.14 - 0.60) more helplessness than normal weight individuals. The disabled had 0.64 unit (95% CI = 0.41-0.88) more helplessness

compared to the retired. An increase in one non-musculoskeletal condition was associated with 0.17 unit (95% CI = 0.09 - 0.24) more helplessness.

Multivariate analysis

Helplessness was the dependent variable and literacy was the independent variable. Literacy was the variable of primary interest. The model was controlled for age, gender, race, body mass index, educational status, marital status and work status. Though age, being obese, and co-morbidity showed significant relation to helplessness in the bivariate model, similar significance was not present in the multivariate model (Table 4.11). However there was another significant association, namely, being black was associated with 0.47 unit (95% CI = -0.74 to -0.19) less helplessness compared to white. Like the bivariate model, the multivariate model showed that the disabled had 0.45 unit (95% CI = 0.16-0.73) more helplessness than the retired participants. An increase of one non-musculoskeletal condition was associated with 0.12 unit (95% CI = 0.05 - 0.20) more helplessness.

Summary

Literacy was not significant in any of the models, as was the case in bivariate and multivariate analysis. My hypothesis (literacy will have a negative association with helplessness) involving the bivariate analysis and multivariate analysis of helplessness as a dependent variable of Aim 3 was not supported.

Table 4.11: Helplessness as dependent variable (N=391).

Explanatory variables	Bivariate	Aim 3 (Multivariate)	Aim 4 (Multivariate)
<i>Low literacy</i>	.14 (.12)	.24 (.14)	.24 (.14)
<i>Intervention</i>	-.06 (.09)		-.05 (.09)
Age	-.01* (.00)	.00 (.01)	.00 (.01)
Male	-.01 (.14)	-.04 (.14)	-.03 (.14)
Black	-.21 (.12)	-.47** (.14)	-.47** (.14)
Other Race (White)	.30 (.27)	.21 (.27)	.22 (.27)
Body Mass Index			
Overweight	.12 (.12)	.02 (.17)	.02 (.12)
Obese	.37** (.12)	.22 (.13)	.22 (.13)
(Normal weight)			
Education			
High school	-.34 (.18)	-.19 (.18)	-.19 (.18)
Some college	-.16 (.17)	-.01 (.18)	-.02 (.18)
College degree	-.31 (.18)	-.08 (.19)	-.08 (.19)
(Less than high school)			
Marital status			
Separated /divorced	-.05 (.17)	.00 (.16)	.00 (.16)
Widowed	-.07 (.11)	.06 (.12)	.07 (.12)
Single	.15 (.20)	.18 (.20)	.18 (.20)
(Married)			
Work status			
Working	-.08 (.15)	-.08 (.16)	-.07 (.16)
Homemaker	.11 (.14)	.04 (.15)	.05 (.15)
Disabled	.64** (.12)	.45** (.15)	.44** (.15)
Other	.21 (.24)	.12 (.24)	.12 (.24)
(Retired)			
Co morbid	.17** (.04)	.12** (.04)	.12** (.04)
R ²		.15	.15

*p<0.05

**p<0.01

Exercise outcome expectation as a dependent variable

Bivariate and multivariate models were run.

Bivariate analysis

Individuals with low literacy did not have less exercise outcome expectation than individuals with adequate literacy in bivariate analysis. There were other bivariate associations which were significant (Table 4.12).

Intervention was associated with 0.18 unit (95% CI = 0.03-0.32) more exercise outcome expectation compared to being in the control group. The disabled had 0.27 unit (95% CI = 0.46-0.09) lower exercise outcome expectation compared to the retired.

Multivariate analysis

Exercise outcome expectation was the dependent variable and literacy which was dichotomized as low literacy vs. adequate literacy was the independent variable. Literacy was the variable of primary interest. The model was controlled for age, gender, race, body mass index, educational status, marital status and work status. Like the bivariate model, the multivariate model showed that the disabled had 0.34 unit (95% CI = -0.57 to -0.10) lower exercise outcome expectation than the retired participants (Table 4.12).

Summary

Literacy was not significant in any of the models. My hypothesis (literacy will have a positive association with exercise outcome expectation) involving the bivariate analysis and multivariate analysis of exercise outcome expectation as a dependent variable of Aim 3 was not supported.

Conclusion

Since literacy was not significant in the above mentioned models where helplessness and exercise outcome expectation were the dependent variables, there is no evidence of mediation. Further, the third step to show mediation where helplessness and outcome expectation are the independent variables is not required hence will not be described. In conclusion, my hypothesis that helplessness and exercise outcome expectation mediate the effect of low literacy on arthritis outcomes was not supported.

Table 4.12: Exercise outcome expectation as dependent variable (N=391).

Explanatory variables	Bivariate	Aim 3 (Multivariate)	Aim 4 (Multivariate)
<i>Low literacy</i>	-.09 (.09)	-.16 (.11)	-.16 (.11)
<i>Intervention</i>	.18* (.07)		.16* (.07)
Age	-.00 (.00)	.00 (.01)	.00 (.01)
Male	-.18 (.11)	-.14 (.12)	-.16 (.12)
Black	.12 (.10)	.18 (.11)	.18 (.11)
Other Race (White)	-.04 (.21)	-.04 (.22)	.08 (.22)
Body Mass Index			
Overweight	-.05 (.09)	-.04 (.09)	-.03 (.10)
Obese (Normal weight)	-.06 (.09)	-.03 (.11)	-.04 (.11)
Education			
High school	-.19 (.14)	-.28 (.15)	-.28 (.15)
Some college	-.07 (.13)	-.17 (.15)	-.15 (.15)
College degree (Less than high school)	-.11 (.14)	-.26 (.16)	-.25 (.16)
Marital status			
Separated /divorced	-.02 (.13)	-.03 (.13)	-.03 (.13)
Widowed	-.01 (.08)	-.07 (.10)	-.08 (.10)
Single (Married)	-.05 (.16)	-.02 (.17)	-.03 (.17)
Work status			
Working	.05 (.12)	-.02 (.13)	-.04 (.13)
Homemaker	.15 (.12)	.11 (.12)	.08 (.12)
Disabled	-.27** (.10)	-.34** (.12)	-.32* (.12)
Other (Retired)	.11 (.19)	.08 (.20)	.08 (.20)
Co morbid	-.04 (.03)	-.02 (.03)	-.03 (.03)
R ²		.06	.07

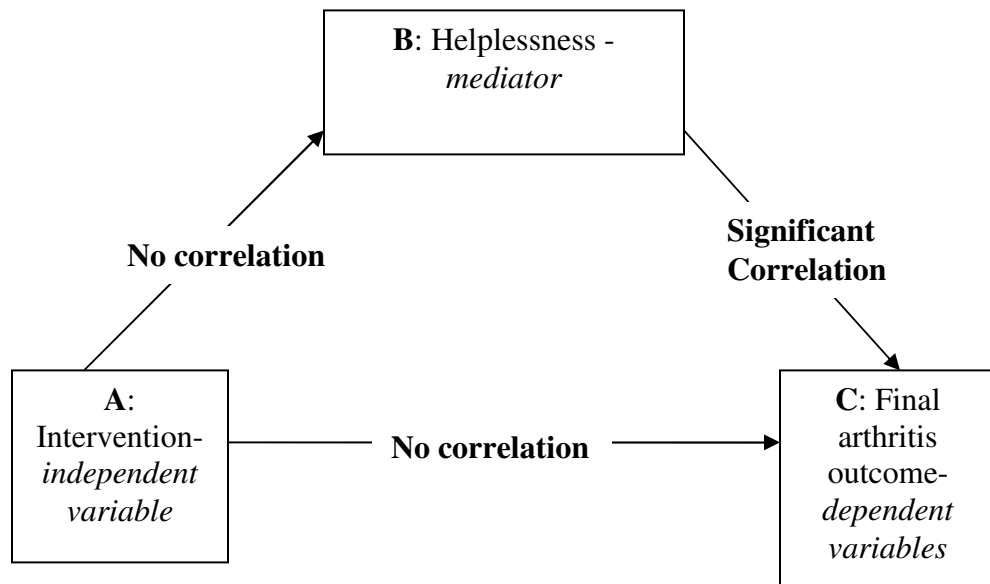
*p<0.05

**p<0.01

4.4.6 Specific Aim 4- correlation

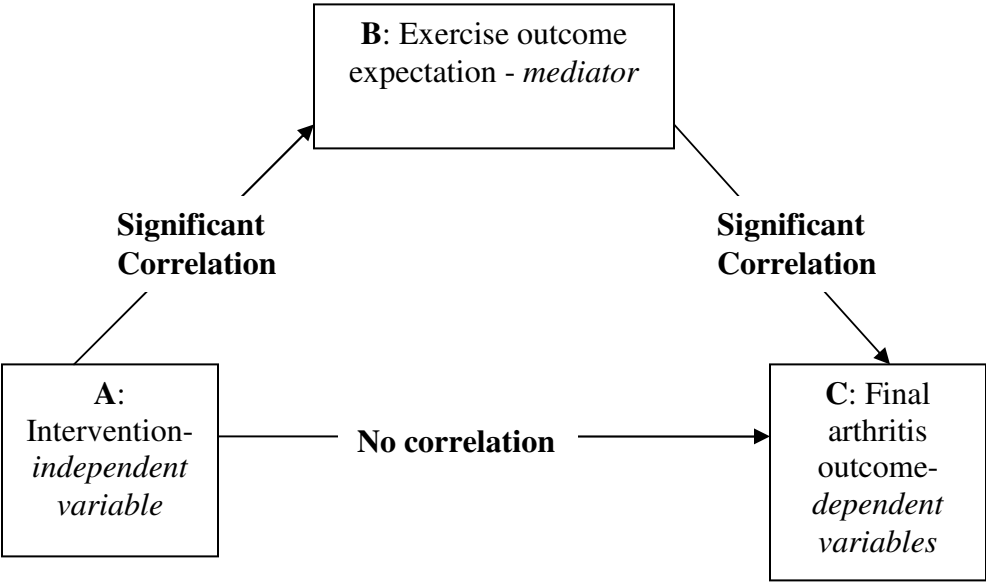
The first part of Specific Aim 4 deals with the impact of mediators, helplessness and exercise outcome expectation on the effectiveness of the intervention, an independent variable in improving final health outcomes (dependent variables) as shown in Figure 4.5 and 4.6. Helplessness and exercise outcome expectation may explain the entire route, in other words, everyone who has intervention feels less helplessness and has more exercise outcome expectation, and thus has a better arthritis outcome. Or more likely, some participants who have intervention, feel less helpless, and have more exercise outcome expectation, and hence have better arthritis outcomes. Hence identification of the mediator is very helpful because it explains the mechanism by which we get from point A to C. There is a precondition that must be met: all three correlations among the three variables in question must be statistically significant.

Figure 4.5: Role of helplessness as a mediator in the relationship between intervention and final health outcomes



Note: All three correlations among the three variables in the figure must be statistically significant to prove mediation.

Figure 4.6: Role of exercise outcome expectation as a mediator in the relationship between intervention and final health outcomes



Note: All three correlations among the three variables in the figure must be statistically significant to prove mediation.

Correlation between helplessness, intervention, and final arthritis outcomes

As shown in Table 4.13, correlations between intervention, helplessness and final arthritis outcomes, namely, final HAQ, final pain, final fatigue, and final stiffness were examined. Helplessness was moderately and significantly correlated with functional disability (0.36, $p < 0.0001$). Similarly, helplessness was moderately and significantly correlated with final pain (0.41, $p < 0.0001$). There were no significant correlations among the other variables of interest, namely intervention and functional disability, intervention and final pain and intervention and helplessness. Helplessness had a moderate and significant correlation with final fatigue (0.35, $p < 0.0001$) and with final stiffness (0.32, $p < 0.0001$) respectively.

Table 4.13: Correlation between intervention, helplessness, outcome expectation and final HAQ, final pain, final fatigue and final stiffness (N=391)

	Interven tion	Helpless ness	Outcome expectation	Final HAQ	Final pain	Final fatigue	Final stiffness
Intervention	1.00						
Helpless ness	-0.03	1.00					
Outcome expectation	0.12*	--	1.00				
Final HAQ	-0.06	0.36***	-0.14**	1.00			
Final pain	-0.10	0.41***	-0.11*	--	1.00		
Final fatigue	-0.07	0.35***	-0.12*	--	--	1.00	
Final stiffness	-0.07	0.32***	-0.08†	--	--	--	1.00

* $p < 0.05$

** $p = 0.01$

*** $p < 0.0001$

† $p > 0.05$

--Not relevant

HAQ = Health Assessment Questionnaire

Correlation between exercise outcome expectation, intervention, and final arthritis outcomes

As shown in Table 4.13, correlations between intervention, exercise outcome expectation and final arthritis outcomes, namely, final HAQ, final pain, final fatigue, and final stiffness were examined. Exercise outcome expectation was mildly and significantly correlated with functional disability (-0.14, $p=0.005$). Similarly, exercise outcome expectation was mildly and significantly correlated with final pain (-0.11, $p=0.03$). There were no significant correlations among the other variables of interest, namely intervention and functional disability or intervention and final pain. Exercise outcome expectation had a mild and significant correlation with final fatigue (-0.12, $p=0.02$) and with final stiffness (-0.08, $p=0.10$) respectively. Exercise outcome expectation was mildly and significantly associated with intervention (0.12, $p=0.02$).

Summary

There was significant correlation between the mediators and final arthritis outcomes. Also, there was significant correlation between outcome expectation and intervention (Figure 4.6), but not between helplessness and intervention (Figure 4.5). However, there was no significant correlation between intervention and final arthritis outcomes. For significant mediation, all three correlations among the three variables must be significant. Since only 1 correlation was statistically significant for the mediator helplessness and only 2 correlations were statistically significant for the mediator exercise outcome expectation, there was no significant mediation.

4.4.7 Specific Aim 4- bivariate and multivariate analysis (first part)

To show significant mediation, besides correlation, multivariate analysis was computed where the mediators were the dependent variables and literacy and intervention were the independent variables. Next, a simultaneous inclusion multiple regression was estimated with literacy, intervention and mediators as the independent variables and final arthritis outcomes as the dependent variables.

Helplessness as a dependent variable

Bivariate and multivariate models were run.

Bivariate analysis

Individuals in the intervention group did not have less helplessness than individuals in the control group in bivariate analysis. There were other bivariate associations which were significant (Table 4.11). One unit increase in age was associated with 0.01 unit (95% CI = -0.02 to -0.00) less helplessness. The obese had 0.37 unit (95% CI = 0.14 - 0.60) more helplessness than normal weight individuals. The disabled had 0.64 unit (95% CI = 0.41 - 0.88) more helplessness compared to the retired. An increase of one non-musculoskeletal condition was associated with 0.17 unit (95% CI = 0.95 - 0.24) more helplessness.

Multivariate analysis

Helplessness was the dependent variable and literacy which was dichotomized as low literacy vs. adequate literacy was the independent variable. Intervention was an independent variable dichotomized as intervention vs. control. Intervention was the variable of primary interest. The model was controlled for age, gender, race, body mass index, educational status, marital

status and work status. Though age, being obese, and co-morbidity showed significant relation to helplessness in the bivariate model, similar significance was not present in the multivariate model (Table 4.11). However there was a significant association, namely, being black was associated with 0.47 unit (95% CI = -0.74 to -0.19) less helplessness compared to white. Like the bivariate model, the multivariate model showed that the disabled had 0.44 unit (95% CI = 0.15-0.73) more helplessness than the retired participants. An increase of one non-musculoskeletal condition was associated with 0.12 unit (95% CI = 0.05-0.20) more helplessness.

Summary

Intervention, the primary independent variable of interest was not significant in bivariate or multivariate models. My hypothesis (helplessness mediates the effect of intervention on arthritis outcomes) involving the bivariate analysis and multivariate analysis of helplessness as a dependent variable of Aim 4 was not supported.

Exercise outcome expectation as a dependent variable

Bivariate and multivariate models were run.

Bivariate analysis

Individuals in the intervention group had 0.18 unit (95% CI = 0.03-0.32) more exercise outcome expectation than individuals in the control group in bivariate analysis (Table 4.12). The disabled had 0.27 unit (95% CI = 0.46 - 0.09) less exercise outcome expectation compared to the retired. Individuals with

low literacy did not have less exercise outcome expectation than individuals with adequate literacy.

Multivariate analysis

Exercise outcome expectation was the dependent variable and literacy which was dichotomized as low literacy vs. adequate literacy was the independent variable. Intervention, which was dichotomized as intervention vs. control was also an independent variable. Intervention was the variable of primary interest. The model was controlled for age, gender, race, body mass index, educational status, marital status and work status. As intervention was associated with more exercise outcome expectation in the bivariate model, similar significance was present in the multivariate model (Table 4.12).

Intervention was associated with 0.16 unit (95% CI = 0.01- 0.30) more exercise outcome expectation compared to the control. Like the bivariate model, the multivariate model showed that the disabled had 0.32 unit (95% CI = -0.55 to -0.08) less exercise outcome expectation than the retired participants.

Summary

Intervention was associated with increase in exercise outcome expectation. My hypothesis involving the bivariate analysis and multivariate analysis of exercise outcome expectation as a dependent variable of Aim 4 was supported. Literacy was not significant in any of the models, as was the case in bivariate and multivariate analysis.

Conclusion

Since intervention was significant in the model where exercise outcome expectation was the dependent variable, the third step to show mediation where exercise outcome expectation is the independent variable is required and hence will be analyzed. However, since intervention was not significant in the model where helplessness was the dependent variable, there was no mediation, and the third step where helplessness is the independent variable is not required.

Exercise outcome expectation as the independent variable

Bivariate and multivariate models were run. For the multivariate, four separate linear models were run, each for a final arthritis outcome, namely: final HAQ, final pain, final fatigue and final stiffness (Table 4.6 - Table 4.9). Exercise outcome expectation was an independent variable along with literacy variable. The literacy variable was dichotomized as low literacy vs. adequate literacy. In addition to the literacy variable and exercise outcome expectation, intervention was also included. The intervention variable was dichotomized as control vs. intervention. Intervention and exercise outcome expectation are variables of primary interest in this model. Each model was controlled for the respective baseline arthritis outcome, age, gender, race, body mass index, educational status, marital status and work status.

Bivariate analysis

A unit increase in exercise outcome expectation was associated with 0.13 unit (95% CI = -0.22 to -0.04) less functional disability (Table 4.6). Further, a unit

increase in exercise outcome expectation was associated with 4.1 units (95% CI = -7.7 to -0.41) less pain (Table 4.7). Similarly a unit increase in exercise outcome expectation was associated with 4.9 units (95% CI = -8.8 to -0.9) less fatigue (Table 4.8). Lastly, a unit increase in exercise outcome expectation was associated with 3.07 units (95% CI= -6.7 to 0.61) more stiffness (Table 4.9).

Multivariate analysis

Four separate linear models were run, each for a final arthritis outcome, namely: final HAQ, final pain, final fatigue and final stiffness. Exercise outcome expectation was an independent variable along with the literacy variable. The literacy variable was dichotomized as low literacy vs. adequate literacy. In addition to the literacy variable and exercise outcome expectation, intervention was also included. The intervention variable was dichotomized as control vs. intervention. Intervention and exercise outcome expectation were variables of primary interest. Each model was controlled for the respective baseline arthritis health status, age, gender, race, body mass index, educational status, marital status and work status.

Final HAQ

Higher exercise outcome expectation was associated with a significant increase in functional disability in the bivariate model, but lost its significance in the multivariate model (Table 4.6). The widowed had 0.17 units (0.07 - 0.27) more functional disability than the married. This value has been consistent in Specific Aim 1 and 2. The disabled compared to retired participants had 0.27

units (95% CI = 0.14 - 0.40) more functional disability. Again, this value has been consistent through Specific Aims 1 and 2.

Final pain

Higher exercise outcome expectation was associated with less pain in the bivariate model, but lost its significance in the multivariate model (Table 4.7). As seen in Specific Aim 2, Specific Aim 4 in this model too showed that the intervention group had 6.33 units (95% CI = -11 to -1.5) less pain than the control group. Since intervention was significant, the literacy*intervention interaction was included in the model, but was not significant. Also males had 7.7 units (95% CI = 0.32 – 15.14) more pain than females.

Final fatigue

Higher exercise outcome expectation was associated with significantly less fatigue in the bivariate model, but lost its significance in the multivariate model (Table 4.8). Being disabled was associated with 12 units (95% CI = 3.5 - 20) more fatigue compared to retired individuals.

Final stiffness

No variables showed significance in this model (Table 4.9).

Summary

Exercise outcome expectation was significant in each bivariate model for final HAQ, final pain, final fatigue, but not for final stiffness. However, in the multivariate models exercise outcome expectation lost its significance for final HAQ, final pain and final fatigue. Intervention was significant in the model where final pain was the dependent variable (Table 4.7). However, this was not the

case for final HAQ, final fatigue and final stiffness (Tables 4.6, 4.8 and 4.9). My hypothesis involving the multivariate longitudinal analysis of Aim 4 (first part) with exercise outcome expectation as an independent variable showed that exercise outcome expectation did not mediate the effect of intervention on arthritis outcomes. Hence my hypothesis was not supported.

4.4.8. Specific Aim 4- second part

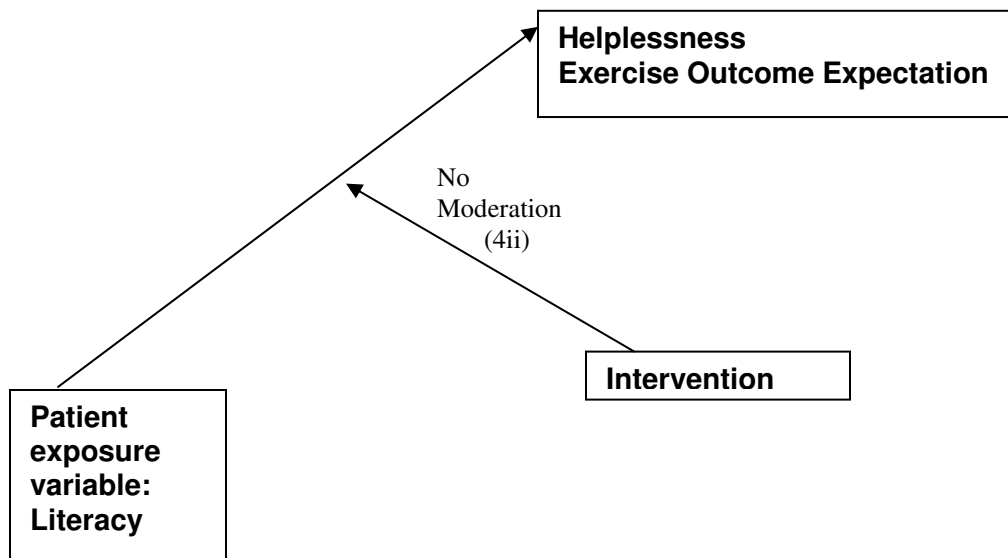
To determine if literacy has a different impact on helplessness and exercise outcome expectation for those exposed to the intervention and those who were not exposed to intervention, two models are run. In the first model, helplessness is the dependent variable with literacy, and intervention as independent variables. Since literacy and intervention were not significant, the literacy*intervention interaction could not be included. Since the interaction was not included, this model was exactly the same as the model in Specific Aim 4 (first part), where helplessness was the dependent variable (Table 4.11), and hence has not been discussed again.

In the second model, exercise outcome expectation was the dependent variable with literacy, and intervention as independent variables. Literacy*intervention interaction would be the primary variable of interest. Since intervention was significant, the literacy*intervention interaction was included. Since the interaction was not significant, this model was exactly the same as the model in Specific Aim 4 (first part), where exercise outcome expectation was the dependent variable (Table 4.12), and hence has not been discussed again.

Summary

Literacy was not significant in both of the models. Intervention was not significant in the model with helplessness as the dependent variable, but was significant in the model with exercise outcome expectation as the dependent variable. However, the literacy*intervention interaction was not significant in this case. My hypothesis of Aim 4 (second part) that literacy affects helplessness and exercise outcome expectation differently for individuals exposed to and not exposed to life style interventions was not supported (Figure 4.7).

Figure 4.7: Result for Aim 4ii



Chapter 5 Discussion and conclusion

This chapter provides a summary of the study and a discussion of the major findings from the four specific aims. Next, the implications for future research and practice are discussed. It concludes with study limitations and conclusions.

5.1 Summary of study

This dissertation consisted of 4 specific aims. The first aim evaluated the associations between literacy and arthritis outcomes. The analysis was cross-sectional and longitudinal using data from two completed RCT's of life style interventions designed for sedentary adults with arthritis, namely PACE and ALED. These results could increase our understanding of the impact of literacy on measurable health outcomes, and further help to understand the causal pathway through which literacy affects health.

The second aim was whether life style interventions have a differential short term impact on arthritis outcomes for individuals with low and adequate literacy. The analysis was longitudinal. These results could inform the development of life style interventions for low literacy individuals. Further, the second part of this aim analyzed whether literacy has a differential impact on arthritis outcomes for those exposed and those not exposed to life style interventions. These results could inform the development of literacy skills for low literacy individuals who are not exposed to intervention vs. those exposed.

The third aim assessed the impact of helplessness and exercise outcome expectation on the relationship between literacy and health outcomes, by mediation. This analysis was longitudinal, and the results could update the progress of psychosocial factors like helplessness and exercise outcome expectation especially in low literacy individuals.

Finally, the fourth aim assessed the impact of helplessness and exercise outcome expectation on the effectiveness of the intervention in improving health outcomes, as a mediator. These results could put in focus the development of psychosocial factors of individuals undergoing intervention, especially low literacy individuals, for improving health outcomes. Further the second part of this aim examined if literacy affects helplessness and exercise outcome expectation differently for individuals exposed to and not exposed to life style interventions. The analysis was longitudinal using both PACE and ALED. These results could enlighten us if development of literacy skills for individuals with low literacy could positively affect helplessness and exercise outcome expectation in individuals not exposed to the intervention vs. those exposed to the intervention.

5.2 Prevalence of low literacy

Twenty percent (89), of the arthritis individuals in the two RCT's PACE and ALED had low literacy (REALM score < 60). These results are comparable with the arthritis literature. In the prospective cross-sectional study in a tertiary referral centre by Gordon and colleagues (2002), 15% had low literacy (REALM score < 60). Similarly, 24% of patients in a community based rheumatology

practice had low literacy (Buchbinder et al., 2006). However, in an analysis by Pincus and colleagues (2000) in an academic rheumatology clinic, 12.5% patients had REALM scores < 60. Our study is different from other arthritis studies, as it is the only study which recruited adults from urban and rural non-clinical settings across North Carolina, unlike other studies which were in clinical settings like academic, tertiary, or community rheumatology practices.

Although the prevalence of low literacy in our population is within the reported range in the arthritis literature, the systematic literature found that 25-50% of adults in the outpatient medical settings had low literacy (Paasche-Orlow et al., 2005). Further, Gazmararian and colleagues (1999) reported low literacy in 27% to 44% of new Medicare enrollees in 4 large US cities. The lower prevalence reported in our study may be due to publication bias, which limits publication of data on populations without high rates of low literacy. Moreover, researchers conducting literacy research, do so in settings that have high rates of low literacy. In the systematic review by Paasche-Orlow and colleagues (2005), it was clear that investigators conduct research in medical settings that provide care for subjects with low socioeconomic status, unlike our study which was done in a community setting. This to some extent accounted for the over representation of black subjects which was 55% of the pooled analysis, unlike our study where black subjects were only 17%. Further, 37% of the pooled analyses subjects had less than high school education, but in our analysis, only 11% had less than high school. Since we did not perform any test of cognitive capacity (though mental competency was roughly estimated), unavailability of

cognitive capacity testing may have resulted in an underestimate of low literacy in our study with elderly arthritis individuals. Also, this study may have been influenced by participation bias. People with low literacy may less frequently take part in research (Baker DW et al., 1996; Parikh NS et al., 1996). Characteristics associated with low literacy included male gender, black race, and fewer years of school completed. This finding is coherent with previous research ((Paasche-Orlow et al., 2005).

5.3 Literacy and educational status

Although low literacy was moderately and significantly associated with less than high school (0.43, $p < 0.001$), 5% of the individuals who had not completed high school, had adequate literacy. Conversely, almost 62% of the individuals with low literacy had high school education or above. Furthermore, 27% of the individuals who had some college, associate, bachelors or even postgraduate degree had low literacy. This finding is consistent with previous research showing that years of school completed is an inaccurate indicator of someone's true educational attainment (Kirsch IS et al., 1993; William MV et al., 1995; Baker DW et al., 1999; Gazamararian JA et al., 1999).

Literacy and educational status probably have bidirectional causal relationships, and both may operate in the same causal pathway for health outcomes (Wolf, Gazmararian, & Baker, 2005; Dewalt and Pignone, 2005). Including literacy and education in the same model may over adjust and lead to an underestimate of the association. Moreover, as the association between low

literacy was moderate and significant; two models were analyzed: literacy alone and both literacy and the number of years of school completed. When the first model with the dichotomized literacy variable was analyzed, literacy remained not significant. Later, the second model was analyzed with both literacy and education, and similar results were obtained. Hence, there was no difference in either the significant variables or their point estimates in the two models. Therefore, it was decided to analyze the model with educational status. In the worst case scenario, adjusting for education may have changed the magnitude of the association between literacy and health outcomes; however, in this case there was no effect on the magnitude of the association.

5.4 Findings from Specific Aim 1

The data suggest that there is no significant association between literacy and arthritis outcomes, namely HAQ, pain, fatigue and stiffness. Similarly in the prospective cross-sectional study by Gordon and colleagues (2004), low literacy did not affect the HAQ score. However, low literacy patients had three times more hospital visits compared with age- and sex-matched rheumatoid arthritis controls over the previous 12 months. This study did not examine the association between literacy and other arthritis outcomes, namely pain, fatigue and stiffness. Pincus and colleagues (2000) in an abstract reported that patients with low literacy had higher functional disability, pain, and global status, indicating poorer status. Since there is a paucity of studies examining the association between literacy and arthritis outcomes, we looked at studies examining educational

attainment in arthritis patients. There are three previous studies which examined educational attainment in arthritis patients. In 1989, Callahan and colleagues reported that patients with rheumatoid arthritis (RA) who had not completed high school showed poorer clinical status than patients who had completed high school. Later in 2004, Ward and colleagues found that among whites, higher education levels were associated with lower mortality due to systemic lupus erythematosus. These associations were not present in ethnic minorities, probably due to under ascertainment of deaths due to systematic lupus erythematosus in less-well educated persons. Pincus and colleagues (2004) found that functional disability and low formal education were significant predictors of premature mortality for patients with rheumatoid arthritis (RA) over a 10-year period in 15 private practice rheumatology settings. Cross-sectional studies assessing the relationship between literacy and health outcomes for various conditions as diabetes, hypertension, HIV infection, depression, migraine headaches, late-stage prostate cancer have yielded mixed results (Literacy and health outcomes, 2004).

5.5 Findings from Specific Aim 2

The data suggest that intervention did not improve short-term arthritis outcomes differently for individuals with low and adequate literacy. Further, literacy did not have a differential impact on arthritis outcomes for those exposed versus those not exposed to life style interventions. To date, there are no longitudinal studies in arthritis that have examined whether interventions improve

arthritis outcomes in low literacy individuals. However, there are five longitudinal studies that examined whether interventions improved health outcomes in conditions like diabetes, heart failure and depression (Rothman et al., 2004 a; Rothman et al., 2004 b; Weiss et al., 2006; DeWalt et al., 2006; Sisk et al., 2006). In one study, low literacy oriented medication management interventions were offered to type 2 diabetes patients with poor glycemic control. Glycosylated hemoglobin (HbA1c) values were collected prior to enrollment, and 6 months after enrollment. The diabetes program significantly improved HbA1c values independent of literacy level (Rothman et al., 2004 a). Rothman and colleagues (2004 b) showed that a diabetes disease management program that addresses literacy level may be particularly beneficial for patients with low literacy. A recent longitudinal randomized controlled trial with one-year follow up showed that depression severity was lower among participants receiving a targeted literacy training intervention in addition to standard treatment than depression severity among participants receiving only standard depression treatment (Weiss et al., 2006). A primary care-based heart failure self-management program designed for patients with low literacy reduced the risk of hospitalizations or death. This difference was larger for patients with low literacy than for those with higher literacy (DeWalt, 2006). The interventions in the above 4 studies were specifically designed to accommodate low literacy patients (Rothman et al., 2004; Rothman et al., 2004; Weiss et al., 2006; DeWalt et al., 2006). However, our study was not specifically designed to accommodate low literacy patients.

Further, three out of the four above mentioned studies considered $\leq 6^{\text{th}}$ grade for patients with low literacy. We would have preferred to dichotomize the literacy variable at 6^{th} grade as is the case in a number of studies. The scale developers have suggested that patients with REALM score ≤ 44 will have the most difficulty to function in the healthcare setting (Davis et al., 1996). However due to a small number of individuals at $< 6^{\text{th}}$ grade, we dichotomized the literacy variable at 9^{th} grade.

5.6 Findings from Specific Aim 3

The data suggest that there was no impact of helplessness and exercise outcome expectation on the relationship between literacy and health outcomes, by mediation. However, helplessness predicted symptoms of pain, fatigue and stiffness. Prospective studies of rheumatoid arthritis patients support the central role of helplessness as a predictor for level of pain, disability, and depression over time (Evers et al., 2001; DeVellis and Blalock, 1992; Smith et al., 1994). However, there are no studies which have studied the mediation role of helplessness in the relationship between literacy and health outcomes in arthritis patients. In 1996, Callahan and colleagues showed that helplessness mediated a component of the association between formal educational level and 5-year mortality in RA patients. The study showed that higher mortality in RA patients was associated with both higher helplessness scores and lower levels of formal education.

If an older adult does not believe exercise will improve health or function, it is unlikely that regular exercise will be practiced (Resnick, 2003). The literature has shown a consistently positive relationship between outcome expectations and related behavior (Resnick et al., 2000; Brassington et al., 2002). Although, outcome expectations have received less attention than self-efficacy in the literature, there is strong support for the relationship between outcome expectations and physical activity (Conn, 1998; Jette et al., 1998; Resnick et al., 2001). However, there is no literature examining the mediation role of exercise outcome expectation in the relationship between literacy and health outcomes in arthritis patients.

5.7 Findings from Specific Aim 4

The data suggest that there was no impact of helplessness and exercise outcome expectation on the effectiveness of the intervention in improving health outcomes, by mediation. Further, literacy did not affect helplessness and exercise outcome expectation differently for individuals exposed to and not exposed to life style interventions. Life style interventions resulted in increase in exercise outcome expectation, but not helplessness. In 1995, Parker and colleagues examined the effect of stress management intervention on health outcomes of RA patients. The stress management intervention showed improvement on measures of helplessness. Similarly, in an arthritis self-care intervention with 12 months follow up in a pretest-posttest study design, intervention had a positive impact despite different levels of formal education

among the groups. Goeppinger and colleagues (1989) examined the effectiveness of the 'Bone up on Arthritis'. The intervention model had a statistically significant positive impact on perceived helplessness. The booklets for the lessons were written at a sixth-grade reading level. Despite pretest differences in knowledge and pain among groups with different levels of formal education, both the direction and magnitude of changes over time were similar.

5.8 Implications for future research and practice

A unique nature of this study was that the RCT was in a community setting with relatively healthy population. One result of this would be lack of congruity of my findings with the literature, as other studies had patients from clinical settings. This initial examination of the conceptual model was promising and suggests a number of paths for future research. First, research is needed to examine the association between literacy and health outcomes. This dissertation was a good attempt at examining the association between literacy and health outcomes. The health outcomes examined were arthritis outcomes specifically arthritis symptoms and self-reported functional status and did not establish a positive association. Future studies could include multiple arthritis outcomes like performance tests and depression. It would be of significance to investigate whether and how literacy affects self-report of health outcomes, and to this end, designing questionnaires that are consistent across literacy levels would be beneficial. Further, there are a variety of literacy measures and cut points, which makes comparison among studies difficult. Refinement and standardization of

literacy measures will help comparison among studies easier, and add to the body of literacy literature.

Second, prospective cohort studies that measure changes in health outcomes and literacy over time are required to understand the causal pathways (including mediators) through which literacy influences health. To date, there are only five longitudinal published studies that have examined whether interventions improve health outcomes in low literacy patients with chronic diseases; namely diabetes, depression and heart failure (Rothman et al., 2004; Rothman et al., 2004; Weiss et al., 2006; DeWalt et al., 2006; Sisk et al., 2006). To the best of our knowledge, there are no published longitudinal studies in other chronic diseases like arthritis that have examined whether interventions improve health outcomes in low literacy individuals. This dissertation was a good first attempt to determine whether life style interventions have a differential impact on arthritis outcomes for individuals with low and adequate literacy. Further, this dissertation was the first attempt to examine if literacy has a differential impact on arthritis outcomes for those exposed and those not exposed to the life style interventions.

However, the life style interventions were short term and did not yield positive results. Future studies could assess the effectiveness of interventions over a long period of time to examine if the interventions mitigate the effects of low literacy.

It is often assumed that improved written communication can improve health outcomes. Improving information delivery alone may not mitigate the observed relationship between low literacy and poor health (Literacy and health

outcomes, 2004). Addressing helplessness, exercise outcome expectation may increase the understanding of effective strategies for addressing poor health outcomes. Third, research is needed to identify mediators that may mediate the effect of low literacy on health outcomes. This dissertation was a first good endeavor in this direction assessing the impact of helplessness and exercise outcome expectation on the relationship between literacy and health outcomes. Helplessness and exercise outcome expectation did not mediate the effect of low literacy on health outcomes. However, helplessness and not exercise outcome expectation predicted arthritis symptoms, namely, pain, fatigue and stiffness. Future studies could examine helplessness and exercise outcome expectations in long term interventions besides other mediating factors like self efficacy, trust in provider, provider satisfaction etc. that could impact the relationship between literacy and health outcomes.

Lastly, research is needed to assess the effect of psychosocial variables on the effectiveness of the intervention in improving health outcomes of low literacy individuals. This dissertation made a good effort to study the impact of psychosocial variables like helplessness and exercise outcome expectation as mediators on effectiveness of the intervention in improving health outcomes. Also, this dissertation tried to determine if literacy has different impact on psychosocial factors like helplessness and exercise outcome expectation for those exposed versus those not exposed to intervention. The results were not positive. Future research can examine other mediators like trust in health provider, self efficacy etc. that may mediate the effect of intervention on health

outcomes. Further, researchers could examine if intervention moderates the relationship between literacy and psychosocial variables.

All these paths for further research would help develop interventions specifically designed for individuals with low literacy. Further directions in research could address how much intervention is adequate to improve health outcomes in low literacy individuals. Also, which components of interventions are specifically beneficial to improve health outcomes in low literacy individuals could be addressed.

5.9 Limitations

- a. The RCT's were conducted in non clinical community settings in North Carolina with relatively healthy population, and this may not be generalizable to patients in other clinical settings.
- b. The duration of intervention was different for the two studies; in PACE the duration was 8 weeks and in ALED the duration was 20 weeks. However, since PACE class met twice a week for one hour; this was a 16-lesson intervention and ALED (the class met once a week for one hour) was a 20-lesson intervention.
- c. PACE was an exercise intervention, and ALED was a behavioral modification intervention. However, the main objective of both the interventions was to increase physical activity.
- d. Follow up assessments at 6 months was done only in the intervention group. This prevented us from studying the outcomes in the control group

at the end of 6 months. Hence we studied the outcomes at the end of intervention to optimize the benefit of including the control group.

- e. Both studies were not targeted towards low literacy individuals.
- f. The power for arthritis outcome pain in aim 2 was not adequate. Power calculation for aim 3 and 4 was not possible. However, since there was no trend of association, inadequate power was probably not an important issue in deciding conclusions.
- g. Literacy was measured by REALM, which has limitations. While it tests print literacy and touches on oral literacy, it does not test numeracy at all. Further, a study comparing REALM performance in African-American and Caucasians, found a substantial discordance in scores even when stratified by education level (Shea et al., 2004) However, the entire test can be administered in 3-4 minutes. This was essential as the participants had a number of questionnaires to fill up, besides doing the self-reported and performance tests. Further, REALM is one of the best tests available. Future research in measuring literacy should allow us to capture all aspects of literacy.
- h. We would have preferred to dichotomize the literacy variable at 6th grade as is the case in a number of studies. The scale developers have suggested that patients with REALM score ≤ 44 will have the most difficulty to function in the healthcare setting (Davis et al., 1996). However due to a small number of individuals at $< 6^{\text{th}}$ grade, we dichotomized the literacy variable at 9th grade. This could have biased our results showing no trend

of association. The relationship between literacy and health outcomes may not be linear. It is possible that the effect of literacy has a threshold, above which, variance in literacy has little effect on outcomes. It may be that patients with very low literacy (those who read below the 6th grade level) could have worse arthritis outcomes than those with higher literacy. As such, we cannot definitively conclude that literacy is not important among patients with arthritis.

- i. No tests for detecting poor vision or cognitive impairment were performed. However, participants were excluded if mental status did not allow them to complete the questionnaire.
- j. All the health outcomes measured in this study were self-reported like HAQ, pain, fatigue stiffness etc. Literacy may affect the quality of data collected by self-report questionnaires (Sentell and Ratcliff-Baird, 2003). This may be important when using Likert-type scale especially the negatively worded items (Williams and Swanson, 2001). Our study had two Likert-type scales, namely helplessness and outcome expectation, and items like neither agree nor disagree may have caused confusion for low literacy individuals. Further, most questionnaires are not validated in low literacy populations; raising questions as to the ability of low literacy individuals to perform up to similar standards of adequate literacy individuals. For example, only the VAS pain score has been tested in low literacy patients. The test-retest coefficient is 0.71 in low literacy patients, compared to a high test-retest reliability coefficient of 0.93 in literate

patients (Burckhardt and Jones, 2003). Perhaps, future studies in arthritis could measure other health outcomes such as performance based tests which are measured by the physical therapist and self-reported questionnaires which are measured orally.

- k. It would be of special interest to observe health outcomes over a period of 1 or 2 years. However due to time and financial constraints, these data could not be collected.

5.10 Conclusion

One in five of the patient population had literacy below the 9th grade level. In this sample, participants with low literacy did not have worse arthritis health outcomes than individuals with adequate literacy. Further, low literacy did not modify the effect of intervention on arthritis outcomes. When literacy, helplessness and exercise outcome expectation were examined as predictors of arthritis outcomes in lifestyle intervention trials; neither literacy, nor psychosocial variables predicted disability. However, helplessness was associated with worse pain, fatigue and stiffness.

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