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Improving Chronic Constipation Health Literacy Proficiency: Animation Versus Traditional Written Pamphlets

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Abstract

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MS, University of Michigan, 2012

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Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

The U.S. health care system is evolving from medical centric to patient centered, augmenting the importance for patients to comprehend and process medical information. The Department of Education indicated that 77 million Americans have a basic or below basic health literacy proficiency and 12% register as health literacy proficient. Animation is a time-tested device for improving health by enhancing comprehension. Chronic constipation (CC) complexity entails physiological, anatomical, and environmental mechanisms. Using the cognitive theory of multimedia learning and dual-channel auditory and visual processing, the primary research question addressed whether an animated educational video improved health literacy for CC more than a traditional written educational pamphlet. A secondary dataset of 100 CC subjects from the University of Michigan was collected using a cross-sectional study design with a convenience sampling strategy of CC patients who underwent anorectal functional testing. Dependent variables were CC Pretest Quiz and CC Posttest Quiz scores, and independent variables included CC education intervention, demographics, health literacy proficiency, and environmental learning variables. Descriptive and analytical statistical methods were employed for data summarization and comparison. The animated educational video had minimal impact ($p = 0.20$) on improving health literacy; however, pretest scores ($p \leq 0.001$), age ($p = 0.03$) and highest level of education achievement ($p = 0.03$) influenced the largest variance between quiz scores. Enhancing health literacy influences social change by empowering individuals with CC to improve quality of life metrics, increase work productivity, and decrease health care utilization costs.

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Dedication

I would like to dedicate this dissertation to my best friend and wife, Laura Jean Tomlinson-Baker, mentors, and parents/parents in law. Each of these individuals challenge me to strive for improving myself daily. These individuals have provided opportunities and encouragement to complete this dissertation journey.

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I am truly grateful for my chair Dr. Raymond Panas. Through serendipitous circumstances at Residency 1 in Atlanta, GA, Dr. Panas and I developed a professional rapport intertwined with a passion for Gastroenterology and a common colleague Dr. William Chey. I am deeply appreciative for his judicious responses, thought provoking commentary, and overall support.

I would like to thank my committee member, Dr. Cynthia Newell for her insight pertaining to my dissertation's topic. The comments provided during each chapter review and presentation defense fortified the final document.

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to recognize our pastor at Metro City Church, Jeremy Schossau, for providing Laura and I with deep understanding for how Jesus died for us to be blessed with our life.

Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction to the Study

Introduction

Contemporary information technology platforms pertaining to health literacy have exponentially grown in utilization and preference over the past two decades. Unfortunately, barriers associated with modern health literacy educational tools such as accessibility, expense, and comprehension may limit the educational apparatus efficacy (Bickmore & Paasche-Orlow, 2012). Thus, health literacy educational platforms must be targeted to incorporate a wide spectrum of health literate individuals to improve global health literacy proficiency. Integrating technology with traditional educational platforms has been demonstrated to counteract health care outcomes related to low health literacy (Wickham & Carbone, 2013). Regardless of age-bracket, an increasing percentage of U.S. citizens use modern technology to communicate and as a primary learning tool (González, Ramírez, & Viadel, 2015). Therefore, contemporary technology provides a platform to improve health literacy proficiency for both global and specific diseases and disorders.

Contemporary technology, especially in the format of e-Learning, has advantages related to accessing large number of individuals quickly and cost-efficiently. Data have depicted a high level of satisfaction by the learner exploring e-Learning resources to foster health comprehension (Sukanlaya, Cameron, & Jamieson, 2013). Even though e-Learning options are abundant, the literature illustrated the strength for utilizing animation as a prominent e-Learning health educational platform. Animation improves long-term comprehension and recall ability by limiting cognitive load capacity (Wong et

al., 2009). The cognitive theory of multimedia learning (CTML) details that comprehension learning is achieved when both auditory and visual cognitive memory channels are refrained from cognitive load capacity (Mayer, 1997). Therefore, animation provides learning through visual and auditory stimuli, simultaneously fostering greater long-term memory compared to traditional single stimulus methods (Meppelink, van Weert, Haven, & Smit, 2015).

Health research projects with underserved cohorts have been scarce compared to dominant populations. Regrettably, this discrepancy in the literature has contributed to health disparities and discordant communication between investigators and minority populations. A study by George, Moran, Duran, and Jenders (2013) elucidated evidence for animation as primary educational e-Learning platform to improve communication between investigators and minority cohorts; moreover, minority individuals expressed a greater willingness to participate in health science research projects if animation was used as the educational intervention. Animation may provide an educational platform to minimize the gap in the literature regarding health determinants and health outcomes between underserved populations and their counterparts.

Functional bowel disorders are highly prevalent globally. Chronic constipation (CC) is included in this disorder spectrum. The prevalence rate for CC is up to 27% in the United States (Higgins & Johanson, 2004). CC is a complex symptom-based disorder with a diverse profile ranging from fecal soiling to obstructed defecation (Heidelbaugh, Stelwagon, Miller, Shea, & Chey, 2015). Consequently, individuals with CC must comprehend etiological reasons for CC to enhance treatment outcomes and improve

quality of life. Prior to this study, CC health literacy proficiency data were nonexistent. Animation has been studied as an education intervention for improving colonoscopy preparation versus traditional pamphlets with motley results (Kurlander et al., 2016). A CC animated educational video provides a platform to use a childlike approach for cultivating constipation comprehension in an adult cohort.

This chapter briefly describes the peer-reviewed literature related to health literacy and animation, societal impact of CC, and gap in the literature pertaining to CC health literacy proficiency. Additionally, the problem statements and purpose of this study are defined. Lastly, the research questions, critical terminology, and limitations of this study will be delineated. Chapter 2 will provide substantially more historical and conceptual details regarding health literacy proficiency, CC, and animation as an educational intervention.

Background

Navigating the complex U.S. health care system is daunting. As this system transitions from a medical professional centric viewpoint to more personal (patient-centered) responsibility, the patient's ability to comprehend and process complicated information is increasingly important. According to the U.S. Department of Education (2006), approximately 77 million American adults have a basic or below basic health literacy proficiency and only 12% register as health literacy proficient. Several predictor variables have demonstrated a greater yield for lower health literacy proficiency; lower socioeconomic status, education level, and race (Furuya, Kondo, Yamagata, & Hashimoto, 2015; Heide et al., 2013; Kaphingst et al., 2015). Lower health literacy

proficiency as an independent factor has been associated with higher health care utilization and cost after controlling for individualistic characteristics and social variables (Haun et al., 2015).

Functional gastrointestinal disorders (FGID) symptoms, such as CC, diarrhea, and abdominal pain, are responsible for 60% of doctor visits per year within the discipline of gastroenterology (Perry et al., 2012). Constipation is one of the most commonly encountered gastrointestinal complaints in clinical practice. The most recent epidemiological constipation systematic review reported that the prevalence of CC in North America was between 10% to 15% (Higgins & Johanson, 2004). Individuals with CC experience a reduced quality of life compared to healthy counterparts (Koloski, Jones, Wai, Gill, & Talley, 2013). Further, individuals with CC utilize significantly more health care resources and less work productivity (Sun et al., 2011).

Traditional methods, written pamphlets, utilized for educating and instructing often elicit reluctance by patients to express the inability to understand material while verbally and nonverbally signaling comprehension to the health care provider (Ross, 2013). Unfortunately, traditional education mediums, such as written pamphlets, have demonstrated low health literacy proficiency for common gastrointestinal tests, such as colonoscopy (Smith et al., 2012). Low health literacy has been a predictor for reducing patient safety during a colonoscopy prompting several endoscope intubations and additional sedative medication resulting from inadequate bowel lavages (Smith et al., 2012). Furthermore, health literacy level impacts gastroenterology economics by

increasing the percentage of repeat colonoscopies for inadequate bowel preparation (Calderwood, Lai, Fix, & Jacobson, 2011).

Health informatics researchers have depicted that patient populations with lower health literacy proficiency are amenable to visual multimedia; this platform includes digital content and audio-video programming (Calderón, Singer, Heslin, & Baker, 2007). Attitudes toward medical treatments and general personal health care directly influence health literacy proficiency. Video-based educational approaches have shown to improve patients' attitudes and decreased anxiety (Boonviriya, Ratanalert, Saengnil, Naowarat, & Ovartlarnporn, 2016). Animation is perceived as the dominant educational tool for technology-based learning, implementing visualizations for abstract concepts (Musa, Ziatdinov, & Griffiths, 2013). Animation tends to retain focus of viewers, enhancing recollection of material and information (George et al., 2013). Animated videos allow creators to control how the critical symbolism and key concepts are conveyed (Champoux, 2005). Educational material in the format of active visual representations in combination with spoken vernacular produced greater information recall and improved attitude compared to written messages (Meppelink et al., 2015). Animation provides an operational method for positively affecting health literacy barriers regardless of culture by emphasizing the health information gap and fostering clinically relevant dialogue between patient and provider (George et al., 2013).

Improving health literacy pertaining to a disease or illness has positive deductive outcome for the individual and society, especially as health care in Western world progresses more toward a greater sense of personal responsibility. Patients have shown to

recall only 29% to 72% of medical information delivered by a health care provider or in a written format (Ley, 1982). By using a contemporary approach to enhance recall comprehension, patients may develop improved mechanisms coping with CC. Strengthening CC symptom recognition by improving CC health literacy will directly ameliorate quality of life metrics: physical, mental, social, and functional. Individuals suffering from CC have less work productivity and more health care utilization costs compared to nonconstipated individuals (Sun, 2011). Therefore, by improving CC health literacy proficiency, as a society, constipated employees of organizations/employers may produce greater productivity and decrease economic burden on the health care system.

Previous evidence for empirically examining the impact of a CC animated educational video for improving CC health literacy proficiency was not available. The complexity of CC entails a lack of specificity of symptoms, inconsistent underlying pathophysiology, medication influences, and environmental mechanisms (Hussain, Everhart, & Lacy, 2015). Therefore, my goal with this dissertation was to examine the effect of a contemporary, less-expensive, and culturally accepted CC medium compared to a traditional CC written educational pamphlet. Furthermore, these data showed whether using modern educational platforms, such as animation, improves health literacy proficiency related to specific diseases/disorders, empowering individuals to comprehend the outcomes of medical decisions.

Problem Statement

Low health literacy proficiency has direct and indirect consequences at the individual and societal levels. As health care transitions from medical professional centric

to patient centered, the growing importance for patients to comprehend complicated anatomical and physiological processes related to their specific disease/disorders for better treatment outcomes is increasingly paramount. According to the U.S. Department of Education (2006), approximately 77 million American adults have a basic or below basic health literacy proficiency, and only 12% register as health literacy proficient. Animation as an educational intervention has demonstrated positive results for improving health care comprehension compared to traditional methods in pediatric and surgical literature. The data pertaining to specific gastroenterology symptom-based disorders did not exist prior to this study. Therefore, because approximately 63 million North American adults have CC, an effective CC health literacy educational tool is required to enhance this cohort's health literacy proficiency to improve quality life and decrease economic resources utilization (Higgins & Johanson, 2004).

Purpose of the Study

The purpose of this quantitative study was to explore the efficacy of a CC animated educational video compared to CC traditional written pamphlets using a CC cross-sectional study design. Additionally, I investigated the relationship between health literacy level, environment determinants, and biological variables in relation to pretest/posttest scores. The dependent variables were the CC Pretest Quiz and CC Posttest Quiz scores. The predictor variables included CC educational intervention, health literacy level, age, sex, body mass index (BMI), highest level of education achievement, socioeconomic status, and barriers to learning.

Research Questions and Hypotheses

The following research questions were addressed in this study:

RQ1: Is there a statistical mean difference between the CC Pretest Quiz and the CC Posttest Quiz following randomization into either the CC traditional written educational pamphlet or the CC animated education video?

$H_0$1: There is no statistically significant mean difference between the CC Pretest and CC Posttest Quiz scores following randomization into either the CC animated educational video or CC traditional written educational pamphlet intervention.

H_a1: There is a statistically significant mean difference between the CC Pretest and CC Posttest Quiz scores following randomization into either the CC animated educational video or CC traditional written pamphlet intervention.

RQ2: What is the relationship between health literacy proficiency level and CC Pretest Quiz score?

$H_0$2: There is no relationship between health literacy proficiency level and CC Pretest Quiz score?

H_a2: There is a relationship between health literacy proficiency level and CC Pretest Quiz score?

RQ3: What is the relationship between health literacy proficiency level and CC Posttest Quiz scores?

$H_0$3: There is no relationship between health literacy proficiency level and CC Posttest CC Quiz scores.

H_a3: There is a relationship between health literacy proficiency level and CC Posttest CC Quiz scores.

RQ4: What is the effect of the CC traditional written educational pamphlet versus CC animated educational video on the CC posttest health literacy quiz score for a cross-sectional CC population undergoing anorectal function testing controlling for the following independent variables: CC Pretest Quiz score, age, gender, race/ethnicity, highest level of education achievement, income level, employment description, level of interest toward learning, best type of learning, and challenges related to learning?

H_04: There is no effect of the randomized group on CC posttest health literacy quiz scores controlling for biological, environmental, and learning motivation variables.

H_a4: There is an effect of the randomized group on CC posttest health literacy quiz scores controlling for biological, environmental, and learning motivation variables.

Theoretical Framework for the Study

The CTML provides theoretical principles for reducing learning fatigue capacity. This theory defines the active process of learning by limiting the maximum cognitive capacity using dual comprehension mechanisms (Mayer, 2005). Thus, CTML illustrates that two separate channels, auditory and visual, are necessary for processing information. Each channel has limited learning capacity because active learning requires mechanisms for filtering, organizing, and integrating information (Mayer, 2014). Because animation requires both auditory and visual acuity compared to the tradition written pamphlets utilizing only visual learning processes, the framework of CTML offered conceptual

principles to evaluate improvement of CC health literacy via the CC animated educational video versus the CC tradition written educational pamphlet method.

Nature of the Study

This study entailed a secondary analysis from data collected at the University of Michigan pertaining to CC health literacy. Data were collected from a parallel-group cross-sectional randomized design trial using a quantitative analysis approach: a baseline health literacy measurement and a CC pretest knowledge assessment, intervention (animation or traditional pamphlet), and a CC posttest assessment. The cohort included individuals, men and women greater than or equal to 18 years of age, scheduled for anorectal function testing with a diagnosis of CC. A quantitative approach established a cause-effect relationship between the CC Pretest Quiz and CC Posttest Quiz scores following a randomized health literacy intervention: CC animated education video or a CC traditional educational written pamphlet.

The analysis plan included demographics for the entire CC cohort and individual randomized groups: CC animated educational video or CC traditional educational written pamphlet. Paired *t* tests were employed to measure mean differences between the CC Pretest Quiz and CC Posttest Quiz scores following the intervention (animation or written pamphlet). Independent *t* tests assessed mean differences between binary groups, men/women, relative to health literacy measurements, CC Pretest Quiz, and CC Posttest Quiz evaluation. Analysis of variance (ANOVA) with post hoc Tukey analysis delineated mean differences among and between groups, age brackets, socioeconomic levels, and education achievement, relative to health literacy proficiency and CC Pretest and CC

Posttest Quiz scores. A linear regression depicted predictors of individuals with CC and lower CC health literacy proficiency determined by CC Pretest and CC Posttest Quiz scores.

Definitions

A clear understanding of the critical terminology used throughout this research project is vital for complete interpretation and the societal extent of this dissertation. The following list chronicles the fundamental terms used throughout this research project.

Anorectal function testing: This test delineates pelvic floor pathophysiological mechanisms for CC and fecal incontinence symptoms (Azpiroz, Enck, & Whitehead, 2002).

Chronic constipation (CC): The American College of Gastroenterology Chronic Constipation Task Force (2005) defined CC as "unsatisfactory defecation characterized by infrequent stool, difficult stool passage or both at least for previous 3 months" (p. S1). Furthermore, CC has been associated with the following characteristics: difficulty to pass stool during defecation (incomplete evacuation), hard/lumpy stool, prolonged time to stool or need for maneuvers to pass stool (Brandt et al., 2005).

Cognitive theory of multimedia learning (CTML): A comprehension process using a dual-channel, auditory and visual, neural circuitry process to limit cognitive load capacity and cultivating long-term memory association (Mayer, 1997).

Functional gastrointestinal disorders (FGID): A heterogeneous symptom-based group of conditions exacerbating gastrointestinal symptoms without structural or biochemical abnormalities (Drossman, 2007).

Health literacy: Health literacy is "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make health decisions" (Ratzan & Parker, 2000, p. 4).

Pelvic floor dysfunction: It refers to the inability to coordinate muscles of abdominal cavity and pelvic floor to effectively evacuate stool in the absence of organic disease related to muscle and/or neurologic pathology (Rao, Welcher, & Leisikow, 1998).

Rapid Estimate of Adult Literacy (REALM): A commonly used health literacy proficiency assessment utilizing recognition of medical terms with a total correct number of responses assigned to a grade level (Davis et al., 1993).

Short Assessment of Health Literacy – English (SAHL-E): An 18-item health literacy assessment including both word recognition and comprehension aptitude (Lee, Stucky, Lee, Rozier, & Bender, 2010).

Test of Functional Health Literacy in Adults (TOFHLA): Assessment of an individual's ability for reading comprehension and numeracy knowledge capability: consisting of 50-items pertaining to comprehension and 17-items related to numeracy. The TOFHLA scoring system is divided into three levels: inadequate, marginal, and adequate functional health literacy (Parker, 1995).

Wide Range Achievement Test- Revised: A 74-item literacy instrument for screening reading, arithmetic, and spelling levels (Jastak & Wilkinson, 1984).

Assumptions and Limitations

CC is a heterogenic symptom-based functional bowel disorder. Thus, the cohort included in this cross-sectional database may not represent the entire CC population.

Regardless of whether the CC participants undergoing anorectal function testing may have experienced similar CC symptoms as other individuals with CC in the general population, their pathophysiology may have been slightly different. Secondly, because these individuals with CC had actively solicited health care advice concerning their CC symptoms, these individuals may have been more motivated and less embarrassed compared to individuals with CC suppressing their symptomology. These assumptions were considered as potential confounders to the outcomes.

The results of this project have boundaries for describing the impact of health literacy status on CC health literacy proficiency. First, selection bias may have limited the strength of the outcome for generalizing toward a global CC community. However, often many CC symptoms are expressed among all etiological CC manifestations. According to Sanchez and Bercik (2011), the North American CC prevalence rate of male and female adults ranged up to 27.2% and approximately 66% met the Rome criteria for functional CC. Functional CC is primary derived from pelvic floor dysfunction, which requires anorectal function testing to evaluate anal sphincter and rectal sensation function. Secondly, the data were collected from the University of Michigan, which is a large referral tertiary health care center. Therefore, the sample may have boundaries when compared to underserved populations and community health care centers' CC patient population. However, the University of Michigan patient population was diverse in age, ethnicity, and race. This diversity profile may extend the boundary of the results.

Overall, the outcomes provide insight to forecast the impact of health literacy proficiency for a large representation of individuals with CC. Because CC symptomology is shared among functional, medicated-induced, colonic inertia, and comorbidity derived CC, the results strengthen the importance for improving CC health literacy proficiency to increase CC etiology comprehension to enrich quality of life metrics and decrease health care utilization.

Significance

The economic burden for insufficient health literacy proficiency in the United States is approximately $106 billion to $238 billion annually (Vernon, Trujillo, Rosenbaum, & DeBuono, 2007). Constipation is the primary diagnosis for an estimated 2.5 million health care visits annually in the United States equating to $6.9 billion (Chang et al., 2010). The average mean total cost is $7,522 for health care provided to each constipated individual seeking health care (Nyrop et al., 2007). Approximately, 90% of constipated individuals seek advice for effective treatment from health care professionals (Schiller, Dennis, & Toth, 2004). As technology shapes modern society, health care, as a system construct, must devise contemporary methods for improving health literacy. Using contemporary methods for cultivating CC health literacy proficiency, constipated individuals may develop a fundamental understanding for etiological reasons manifesting CC symptomology. Using the constipation knowledge, constipated people may develop greater awareness and prevention techniques to symptoms increasing quality of life and limiting the number of work absences (Belsey, Greenfield, Candy, & Geraint, 2010; Heidelbaugh et al., 2015). Furthermore, this knowledge provides empowerment for

constipated individuals by increasing confidence in a managing a rescue remedy limiting symptom severity. By developing a personalized constipation treatment plan, constipated individuals may contribute to lowering health care expenditures by decreasing emergency room visits and hospitalizations related to constipation symptoms (Sanchez & Bercik, 2011).

Besides constipated individuals, additional stakeholders may benefit from utilizing contemporary modalities, animation, to improve CC health literacy. Data have shown that spouses (partners) of constipated individuals have a lower quality of life metrics as a group compared to single constipated individuals (Wald et al., 2007). Also, primary care physician groups and organizations might utilize this contemporary prevention approach for their constipated patients as the number of Americans living with chronic diseases/disorders have been projected to increase from 123 million to 157 million by 2020 (Bodenheimer, Chen, & Bennett, 2009). Chronic diseases/disorders have a direct impact on health care economic burden: hospitalizations, out-patient visits, and pharmacology. The results of this study provide a conceptual framework for developing inexpensive and culturally neutral material using animation for a variety of chronic conditions improving health literacy proficiency and enhancing symptom awareness.

Summary

This chapter briefly details the importance for assessing CC health literacy proficiency for both CC individual and society. As health care in North America transitions toward a more patient-centered system, this transition infers more personal responsibility for one's health care than in the previous health care constructs. This

philosophical alteration indicates the importance for understanding reasons for diseases/disorders and comprehending effective strategies to limit the impact of the disease/disorder on quality of life. CC is a highly prevalent symptom-based disorder affecting many individuals. Unfortunately, limited data and contemporary educational CC tools are unavailable for understanding CC etiology. Therefore, using a time-tested childlike approach in the form of animation, individuals experiencing CC may develop a deeper understanding for the inability to evacuate stool.

Chapter 2 provides a thorough representation of the literature related to health literacy assessment, social determinants pertaining to health literacy, direct and indirect impact of CC, and a historical review of animation as an education platform. Finally, Chapter 2 concludes by detailing the construction and utilization of the CTML.

Chapter 2: Literature Review

Introduction

This chapter provides extensive and detailed information describing the current state of health literacy in relation to social determinants. Numerous validated health literacy instruments are available to measure health literacy proficiency transcribed into a specific grade level or ordinal category. Each health literacy instrument has advantages targeting key health literacy concepts and limitations pertaining to time consumption for administering. The scientific literature isolating health literacy proficiency as a dependent variable is relatively new in scope. Therefore, methodology for measuring and health literacy proficiency and normative values are controversial and debatable.

FGID, dyspepsia, irritable bowel, syndrome, CC, and so forth, impact the quality of life of millions of people globally. FGID are common gastrointestinal disorders directly and indirectly influencing social lifestyle and health care economics. CC is a symptom-based disorder with a multifaceted etiology. The CC spectrum includes the inability to defecate, fecal incontinence from fecal overload, and hypo-rectal sensation. CC health literacy educational platforms are limited. This literature review litigates a case for utilizing animation to improve CC health literacy similar to methods employed in the diabetic and pediatric literature. The theory rationalizing a greater impact for using animation to improve health literacy proficiency is the CTML, which deploys auditory and visual channels simultaneously limiting learning capacity prior to long-term memory comprehension.

Literature Search Strategy

I organized my literature search strategy into five sections: (a) validated literacy instruments, (b) the construct of health literacy, (c) functional bowel disorders, primarily CC, (d) animation, and (e) social determinants for health literacy proficiency. After reviewing the focal objectives from numerous databases, I selected six databases for my literature search that matched the aims of this dissertation: ERIC, Education Source, PubMed, Science Direct, Psychology Databases Simultaneous Search, and Google Scholar. Following an inclusive literature search, only peer-reviewed manuscripts, relevant books, and U.S. departmental statements and position papers were included for further review. Because animation has been utilized for over a century regarding education, I did not include a specific date in terms of limiting my scope review. However, during the final review of collected information, the date of publication was taken into consideration due to relevancy toward the dissertation objectives.

My search term strategy included using Medical Subject Heading (MeSH) terms categorized by the U.S. National Library of Medicine. These MeSH terms are used to index manuscripts by key indicators. I constructed four main MeSH term categories linking these MeSH terms to keyword: (a) MeSH term Education and keywords *literacy and health literacy*, (b) MeSH term Technology and keywords *educational, audiovisual, multimedia, history, and trends*, (c) MeSH term Signs and Symptoms, Digestive and keywords *constipation and health literacy, constipation and diagnosis, constipation and economics, constipation and epidemiology, and constipation and physiology*, and (d) MeSH term Demography and keywords *health literacy and health status, health literacy*

and epidemiology, health literacy and trends, health literacy and socioeconomic, health literacy and gender, and health literacy and education status, and health literacy and income.

Health Literacy

Definition

The empirical construct of health literacy has expanded over the past decade related to personal functionality navigating the evolving health care system and evidence-based research projects. As health literacy transcends through the fabric of global society, the definition of health literacy has prompted debate and misperception among different audiences. The American Medical Association Ad Hoc Committee on Health Literacy (1999) defined health literacy as the "constellation of skills, including the ability to perform basic reading and numerical task required to function in the health care environment" (p. 553); these tasks include "the ability to read and comprehend prescription bottles, appointment slips, and other essential health-related materials" (p. 552). This definition implied that health literacy is dynamic rather than a static construct by implying that individuals must perform an active role within their own health care.

The definition of health literacy has progressed from the standpoint of an individual's ability to perform literacy skills to incorporating an individual's acquisition and processing capacity. The Institute of Medicine and *Healthy People 2010* (as cited in Ratzan & Parker, 2000) defined health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make health decisions" (p. 4). This health literacy definition introduces the

importance for the capacity of how an individual function within the health care system. These health literacy functional skills include actively participating with a health care professional during a medical encounter, comprehending and providing consent, ability to advocate for one's health rights, and a basic ability to negotiate within the health care system (Ad Hoc Committee on Health Literacy, 1999). Therefore, health literacy is multidimensional including individual and interpersonal health care factors influenced by the complex health care system and environmental factors (Yuen et al., 2016). These health literacy definitions illustrate that health literacy proficiency is an independent factor that determines health-related decisions and health care actions (Gaglio, 2016).

Meticulous definitions pertaining to health constructs provide fundamental elements for developing evidence-based approaches to overcome health disparities. The complex definition of health literacy incorporates core principles and dynamic themes required for implementing defined models depicting the interlink between the individual and health care organizations/systems to improve health literacy proficiency. Wagner, Austin, and Von Korff (1996) developed the chronic care model prompting engagement among patients, families, and health care professionals concerning health care decision processes and management. The chronic care model was utilized to formulate the health literacy care model denoting the interaction between patients and health care professionals and organizations (Koh, Brach, Harris, & Parchman, 2013). The health literacy care model was constructed to implement a strategy for the patient, health care professional, and organization to play an active role for improving health literacy proficiency and health outcome measures (Figure 1).

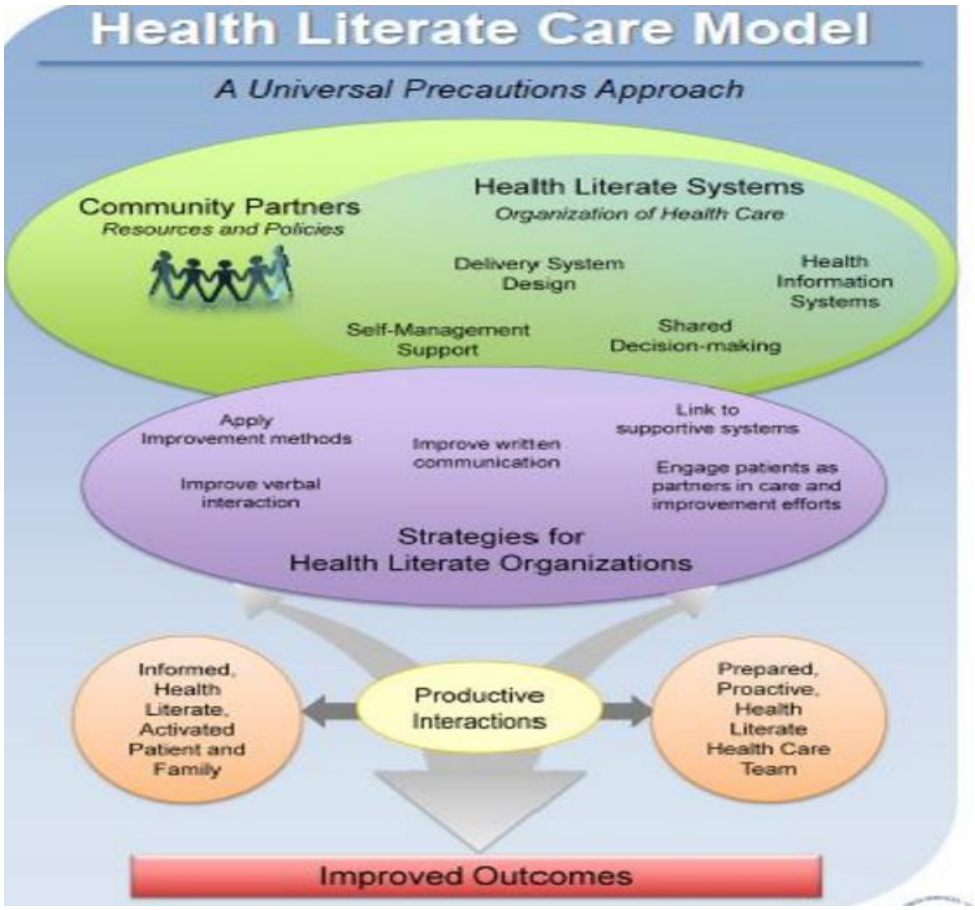

Figure 1. Health literate care model. Adapted from "A Proposed 'Health Literate Care Model' Would Constitute a Systems Approach to Improving Patients' Engagement in Care," by H. K. Koh and C. Brach, 2013, *Health Affairs, 32,* p. 358.

Measurement Instruments

Numerous health literacy measurement instruments exist, $N = 51$, assessing a variety of aspects pertaining to health literacy proficiency. Variations within these instruments have elicited inconsistencies and challenges for interpreting results (Haun, Valerio, McCormack, Sørensen, & Paasche-Orlow, 2014). The diversity of health literacy instruments primarily evaluates health literacy domains, such as print, numeracy, communication, and navigation skills rather than an individual's health literacy capacity

to comprehend and utilize the information to formulate a medical decision. General literacy proficiency refers to basic reading and speaking aptitudes; conversely, health literacy refers to the capacity to read, comprehend, and act upon health information (Andrus & Roth, 2002). Andrus and Roth (2002) and Pawlak (2005) denoted seven of the most common utilized health literacy screening assessments (Table 1).

Table 1

Literacy and Health Literacy Tests

Variable	WRAT-R	REALM	MART	SORT-R	PIAT-R	IDL	TOFHLA
Description	Word recognition test	Medical word recognition test	Medical word-recognition test using prescription bottles	Word recognition test	Reading recognition and comprehension test	Reading comprehension test	Functional health literacy test
Age	5 – 74 yrs	Adults only	High-school age	4 yrs and older	All ages	All ages	Adults only
Administration time (minutes)	3 – 5	2 -7	3 – 5	5 – 10	60	20 – 30	22 (7 for short version)
Scoring	Raw score of 1 – 57, converted to grade equivalent	Approximated grade level: 3 and 4 – 6, 7 – 8, or 9 and above	Raw score converted to grade equivalent	Results converted to age and grade equivalents	Comprehension subtest score determines grade level	0 – 8, 0 = failure at Grade 1 level, 8 = Grade 8 level or above	Inadequate, marginal, or functional health literacy
Advantages	Quick	Quick, uses medical terminology	Nonthreatening, quick	Quick	Assess comprehension	Available in Spanish	Measures functional health literacy, available in a shortened form and in Spanish
Limitations	Difficult test	Assigns only-grade-range equivalents	No clinical experience published	Small print and many items intimidating, not recommended for poor readers	Long	Long	Long version is time consuming, timed test can be frustrating

(table continues)

Variable	WRAT-R	REALM	MART	SORT-R	PIAT-R	IDL	TOFHLA
Correlation with other tests (r value)	PIAT-R 0.62 – 0.91	WRAT 0.88, SORT-R 0.96, PIAT-R 0.97, TOFHLA 0.84	WRAT 0.98	PIAT-R 0.83 – 0.90	Not available	0.65 – 0.70 with other English assessments	WRAT 0.74, REALM 0.84

Note. WRAT-R = Wide Range Achievement Test Revised (Davis, Michielutte, Askov, Williams, & Weiss, 1998; Hanson-Divers, 1997; Jastak & Wilkinson, 1993; Lasater & Mehler, 1998); REALM = Rapid Estimate of Adult Literacy in Medicine (Ad Hoc Committee on Health Literacy for the Council of Scientific Affairs, American Medical Association, 1999; Davis, 1998; Davis et al., 1993; Lasater & Mehler, 1998); MART = Medical Terminology Achievement Reading Test (Hanson-Divers, 1997). SORT-R = Slosson Oral Reading Test-Revised (Davis, 1998; Lasater & Mehler, 1998; Slosson, 1990); PIAT-R = Peabody Individual Achievement Test-Revised (Jackson, Davis, Murphy, & George, 1994; Lasater & Mehler, 1998; Markwardt, 1997;); IDL = Instrument for the Diagnosis of Reading (Blanchard, Garcia, & Carter, 1989; Davis, 1998;); TOFHLA = Test of Functional Literacy in Adults (Blanchard,1989; Nurss, Parker, Williams, & Baker, 1998; Parker, Baker, Williams, & Nurss, 1995). Literacy and health literacy tests. Reprinted from "Health Literacy: A Review," by M.R. Andrus and M.T. Roth, (2002), *Pharmacotherapy*, *22*, p. 284-285.

The outcome metrics for assessing general literacy and health literacy proficiency are based upon three literacy scales: Prose Literacy, Document Literacy, and Quantitative (Kirsch, Jungeblut, Jenkins, & Kolstad, 2002). Prose Literacy refers to the knowledge and skills required to comprehend and utilize information located within the text of documents. Document Literacy is the understanding requisite to locate information within the text of documents. Quantitative Literacy is the capacity to apply arithmetic processes indicated within the prose material. Kirsch et al. (2002) divided these three scales into five levels based upon correct answers to set of questions pertaining to each of the three, Prose, Document, and Quantitative, scales; Level 1 (0-225), Level 2 (226-775), Level 3 (276-325), Level 4 (326-375), and Level 5 (376-500). These levels provide opportunities to denote progression in skills and aptitude, ranging from simplistic to complex, within these three literacy scales rather than statistical analyses thresholds.

Health literacy instruments convert a raw score value into a corresponding grade level. Reading competency and information comprehension is a vital element related to literacy. The readability of health educational materials and relative documents are gauged by appropriate reading grade level (Ley & Florio, 1996). The academic grade levels for health documents are evaluated by examining words per sentence, syllables per word, and/or word familiarity (Dale & Chall, 1948). Often, the academic grade level is associated with literacy categorization. The U.S. Census Bureau (1982) defined adult illiteracy with achieving an eighth grade education or less. As more validated health literacy instruments are constructed, the two most common health literacy instruments used for concordance agreement are Rapid Estimate of Adult Literacy (REALM) and the

Test of Functional Health Literacy in Adults (TOFHLA). REALM categorizes literacy as the following: low literacy (at or below sixth grade level), marginal literacy (seventh to eighth grade level), and functional literacy (ninth grade level or above; Davis et al., 1993). Conversely, the TOFHLA instrument categories for literacy are inadequate (unable to read and interpret health texts), marginal (difficulty reading and interpreting health texts), and adequate (can read and interpret most health texts; Parker, Baker, Williams, & Nurss, 1995).

The validation of the REALM was performed by measuring the responses between two standardized reading and recognition instruments, Slosson Oral Reading Test (SORT) and the Peabody Individual Achievement Test-Revised (PIAT-R). REALM is a 125-word test arranged into four columns by the number of syllables screening an individual's ability to pronounce common medical and lay terms providing health care professional a quick literacy assessment (Davis, 1991). In 1993, Davis et al., validated a shortened REALM test from 125 words to 66 words; this shortened form decreases test administration and scoring time. The raw REALM scores are converted into a specific grade level (Table 2).

Table 2

REALM Scoring System

Raw score	Grade range	
0-18	Grade 3 and below	Will not be able to read most low literacy materials composed primarily of illustrations, or audio or video tapes.
19-44	Grade 4 to 6	Will need low literacy materials; may not be able to read prescription labels.
45-60	Grade 7 to 8	Will struggle with most patient education materials.
61-66	High school	Will be able to read most patient education materials.

Note. From "Rapid Estimate of Adult Literacy in Medicine: A Shortened Screening Instrument," by T. C. Davis et al., (1993), *Family Medicine, 25*, p. 434.

SORT is a standardized test to evaluate reading recognition by gauging the ability to accurately pronounce words at different levels of difficulty (Slosson, 1963). PIAT-R is a measurement identifying achievement levels for reading recognition, reading comprehension, and overall reading skills translated into specific grade levels (Dunn & Markwardt, 1970). REALM performed statistically well against SORT and PIAT-R in relation to identifying low literacy individuals. A highly positive correlation between REALM and SORT pertaining to reading recognition ($r = 0.95$, $p \leq 0.001$) and REALM and PIAT-R comprehension acumen ($r = 0.81$, $p \leq 0.001$) (Davis, 1991). The Cronbach-

alpha assessing internal consistency for REALM was $\alpha = 0.99$, $p \leq 0.001$ and test-retest reliability equaled $r = 0.98$, $p \leq 0.001$ (Davis, 1991). After the REALM, SORT, and PIAT-R raw scores were converted into a grade level, the mean grade level among all three instruments were nearly identical, REALM (seventh to eighth grade), SORT (7.4), and PIAT-R (8.0) (Davis, 1991). Specifically comparing converted raw scores into grade levels, 59% of REALM participants scored below a ninth grade level compared to 57% of SORT and 51% of PIAT-R participants (Davis, 1991).

The TOFHLA was developed to assess an individual's ability for reading comprehension and numeracy knowledge. TOFHLA consist of 50-items pertaining to comprehension and 17-items related to numeracy (Parker, 1995). The TOFHLA scoring system is divided into three levels: inadequate, marginal, and adequate functional health literacy (Table 3). The TOFHLA instrument was validated against REALM and the Wide Range Achievement Test-Revised (WRAT-R). WRAT-R is a 74-item literacy instrument for screening reading, arithmetic, and spelling levels (Jastak & Wilkinson, 1984). The Cronbach-alpha evaluating internal consistency for TOFHLA was high, $\alpha = 0.98$, $p \leq 0.001$ and test-retest reliability equaled $r = 0.92$ (Parker, 1995). TOFHLA had high correlations with REALM, $r = 0.84$, and WRAT-R, $r = 0.74$, $p \leq 0.001$ respectively (Parker, 1995).

Table 3

TOFHLA Scoring System

Level	TOFHLA Score	Functional Health Literacy Description
Inadequate Functional Health Literacy	0-59	Unable to read and interpret health texts.
Marginal Functional Health Literacy	60-74	Has difficulty reading and interpreting health texts.
Adequate Functional Health Literacy	75-100	Can read and interpret most health texts.

Note. Adapted from *Test of Functional Health Literacy in Adults* (p.13), by J.R. Nurss, R.M. Parker, and D.W. Baker, (1995), Snow Camp, NC: Georgia State University.

The Short Assessment of Health Literacy-English (SAHL-E) is an 18-item health literacy assessment including both word recognition and comprehension aptitude (Lee, Stucky, Lee, Rozier, & Bender, 2010; Table 4). SAHL-E validation process utilized REALM and TOFHLA English version (TOFHLA-E) for comparison. The Cronbach-alpha for internal reliability was $\alpha = 0.92$ and test-retest reliability, $r = 0.86$ (Lee, 2010). SAHL-E had high correlations with REALM, $r = 0.94$, $p \leq 0.05$, and a moderate correlation with TOFHLA-*E*, $r = 0.68$, $p \leq 0.05$ (Lee, 2010).

Table 4

SAHL–E

Stem	Key or Distractor		Don't Know
1: kidney	_urine	_fever	_don't know
2: occupation	_work	_education	_don't know
3: medication	_instrument	_treatment	_don't know
4: nutrition	_healthy	_soda	_don't know
5: miscarriage	_loss	_marriage	_don't know
6: infection	_plant	_virus	_don't know
7: alcoholism	_addiction	_recreation	_don't know
8: pregnancy	_birth	_childhood	_don't know
9: seizure	_dizzy	_calm	_don't know
10: dose	_sleep	_amount	_don't know
11: hormones	_growth	_harmony	_don't know
12: abnormal	_different	_similar	_don't know
13: directed	_instruction	_decision	_don't know
14: nerves	_bored	_anxiety	_don't know
15: constipation	_blocked	_loose	_don't know
16: diagnosis	_evaluation	_recovery	_don't know
17: hemorrhoids	_veins	_heart	_don't know
18: syphilis	_contraception	_condom	_don't know

Note. Adapted from "Short Assessment of Health Literacy – Spanish and English: A comparable test of health literacy for Spanish and English," by Lee, S.Y.D., Stucky, B.D., Lee, J.Y., Rozier, G., & Bender, D.E., (2010), *Health Services Research, 45*, p. 1113.

Limitations exist for all health literacy measurement instruments. TOFHLA requires a lengthy time to administer and perform, ranging from 22 minutes for the long version and 10 minutes pertaining to the short version providing logistic challenges for busy health care operations (Woodwell & Cherry, 2004). REALM does not discriminate beyond the ninth grade level, elicits minimal data assessing health literacy comprehension, and only available in the English language (Davis, Keenen, Gazmararian, & Williams, 2005, p.165; Weiss et al., 2005). As our society incorporates a global population, the SAHL-E utilizes primarily Western terminology. Thus, SAHL may

provide terminology recognition challenges for global citizenry (Maat, Essink-Bot, Leenaars, & Fransen, 2014). These limitations to highly implemented and recognized health literacy measurement instruments force investigators to apply the most effective instrument depending on length of administration time, sample characteristics, and outcome objectives.

Social determinants. Health information is complicated and complex. The discipline of health progresses rapidly generating an abundant amount of information. The capacity for an individual to comprehend and process health information for making appropriate health decisions rely on several social determinants. Health information must be crafted in a reasonable plain language offering the opportunity for individuals to access appropriate information, comprehend new knowledge, and utilize knowledge appropriately (Plain Language Action and Information Network, 2005). Ethnicity groups respond to preferred cultural beliefs, societal norms, and shared practices. These cultural identifiers affect communication quality, knowledge comprehension, and responding to health information. Therefore, cultural competence relates to the ability of health care organizations and providers to recognize the influence of cultural characteristics on health outcomes (U.S. Department of Health and Human Services, 2001). Within society, certain groups of individuals have shown to be higher risk for low health literacy proficiency; they include elderly age-brackets, less education achievement, and lower income levels (Kutner, 2006). Risk factors for lower health literacy proficiency are challenge for health care professionals, governmental policies, and community stakeholders. However, the central goal is to ensure limitations experienced by these

groups are eradicated and health care information is appropriate regardless of ethnicity, age, education, and incomes levels.

As the Western health care system transitions from a medical professional centric viewpoint to more personal (patient-centered) responsibility, the patient's ability to comprehend and process complicated information is increasingly important. However, as health care expands in complexity, the rates for health literacy *proficiency* decreases. According to the U.S. Department of Education (2006), approximately 77 million American adults have a *basic* (47 million) or *below basic* (30 million) health literacy proficiency and only 12% register as health literacy *proficient*. Literacy scales include prose, documentation, and quantitative. One's ability to utilize these literacy skills to acquire, comprehend, and process information to formulate a medical decision determines their health literacy proficiency level. The Board of Testing and Assessment (BOTA) committee devised thresholds for health tasks using a 67% probability of successfully answering literacy questions; these health literacy cut-off thresholds provide the same general literacy proficiency levels to prose, documentation, and quantitative literacy tasks (Hauser, Edley, Koening, & Elliott, 2005). A systematic review of 85 studies including 31,129 subjects revealed a pooled prevalence rate of 26% (95% CI [22% - 29%] and prevalence range of 0% to 68%) for low health literacy (Paasche-Orlow, Parker, Gazamarian, Nielsen-Bohlman, & Rudd, 2005). Furthermore, in the same pooled analyses, the marginal health literacy prevalence rate was 20% with 95% CI [16% - 23%] and prevalence range of 11% to 65% (Paasche-Orlow, 2005).

Ethnicity/race. Adult health literacy prevalence rates differ by ethnicity and race. The *National Assessment of Adult Literacy (NAAL)* denoted that 14% of non-Hispanic White American adults compared to 2% of Black American adults and 4% of Hispanic American adults registered as health literacy *proficient*; conversely, only 9% of non-Hispanic White American adults versus 24% of Black and 41% of Hispanic American adults met the criteria for *below basic* health literacy proficiency (Kutner, Greenberg, Jin, & Paulson, 2006). Similar health literacy trends were demonstrated within a community health center patient population where both Black and Hispanic American adults depicted lower health literacy proficiency rates than non-Hispanic White Americans adults controlling for education strata (Kaphingst, Goodman, Pyke, Stafford, & Lachance, 2012).

Education achievement. Education achievement has demonstrated a relationship for categorizing health literacy proficiency levels. The *NAAL* described 75% of American adults without a high school diploma registered as *below basic* or *basic* health literacy level compared to 44% of high school graduates (Kutner, 2006). A strong positive linear relationship among education achievement, high school to college, and health literacy proficiency was shown as mediator for health status (der Heide et al., 2013). However, several studies have provided caution toward the accuracy of the education achievement predictor variable associated with health literacy proficiency levels as patients often read several grade levels lower than their highest achieved grade level (Baker, Johnson, Velli, & Wiley, 1996; Meade & Byrd, 1989).

Age. The U.S. population is increasingly getting older as life spans extend and the largest generation, baby boomers, live longer. Over the next quarter-century, Americans over the age of 65 years of age will equate to nearly 72 million people; approximately 20% of the U.S. population (Centers for Disease Control and Prevention, 2013). Reading comprehension is a vital aspect of literacy proficiency. As Americans' age, especially within their elderly years, reading ability declines directly lowering health literacy proficiency (Parker, 2000). Categorizing age by years into brackets denotes a decreasing percentage who register as health literacy *proficient* (Kutner, 2006).

Income status. Socioeconomic status and income levels contribute to health inequities. However, the constructs of the variable, socioeconomic status, is a challenge to concisely define. Socioeconomic status includes numerous factors suchlike marital status, income, car ownership, utilization of public assistance, and employment status (Cutilli, 2007). Medicaid health insurance provides coverage for low income individuals. Currently, Medicaid enrollees, approximately 56 million individuals, equate to 17.5% of the U.S. population (The Henry J. Kaiser Family Foundation, 2016). Medicaid enrollees have a *basic* or *below basic* health literacy level of 60% compared to only 3% registering as health literate *proficient* (Kutner, 2006). Baker (2002) described that Medicare managed enrollees with inadequate health literacy proficiency were 67.1% more likely to be hospitalized compared to 36.6% of adequate health literate Medicare enrollees dichotomized by a $15,000 threshold. A preoperative cohort earning a lower income was associated with nonadherence to postsurgery instructions compared to a higher income group: 31% versus 61%, $p \leq 0.001$ (Chew, Bradley, Flum, Cornia, & Koepsell, 2004).

Dividing income into categories, blue collar versus white collar, for community dwelling Medicare enrollee patients; 30.3% of blue collar patients registered as inadequate for health literacy compared to 11.9% white collar patients, $p \leq 0.001$ (Gazmararian et al., 1999). Conversely, a minority English speaking cohort seeking acute care denoted insignificant and inconsistent differences between socioeconomic status thresholds and health literacy proficiency (William et al., 1995).

Economic burden. Health literacy proficiency has a direct impact on health care expenditure and costs. The economic expenditures for low health literacy proficiency are measured on two different levels: a system assessment and a patient perspective (Eichler, Wieser, & Brűgger, 2009). The system level includes the entire U.S. health care system. Low health literacy proficiency corresponds to 3% - 10% of total health care costs per year in the United States (Vernon et al., 2007). This percentage equates to $106 to $238 billion annually (Vernon et al., 2007). At the patient perspective level, low health literacy proficiency affects individual financial resources. Patients with low health literacy proficiency spend additional $143 to $7,798 more per year compared to a reference group with adequate health literacy proficiency (Sanders, Thompson, & Wilkinson, 2007; Weiss & Palmer, 2004).

Hospital utilization. Health literacy proficiency has shown to predict higher number of Emergency Room (ER) visits and hospitalizations. Additionally, lower health literacy proficiency is associated with higher health care utilization costs. Patients with low health literacy has a statistically significant ($p = 0.03$) higher number of ER visits annually compared to adequate health literacy (Griffey, Kennedy, McGownan, Goodman,

& Kaphingst, 2014). These increase number of ER visits for low health literacy patients equate to marginally greater economic burden compared to adequate health literacy levels per: 95% CI [- $166 - $3267], $p = 0.08$ (Howard, Gazmararian, & Parker, 2005). The crude relative risk ratio of hospitalizations for Medicare patients with low health literacy was greater than Medicare patients with adequate health literacy levels: RR = 1.43; 95% CI [1.24-1.65] (Baker et al., 2002). Moreover, inpatients with higher levels of health literacy proficiency depicted a higher desire to participate in problem-solving strategies pertaining to their health care and the discharge process compared to lower health literacy patients (Goggins et al., 2014). Furthermore, the mortality rate measured by the Adjusted Hazard Ratio for lower health literacy discharged patients with acute heart failure was significantly higher compared to higher health literacy proficient acute heart failure discharged patients: HR = 1.34; 95% CI [1.04 - 1.73], $p = 0.02$ (McNaughton et al., 2015).

Medical care adherence. Patient adherence to medical treatments and pharmaceutical regimens is a complex and challenging issue. Barriers for adherence to medical treatments and drug regimens include low health literacy proficiency, complicated medical regimens, ineffective health care communication dissemination from health care professionals, and limited access to health care requirements (Brown & Bussell, 2011). Up to 40% of nonadherence to medical treatment is related to patients misunderstanding medical instruction, forgetting medical advice, and simply ignoring medical directions from health care professionals (Dimatteo, 2004). A meta-analysis of English language citations from 1966 - 2013 illustrated a positive weak correlation

between health literacy proficiency and medication adherence, $r = 0.08$, $p \leq 0.001$ (Zhang, Terry, & McHonry, 2014). Similarly, a meta-analysis of English language citations from 1948 - 2012 denoted a positive weak correlation between high literacy proficiency and nonmedical regimens for a cardiovascular cohort, $r = 0.14$; following a health literacy intervention, the adherence outcomes slightly increased, $r = 0.16$ (Miller, 2016). Regardless of the positive weak relationship between health literacy proficiency and medical treatment adherence, health literacy may not be the primary predictor for adherence, yet it contributes to noncompliance of medical treatments and pharmaceutical obedience.

Patient-physician communication. Communication quality between physician and patient is vital to establishing a productive collegial relationship toward treating one's disease/disorder. Effective physician-patient communication encompasses the facilitation of an accurate diagnosis, reciprocal counselling appropriately, disseminating understandable therapeutic instructions, and establishing a caring relationship (Breeder, Bouleuc, & Dolbeault, 2005). In a diabetic cohort, the higher mistrust related to medical care between physician and patient was associated with diabetics registered as lower health literacy proficient compared to diabetics with higher health literacy proficiency (White et al., 2016). A survey of discharged hospitalized general medicine patients participated in a two-group study, inadequate versus adequate health literacy proficient, pertaining to their physician-patient communication quality. Inadequate health literacy discharged patients reported lower ratings for all three domains: responsiveness from physicians to patient concerns, communication clarity, and explanation of therapeutic car

(each domain, $p \leq 0.05$) (Kripalani, Jacobson, Mugalla, & Vaccarino, 2010). A survey of 5,929 patients from different types of health care organizations, hospitals and community clinics, regarding physician-patient communication quality depicted 79% of patients with inadequate high literacy proficiency reported a lower quality of communication compared to adequate health literate patients (Wynia & Osborn, 2010). Effective physician-patient communication is central to optimizing medical treatments and adherence to medical instructions. Therefore, additional attention is warranted toward the health literacy proficiency level of patients regardless of health care organization setting.

FGID

FGID is a heterogeneous symptom-based group of conditions exacerbating gastrointestinal symptoms without structural or biochemical abnormalities (Drossman, 2007). FGID are derived from a constellation of physiological factors, motility abnormalities, immune function, altered central nervous system, and visceral hypersensitivity and/or altered bacterial flora, prompted by environmental factors, early life stress, and/or genetics manifesting FGID symptomology (Drossman & Hasler, 2016). FGID are classified into six domains by anatomical region: Esophageal, Gastroduodenal, Bowel, Functional Abdominal Pain, Biliary, and Anorectal (Drossman & Dumitrascu, 2006). These symptomatic disorders affect public health domains because they commonly disrupt quality of life and prompt economic burden (Faresjo et al., 2007; Nyrop et al., 2007).

Epidemiology

FGID are highly prevalent within the United States; approximately 25% of the population seek medical advice for these symptomatic disorders (Talley, 2008). Few incident rate reports pertaining to FGID domains have been conducted due to the challenge for classifying symptom onset and only a subset of subjects seek care for FGID: Functional Esophageal Disorders (main symptom gastroesophageal reflux), 5/1,000 persons per year, Functional Dyspepsia (primary symptoms abdominal bloating, gas, nausea, and vomiting), 15.3/1,000 persons per year, and Bowel Disorders (primary symptoms CC and diarrhea), 151/100,000 person per year (El-Serag, Sweet, Winchester, & Dent, 2014; Saito, Schoenfeld, & Locke, 2002; Wallander, Johansson, Ruigómez, Rodríguez, & Jones, 2007). FGID are highly prevalent within society especially for the Functional Esophageal, Functional Dyspepsia, and Bowel Disorder Domains. The prevalence of Functional Esophageal Disorders in the United States is 18.1% - 27.8% (El-Serag et al., 2014). In a systematic review by El-Serag and Talley (2004), the prevalence rate for Functional Dyspepsia was 11.5% - 14.7%. The Bowel Disorder Domain has a prevalence rate of 11% globally (Canavan, West, & Card, 2014).

Age and Gender

FGID symptomology differs pertaining to age and gender. Functional Esophageal Disorders symptoms are twice as common in younger age brackets, 15-34, compared to older age brackets, ≥ 45 years of age; however, males and females experience Functional Esophageal Disorder symptoms equally (Galmiche et al., 2006). The prevalence of Functional Dyspepsia symptoms increases with age: 7.7% at age 15-17 years, 17.6% at

18-24 years, 18.3% at 25-34 years, 19.7% at 35-44 years, 23.7% at 55-64 years, and 24.4% ≥ 65 years, $p \leq 0.0005$ (Piessevaux et al., 2009). A meta-analysis by Ford, Marwaha, Sood, and Moayyedi (2015) depicted a slightly higher pooled prevalence for Functional Dyspepsia symptoms for females compared to males (25.3% vs. 21.9%). Bowel Disorder symptoms occur in all age-brackets; however, 50% of first reported Bowel Disorders symptoms transpire for individuals less than 35 years of age and the prevalence of Bowel Disorder symptoms are 25% lower in individual greater than 50 years of age (Lovell & Ford, 2012). Bowel Disorder symptoms are reported by females 1.5 - 3.0 times greater than males (Canavan, 2014).

Economic Burden

The economic impact of FGID is inconclusive due to onset of symptomology and close symptom profiles of other diseases/disorders. A U.S.-based study examined the economic impact of Americans living with at least one chronic disease. Chronic diseases accounted for $659 billion annually, direct and indirect costs (Hoffman, Rice, & Sung, 1996). An economic review of Functional Digestive Diseases within eight industrial nations, including the United States, estimated annual cost of FGID is $41 billion (Fullerton, 1998). FGID symptoms are responsible for large number of outpatient visits per year. The *National Ambulatory Medical Care Survey* sponsored by the Centers for Disease Control and Prevention (2009) provided data for symptoms promoting outpatient visits and diagnoses denoted by physicians for outpatient visits using the International Classification of Diseases (ICD) -9 codes; FGID symptoms prompted 86.2% of outpatient doctor visits and the top four diagnoses scribed by physicians.

CC

Definition

CC is a common complaint by patients seeking health care advice and as a primary diagnosis for outpatient clinic visits. The *National Ambulatory Medical Care Survey* sponsored by the Centers for Disease Control and Prevention (2009) illustrated that constipation ranked third for prompting outpatient health care visits, approximately 3.2 million annually, and ranked fourth by officially ICD-9 billion code, an estimated 4 million. CC is divided into two categories, primary (functional) and secondary. CC may manifest from a multitude of physiological and anatomical reasons. The American College of Gastroenterology Chronic Constipation Task Force (2005) defined CC as "unsatisfactory defecation characterized by infrequent stool, difficult stool passage or both at least for previous 3 months" (p. S1). The difficulty to pass stool was further described as straining during defecation (incomplete evacuation), hard/lumpy stool, prolonged time to defecate, or the requirement for manual maneuvers to pass stool (Brandt et al., 2005).

Currently, CC has no definitive biological biomarker. The primary etiological reasons for CC are delayed colonic transit motility and outlet obstruction or pelvic floor dysfunction. Prolonged colonic motility depicts normal resting colonic motor pattern and blunted colonic peristalsis post meal and colonic stimulants (Rao, 2009). The etiological reason of delayed colonic transit encompasses 15% - 30% of CC adults (Frattini & Nogueras, 2008). Pelvic floor dysfunction refers to the inability to coordinate muscles of the abdominal cavity and pelvic floor to effectively evacuate stool in the absence of

organic disease related to muscle and/or neurologic pathology (Rao, Welcher, & Leistikow, 1998). This type of functional CC has a prevalence rate of 7% in adults (D'Hoore & Penninckx, 2003). CC symptoms may exhibit from behavioral and environment stressors; where upon, a 62% of a CC cohort experiencing behavioral stressors reported at least 1 or more bowel movements per day (Sandler & Drossman, 1987). Secondary causes for CC symptomology are derived by medication side effects, neurological diseases, and systemic illnesses (Páre et al., 2007).

Epidemiology

A systematic review by Higgins and Johanson (2004) illustrated the prevalence rate for CC in North America ranges from 1.9% - 27.2%; after adjusting for conservative metrics related to various outliers, an estimate CC prevalence rate equates to 12% - 19%. This CC prevalence rate encompasses approximately 63 million North American adults (Higgins & Johanson, 2004). A survey of a large cohort of community based White residents provided data to calculate the incidence rate for the onset of CC symptoms in North America is 40/1,000 person-years (Talley, Weaver, Zinsmeister, & Melton, 1992). The stability of this incidence rate was determined by re-surveying the individuals with CC within this community-based cohort following CC intervention; 89% of these individuals with CC had no change CC symptomology surveyed 12 to 20 months' post intervention (Talley, 1992).

Gender. CC has been demonstrated to be more prevalent in adult females compared to males: 1.01 to 3.77 (Higgins & Johanson, 2004). This most epidemiological CC female-to-male is consistent with older prevalence CC data. A large U.S. population-

based self-reported survey study denoted a prevalence of CC in 20.8% of females compared to 8.0% in males (Everhardt et al., 1989). Furthermore, the Epidemiology Study of Constipation (EPOC) study determined the prevalence rate of females meeting the clinical criteria for CC was 16% compared to 12% for males (Stewart et al., 1999). Higher adjusted odds ratios for CC symptomology were illustrated between CC adult females and males: longer duration of CC symptoms (AOR = 2.00, 95% CI [1.05 - 3.82]), infrequent bowel movements (AOR = 2.97, 95% CI [1.67 - 5.28]), and unsuccessful attempts at evacuation, defecation (AOR = 1.74, 95% CI [1.01 - 3.00]) (McCrea et al., 2009).

Age. Numerous studies have demonstrated that CC manifestation and symptomology increases with age. However, the age-bracket categorization has been inconsistent throughout the literature. The *National Disease and Therapeutic Index (NDTI)* provides statistics summarizing the frequency physicians are visited, and after isolating the diagnosis code for constipation, a significant age-related frequency percentage increase occurred between 60-64 and ≥ 65 years of age, 1.3% to 4.1% (Sonneberg & Koch, 1989). Two additional large survey studies denoted similar trends for evidence toward increasing CC with age. The oldest self-reported survey was distributed to American Cancer Society volunteers, approximately 1 million American adults. This survey categorized age-brackets into 5-year age-brackets. The data illustrated a consistent increasing odd ratio for reporting constipation starting with age-bracket, 30-34, OR = 1.00 through ≥ 85, OR = 2.58 (Hammond, 1964). The first *National Health and Nutrition Examination Survey (NHANES-1)* demonstrated a similar trend toward age and

reporting of constipation. *NHANES-1* included a sample of 20,749 adults of a diverse demographic and geographical profile. This *NHANES-1* revealed that the age-bracket of 30-59 years had an OR = 1.72 compared to the age-bracket 60-75 years, OR = 2.88 versus the nonconstipated participants (Sandler, Jordan, & Shelton, 1990).

More recent data has shown comparable trends between age and constipation. A review article by McCrea, Miaskowski, Stotts, Macera, and Varma (2009) pooled the prevalence rate of age and constipation within the published literature: individuals 50 years of age and younger have a constipation prevalence rate of 2.6% - 28.4% and greater than 70 years of age the prevalence rate range increases to 7.7% - 42.8%. Even as females and males age, CC remains more prevalent for females compared to males. A review of constipated elderly individuals displayed that the constipation prevalence rate for females greater than 65 years of age was 26% versus male 16%; furthermore, the constipation prevalence rate increases for individual greater than 84 years of age, females (34%) and males (26%) (Gallegos-Orozco, Foxx-Orenstein, Sterler, & Stoa, 2012).

Race. A systematic review by Higgins and Johanson (2004) reported a higher prevalence for CC in non-Caucasians compared to White adults, OR (Range) = 1.13-2.89, and the non-White/White ratio range from 1.13-2.89. Conversely, a large U.S. population-based survey of American adults, *N* = 10,030 who met clinical criteria for Irritable Bowel Syndrome-Constipation denoted 79% were White/Caucasian compared to 21% of minority races (Heidelbaugh et al., 2015). A population-based cross-sectional study of American adults greater the 50 years of age using the *National Health and Nutrition Examination Survey (NHANES)*, 2005-2010, *N*= 8,317, categorized race and

ethnicity as non-Hispanic White, non-Hispanic Black, and Hispanic (including Mexican Americans). The data described a CC higher prevalence for men in non-Hispanic White, 6.8%; 95% CI [5.3% - 8.6%], compared to a combination of the other groups, 4.1%; 95% CI [3.2% - 5.4%]; contrarily, the prevalence of CC between the same two groups were similar, non-Hispanic White (11.3%; 95% CI [9.6% - 13.2%]) versus other two groups (11.9%; 95% CI [10.2% - 13.9%]; Uduak et al., 2016). Minority groups are rarely subdivided for analysis because limited non-White participants among population-based North American studies.

Socioeconomic status. Prevalence rates of FGID symptoms increase with lower socioeconomic status metrics. CC depicts this particular trend for the predictor variable, socioeconomic status. Income categorization is inconsistent within various research projects. However, lower income brackets have greater odd ratios for constipation compared to higher income brackets in self-reported CC studies and a similar trend in clinically diagnosed CC participants with less of an effect. The self-reported *National Health and Nutrition Examination Survey* (*NHANES-1*) project represented CC participants with an income of < $7,000 had an OR = 2.16 compared to participants earning more than $15,000, OR = 1.00 (Sandler, 1990). The *National Health Interview Survey* utilized a self-report methodology for illustrating CC participants earning less than $10,000 have an OR = 3.42 compared to CC participants in the greater than $35,000, OR = 1.00 (Johanson, 1994, p.574). Pare, Ferrazzi, Thompson, Irvine, and Rance (2001) performed a CC self-report analysis of a large Canadian population-based cohort with larger diverse income brackets. The data analysis demonstrated that CC participants

producing less than $20,000 annually have an OR = 1.55 versus CC participants earning more than $80,000, OR = 1.00. The *EPOC* sample included CC participants meeting the Rome clinical criteria for constipation had similar odd ratios for CC: less than $20,000, OR = 1.00, versus greater than $50,000, OR = 1.02 (Stewart, 1999). Pare et al. (2001) performed a subanalysis with their self-reporting CC sample who meet the Rome clinical criteria for constipation; income brackets for CC participants earning less than $20,000, OR = 1.84, compared to greater than $80,000, OR = 1.00.

Education achievement. An inverse relationship between CC and education achievement were denoted in a large self-reported survey: *NHANES-1*, less than 6 years of completed school had a prevalence of 21.7% compared to more than 13 years of education, 11.2% (Sandler, 1990). Conversely, the association of a higher CC prevalence rate in lower education categories is less prominent in participants qualifying for clinical constipation criteria compared to self-reporting CC symptomology survey studies (Páre, 2001; Stewart, 1999; Talley, 1992).

Economic burden. The health care burden pertaining to CC symptomology regardless of self-reported or utilizing clinical criteria is significantly high. An estimated 2.5 million individuals will undergo CC evaluations annually; the estimated costs for these annual CC evaluations are $6.9 billion (Chang et al., 2010). Extrapolating from the 2.5 million CC evaluations, the annual approximately cost for empirical laxatives is $500 million (Crowell, Harris, Lunsford, & Dibaise, 2009). Nyrop et al. (2007) estimated the mean total direct and indirect costs in health care for each CC patient annually is $7,522. Besides economic burden, CC symptomology has a significant impact on work

productivity and employment attendance: 30% of individuals with CC report less work productivity, 13% indicate absenteeism for CC symptoms, and 10% state tardiness for CC symptomology (Hunt, 2007). Additional data found that individuals with CC reported a loss of 2.4 productive days per month associated with CC symptoms (Johanson & Kralstein, 2007). CC patients as a whole have an estimated 0.4 days/year of work absence equating to 13.7 million days of restricted activity in the United States each year (Sonnenberg, 1989).

Terminology

The term constipation is often interchangeably used within the community and clinical medicine. A committee of gastroenterologists assembled a consensus group, which met in Paris, the *Congress of Pediatric Gastroenterology, Hepatology, and Nutrition (PAACT)*, to examine constipation terminology for improving constipation etiology and treatments (Benninga et al., 2005). They constructed a list of readily used terms describing constipation in the literature. They were fecal impaction, pelvic floor dyssynergia, anismus, functional constipation, dyssynergia, and outlet obstruction (Benninga, 2005). This diverse list of terminology affects health literacy, comparative research, and overall health care quality.

Health Literacy Interventions

Various health literacy interventions have been studied to examine the effects pertaining to comprehension enhancement, document design, numerical presentation, pictorial efficacy, and readability layout in association to traditional and alternative media formats. Health literacy as a research paradigm is relatively new. The concept for the

definition of health literacy first emerged in peer-reviewed literature in 1974 by Simmonds. Then, these concepts were further developed by the American Medical Association (1999) structuring framework for baseline requirements to utilize health information to formulate answers pertaining to health questions. The U.S. Department of Health and Human Services (2000) officially distributed an official definition for health literacy in the *Healthy People 2000* report (pp. 11-20). A diverse amount of literature has been published in a plethora of journals from a wide array of scientific disciplines relevant to health literacy *proficiency*. The diversity of health literacy publications utilizing various constructs and concepts to explore health literacy provide challenges for generalizing outcomes.

E-Learning has rapidly increased for offering available information, accessibility, and community utilization. Governmental agencies, suchlike the National Institute of Health use the internet as their primary source for disseminating health information (Bylund, Sabee, Imes, & Samford, 2007). This method provides easy access to updated health information for a diverse population. However, this information delivery source includes challenges related to e-Learning literacy proficiency, age, and quality of health information (Jaeger & Xie, 2009; Robins, Holmes, & Stanbury, 2010).

Alternative Document Design

An RCT conducted by Greene, Peters, Mertz, and Hibbard (2008) examined the importance for the order of common features pertaining to a health plans to increase comprehension. They developed three different models to study: a side-by-side comparison of health plans with the common features listed first, a short version with two

advantages and two disadvantages included in the health plan information, and a long version including four advantages and four disadvantages in the health information. The groups were divided by their Numeracy literacy proficiency; 50% of the sample scored low on a numeracy literacy assessment constructed by Liptus, Samsa and Rimer (2001). The comprehension scale to the health plan questions was 0-6. The side-by-side comparison model with common features of the health plans listed first should no comprehension differences between the high and low numeracy literacy groups. Conversely, the short-form, listing only two advantages and disadvantages related to common features of the health plans depicted a higher mean comprehension response score for the high numeracy literacy group compared to the lower numeracy literacy group, +0.7 versus +0.3, $p \leq 0.05$. Similar significant difference correlated with the long model, the high numeracy literacy group increased their mean comprehension response score greater than the low numeracy literacy group, +0.05 versus -0.5, $p \leq 0.05$. This study demonstrated that comprehension of common features is affected by the length of information and complexity of documentation method.

An RCT by Peters, Dieckmann, Dixon, Hibbard, and Mertz (2007) studied the quantity of essential and nonessential health information associated with food quality denoted for high numeracy literacy and low numeracy literacy groups (experimental) compared to a control group. The control group answered the same comprehension questions without ordering the essential health information: nonordered and nonessential food-health information. The intervention categories for the experimental groups consisted of ordered essential and random nonessential food-health information and only

essential food health information. Each group provided answers to comprehension questions with a scoring range of 0-3. The high numeracy literacy group had a similar mean comprehension score when the health-food information was ordered with essential and nonessential items compared to the control group, p = NS; contrariwise, the low numeracy literacy group increased their mean comprehension score by +0.6 in this particular ordering format compared to the control group, $p \leq 0.01$. Within the essential health information intervention category, the high numeracy literacy group increased their mean comprehension score by 0.3 compared to control group, $p = 0.01$; as well as the low numeracy literacy group, +0.7, $p \leq 0.01$. This study indicates the importance for minimizing the amount of health information and concentrating on simplifying the representation of essential health information for maximizing comprehension in individuals with lower health literacy *proficiency* components.

Numerical Presentation

Quantitative information is readily utilized in modern day health care environments. The societal norm is that a far majority of adults clearly understand how to solve simple quantification problems. The quantified markers are used to measure health outcomes by patients and the public. Unfortunately, recent literature demonstrates that adults have difficulty solving simple ratio and decimal problems; this discordance between a societal norm and reality may prompt impact the health decision making process (Reyna & Brainerd, 2008).

A survey of United States and German adults 25-69 years of age were asked to respond to the baseline risk and treatment effect of a new hypothetical cholesterol

medication for heart diseases based upon four fractions with different denominators (Garcia-Retamero & Galesic, 2009). Each participant completed a numeracy literacy assessment (Liptus, 2001). Then, the entire sample was separated into two groups: high numeracy literacy or low numeracy literacy. The independent variable was the number of deceased patients treated versus nontreated with the hypo ethical cholesterol medication manipulated by the denominator. The low numeracy literacy group overestimated risk reduction when the number the number of treated patients was lower than those who did not receive the medication more often than the high numeracy literacy group, 71% versus 25%. Conversely, 67% of the low numeracy literacy group underestimated the risk reduction for the hypothetical cholesterol medication compared to 19% of the high numeracy literacy group.

By adding icons to the numerical information, the denominator confusion was markedly improved especially in the low numeracy literacy group pertaining to over-estimating risk reduction, reducing the percentage 71% to 42%. The high numeracy literacy group lowered their percentage for risk reduction to 15%. Using simplified multimodal approach to quantified measurements and abridging the presentation for mathematical problems associated with health care decisions may enhance health literacy *proficiency*.

Pictorial Representation

The efficacy for interventions related to improving health outcomes by increasing medical advice adherence may benefit from a combination approach rather than using only one singular intervention technique. An RCT by Yin et al. (2008) demonstrated the

impact of adding pictorial images to traditional medical dosing instruction sheets. The sample included, *N*= 245, lower socioeconomic status parents/caregivers of children aged 30 days to 8 years of age prescribed liquid medicine for a variety of diseases/disorders. The experimental groups received medical counselling for liquid medicine dosing with plain language instructions and pictorial images while the control group only received traditional standard medical counselling. The experimental group had less errors with dose frequency (0.0% vs. 15.1%, $p = 0.007$), inconsistent medication preparation (10.9% vs. 28.3%, $p = 0.04$), and daily dosing (5.0% vs. 35.3%, $p = 0.03$) compared to the control group.

Pictorial images have been used to improve medicine instruction comprehension and adherence adult cohorts. Drowse and Ehlers (1998) conducted a comparative study randomizing a primary female, 93%, adult cohort, $N = 87$, prescribed antibiotics into two groups: a text-only (control) versus text plus pictogram (experimental). The measurements assessed were comprehension and adherence. Comprehension was evaluated by structured interviews, and adherence was gauged by manual pill counts at different time points. The experimental group achieved a 95% comprehension rate compared to 70% for the control group, $p \leq 0.01$. Antibiotic adherence was greater in the experimental group versus the control group: 90% versus 72%, $p \leq 0.01$.

e-Learning

This health literacy technique intervention has the potential to disseminate information quickly, less expensive, to a greater number of individuals compared to traditional methods. However, as researchers, e-Learning includes additional biases,

computer literacy proficiency, technology access, and an aging society. A pilot study by Holubar et al. (2009) studied the effect of an e-Learning module pertaining to improving colon cancer literacy in a community-based population: $N = 22$, mean age 77.2 years, 55% female, and 67% had an educational achievement of some graduate school. The study design was a pre–post trial. A baseline colon cancer literacy evaluation was assessed, followed by undergoing the e-Learning module, and lastly completing a postcolon cancer literacy assessment. The posttest colon cancer literacy assessment improved by 7% from baseline after the e-Learning module, $p = 0.04$. Additionally, a self-reported 100% satisfaction score was reported regarding the colon cancer e-Learning module.

E-Learning has also been used to evaluate symptom score comprehension. A study by Bryant et al. (2009) consisted of a random convenience sample of men, $N = 232$, from two different university hospitals being monitored for benign prostate hypertrophy. The sample was divided into two groups: print-text only and print plus video (multimedia). Multimedia entailed a computerized video reading the symptom questions to the participant. The effectiveness of the multimedia intervention was assessed for comprehension (mean number of errors) and proportion of participants understanding the symptom score questions. The multimedia group depicted greater comprehension measured by fewer number of symptom score question errors compared to the print-text only group, 1.97 versus 3.48, $p \leq 0.001$. A subanalysis was conducted evaluating comprehension after undergoing the multimedia intervention where errors related to the symptom score questions decreased from 4.55 to 2.24 in participants with low literacy

proficiency, $p = 0.03$, and within the high literacy proficient group, the mean number of errors decreased from 3.10 to 1.86, $p \leq 0.001$. The proportion of participants understanding the symptom score questions were 19% points higher in the multimedia group compared to the print-text only.

Animation

E-Learning has dominated the educational and instructional discipline the past two decades. E-Learning refers to learning using contemporary mediums, suchlike computer-assisted and digital formats, constructed using traditional learning theoretical concepts (Ruiz, Mintzer, & Leipzig, 2006). This type of learning often corresponds to multimedia learning. Multimedia learning provides learners with verbal exposure to education material, text or narration, and in conjunction to pictorial representations via photos, illustrations, or video/animation (Mayer & Moreno, 2002). Animation is the primary form of e-Learning. Animation is defined by simulating motion to static drawings, which involves four distinct features: pictorial representation, motion - movement, and simulation from static drawings (Mayer, 2002).

The implementation of e-Learning modules has elicited numerous advantages to enhanced learning suchlike, targeted learning isolating concepts, accessibility to essential information quickly, the ease of updating material maintain relevancy, and more effective methods of distributing education material (Rosenberg, 2001). Furthermore, animation has shown to more favored by students for addressing difficult topics compared to verbally or numerically (Lowe, 2003). Conversely, multimedia learning incorporates disadvantages for learners: the multimedia creators may have incongruent motives to

education advancement, advanced cognitive processes may be required to comprehend abstract concepts in a motion platform, and the inconsistency within the literature for the optimal design to evolve learning (Hasler, Kersten, & Sweller, 2007; Lowe, 2003; Plötzner & Lowe, 2004).

Social determinants providing challenges for individuals to improve health literacy *proficiency* has shown to have less of an impact when animation is employed to enhance health literacy. Animation has illustrated to clarify conceptual relationships using the efficacy of visual application (Weiss, 2002). Peer-reviewed literature has demonstrated the positive attributes for increasing health literacy *proficiency* in common challenged cohorts. An extensive body of research has been published exploring the outcomes of animate interventions correlated with health information comprehension, medical instruction recall, and maintaining concentration (attention).

As our society trends rapidly toward an older population and a pervasive computer-based culture, this transition provides challenges for elderly individuals. By 2050, individuals 65 years of age and older in the United States is projected to be 83.7 million; this projection is nearly double for the number of individuals in this age-bracket from the year 2012, 43.1 million people (Hogan, Perez, & Bell, 2008). A between-subject experimental study by Meppelink et al. (2015) explored the effect of health literacy *proficiency* in older age group related to instruction recall and attitude metrics for colorectal cancer screening. The minimum age for the cohort was at least 55 years. The demographics of the sample, $N = 231$, was 68.2 and 52.4% male. The sample was divided into two groups: low and high health literate. Two different interventions were examined:

spoken versus written and illustration versus animation. The low health literate group had a greater instruction recall, $p = 0.03$, and attitude toward colorectal cancer screening, $p = 0.02$, for the spoken format compared to written messages. Animation by itself did not improve either of the metrics for the low health literate group. However, animation combined with spoken messaging significantly improved instruction recall for the low health literate group, $p = 0.02$. Using the combination of animation and spoken messaging, both groups, low and high health literate, reported similar instruction recall, on a scale of 0-28, mean scores: 13.24 versus 15.50, $p = 0.12$.

A descriptive study by Neafsey et al. (2008) denoted the vigor for animated education programs to positively empower elderly individuals with low health literacy proficiency to adjust their thought-process concerning hypertension medication. The sample, $N = 17$, with a minimum of age of 60 years were included in the descriptive study: mean age = 80.4, 94% female, and a sixth-grade literacy level. After completing the Patient Education Program pertaining to hypertension medication, participants reported, agree or strongly agree to the following questions:

- 91%: The program will help me want to change how I use medicines.
- 91%: The program helped me think of questions to ask my doctor.
- 55%: After using this program, I will make some changes in how I use medicine.
- 64%: After using this program, I will change when I take some medicine.

Minorities have a lower health literacy compared to the general population (Paasche-Orlow, Taylor, & Brancati, 2003). Moreover, minorities populations are

inadequately represented in clinical research trials (Allmark, 2004). These populations have lower confidence in fidelity and honesty toward health care physician. In a univariate model, race/ethnicity was significantly associated with health care distrust, $p \leq 0.001$, and in adjusted-model, Black and Hispanic individuals had a higher mean score of distrust, 16.5, 95% CI [16.1% -16.9%] and 17.1%, 95% CI [16.7% - 17.4%], respectively, compared to Whites, 15.2%, 95% CI [15.0% - 15.3%] (Armstrong, Ravenell, McMurphy, & Putt, 2007) Therefore, limited clinical research is available concentrating solely on minority populations.

A qualitative study by George et al. (2013) described the opinions of minority populations only following a 7-minute animation video highlighting the importance for participating in clinical research. The sample, $N = 112$, had a mean age of 54.1 and 55% female; the race/ethnicity distribution was 22% African American, 33% Latino, 21% Native Hawaiian, and 24% Filipino. The positive descriptors for the concept of acceptance for using animation as a clinical research information tool were “engaging”, “lively”, and “ease to relate”, and the negative descriptors were “tone” and character redundancy.” Secondly, comments reported after watching the clinical research information animated video were “understand their own knowledge gaps” and “the willingness to seek more information after watching the video.” These qualitative descriptors provide insight for the importance to bridge the communication gap between minority population and health care professional to improve health literacy, health prevention, and quality of life metrics.

Comprehension. Physician-patient communication pertaining to medical advice and instructions are often perceived differently. The dissemination of material by physicians has been demonstrated to entail complex terminology and scientific sentence structures prompting increase anxiety by the patient (Houts, Doak, Doak, & Loscalzo, 2006). This communication pattern is enhanced for lower health literate patients. Gazmararian (1999) denoted that 23% of English speaking individuals were not sufficiently capable of reading and/or comprehending medical instruction delivered by their health care provider. For the same population sample, this inadequate comprehension was heightened for minorities compared to White individuals, Black OR = 3.54; 95% CI [2.58-4.58] and non-White Hispanic OR = 2.50; 95% CI [1.34-4.69], lower income employment categories versus higher earning employment classifications, OR = 2.12; 95% CI [1.48-3.03], and lower education achievement compared to at least more than high school diploma, OR = 6.09; 95% CI [4.36-8.37].

Austin, Matlack, Dunn, Kesler, and Brown (1995) performed a randomized experimental study, $N = 101$, for Emergency Room discharged patients for a laceration residing in a rural geographical region. The control group received text-only discharged instructions versus the experimental group obtaining animated pictures with corresponding text. The text within each intervention was identical. A follow-up interview conducted by a blind-interviewer from the disseminated instruction stage of the study. Discharged patients receiving animated pictures with text (experimental group) had an OR = 1.5 more likely to respond with 5 or more correct responses to the blind-interviewer's questions compared to the group receiving text-only discharged instructions

(control group), $p = 0.03$. Overall, 65% of the experimental group answered five or more questions correctly compared to 43% of the control group. Females in the experimental group were 1.7 times more likely to answer more than five questions correctly compared to females in the control group, $p = 0.006$. Lower education achievement, no more than high school education, in the experimental group had an OR = 1.8 for answering five or more questions correctly versus similar education level participants in the control group, $p = 0.03$. Lastly, minorities, non-Whites, in the experimental group were twice as likely to answer five or more questions accurately compared to non-Whites in the control group, $p = 0.03$.

A pilot study of low health literate patients, $N = 60$, by Mansoor and Dowse (2003) studying the effect of a traditional instruction leaflet (control group) versus an animated-text (experimental) intervention for properly administering a topical medication, Nystatin. The prose in the leaflet was identical to the animated-test intervention. The patients were randomly selected into either the control or experimental group. After completing their intervention, they were asked a series of questions corresponding to the instructional material. The response to the question, "How must you take this medication?", 93% of the experimental group answered correctly versus 47% of the control group, $p \leq 0.001$. In addition, the question associated with the timing of applying the medication, "What are the actual times?", 73% of the experimental group answered accurately compared to 3% of the control group, $p \leq 0.001$.

Miscommunication is common between low health literate parents/caregivers and health care providers. Leiner, Handal, and Williams (2004) conducted a randomized

prospective pre–posttest trial, $N = 192$, of parents/caregivers receiving a polio vaccination for their child. The participants were randomized into two groups: traditional pamphlet (control group) and an animated video (treatment group). The prose in the animated video was identical to the text within the educational pamphlet. Each participant completed a pretest questionnaire including polio vaccination facts. The baseline (pretest) mean scores, range from 0-5, were similar between the treatment and control groups, 3.04 versus 2.94, $p = 0.75$. Conversely, the posttest mean score, range from 0-8, were significantly higher for the treatment group compared to the control group, 6.24 versus 5.03, $p \leq 0.001$. 30.2% of the treatment group answered all the posttest polio vaccination questions correctly compared to 0% of the control group.

Memory recall. Using a form of animation to elicit enhanced memory recall has demonstrated conflicting results over the past decades. A stratified randomized control trial examining memory recall of basic and clinical pulmonary function information among first and second year medical students, $N = 163$, using an animated module. Each group took a pulmonary function pretest, yet the control group completed the pretest questions prior to watching the animated module and the experimental group viewed the animated module prior to completing the pretest. The experimental group performed 10% better than the control group: first year medical students, $p \leq 0.004$, and second year medical students, $p = 0.006$. Contrary, memory recall between groups receiving text-only compared to an animated pictorial book including identical text illustrated no difference between the two groups for enhancing information related to gout; however, the sample

may have been bias because all participants reported a high motivation to learn more about gout (Moll, Wright, Jeffrey, Goode, & Humberstone, 1977).

Age differences may elicit different memory recall responses using animation as health literacy intervention. A fMRI, Functional Magnetic Resonance Imaging, study illustrated that young and old adults have similar neural circuitry for encoding new memories, yet age variances in the prefrontal cortex, primarily responsible for cognitive behavior and decision-making, and the temporal lobe, responsible for sensory input suchlike visual representations, occur during the learning process (Morcom, Good, Frackowiak, & Rugg, 2003). A prospective 2 X 2 experimental study by Boucheix, Lowe, and Bugaiska (2015) demonstrated that younger people recall information faster than older counterparts regardless of the speed of the animation video, $p = 0.03$, or if the video was static or animated, $p \leq 0.001$.

Attention. Maintaining an individual's attention and focus is challenging. Research infers that implementing effective animated instructional videos investigators must constantly focus on the participants' visual short-term memory capacity balancing the duration of the animated video (Robitille & Jolicoeur, 2006). There are specialized nerve cells within the brain that perceives motion and elicits short term focus on the source (Goldstein, 1989). Diao and Sundar (2004) provides evidence that physiological responses, such as cardiac rhythms, change frequency responding to different types of animation. A study by Hong and Kar Yantam (2004) detected that the density of the animation flash secured an individual's attention, but the increase in attention did not

illustrate greater recall of information. The neural complexity associated with obtaining and maintaining the attention of an individual utilizing animation warrants more research.

Health Literacy: CC

Health literacy studies concentrating on CC are nonexistent. However, Gastroenterology, the scientific discipline who specializes in accurately diagnosis etiology for CC symptomology and clinically managing symptomology, has conducted a fair amount of rigorous research projects exploring the effects of health literacy on Gastroenterology fellowship training, medicine adherence, and adequate bowel preparation for a colonoscopy. The discipline the past decade has recognized and dedicated additional resources to studying how health literacy proficiency directly affects the physician-patient communication dialogue especially in asymptomatic chronic diseases (Tormey, Farraye, & Paasche-Orlow, 2016).

As chronic gastrointestinal diseases/disorders increase in prevalence, the transition for patients from pediatrics to adolescents to adult care relies on an adequate health literacy level to comprehend and participate in one's health care decisions. A study by Huang, Tobin, and Tompane (2012) illustrated discordance between Inflammatory Bowel Disorder patients of at least 10 years of age readiness to transition into an age appropriate medical care compared to their physician in relation to health literacy proficiency, 11% versus 47%. The physician's opinion for readiness to transition within this cohort poorly correlated with measured health literacy level, $r = 0.006$, $p = > 0.05$. Furthermore, a study by Balzora et al. (2015) investigated new examination components detailing specific types of mock patients. One of the new examination components

targeted a patient with *below basic* health literacy proficiency; only 18% (2/11) corrected identified the mock patient with *below basic* health literacy proficiency. Common medications for gastro-esophageal reflux (GERD) and dyspepsia are Proton Pump Inhibitors (PPI) and Nonsteroidal Anti-inflammatory Drugs (NSAID). A large community survey study of patients seen in Gastroenterology, Internal Medicine, and Otolaryngologist outpatient clinics, N = 1,000, reported that 35.3% of these patients were incorrectly following pharmaceutical instructions dispersed by a health care professional (Choi, Afshar, & Coyle, 2008).

Colonoscopy is the primary screen test for assessing common predictors for colon cancer (U.S. Preventative Services Task Force, 2008). Colon cancer is the third most common cancer in the United States (Jemal, Siegal, & Wald, 2008). A recent meta-analysis of 28 U.S. cross-sectional studies demonstrated no difference for increase colon cancer prevalence for patients undergoing a colonoscopy with an indication of CC (Power, Tally, & Ford, 2013). Similarly, a Chinese population-based study denoted the prevalence pertaining to a colonoscopy indicated from functional bowel disorder symptoms were unequal: functional abdominal pain 20.8%, functional diarrhea 57.1%, and CC 42.9%, yet no differences in the incidence of colon polyps, colon cancer, and colitis (Lai, Zhe, & Zhang, 2015).

Health literacy proficiency is a predictor variable for colonoscopy bowel preparation studies. Over the past decade, a form of animation as an intervention has demonstrated positive effects for improving bowel preparation for low or inadequate health literate patients. A study by Hsuch et al. (2014) utilized an education film to

highlight the importance for proper bowel preparation; 80.8% of the experimental group (education video) had higher adequate bowel preparation scores compared to 48.2% of a control group. Using the validated Boston Bowel Preparation Scale, Tae et al. (2012) conducted a blinded- RCT utilizing an animated cartoon for instructing how to perform a bowel preparation: control group (traditional written material) and the experimental group (watched the cartoon video). A lower score on the Boston Bowel Preparation Scale indicates a more adequate bowel lavage. The experimental group had a lower mean score compared to the control group, 6.12 versus 7.44, $p \leq 0.01$. A multivariate analysis from a sample of $N = 456$ patients recruited from a Family Medicine Residency Clinic showed a decrease in likelihood for undergoing preventative colon cancer screening in marginal health literate, OR = 0.52; 95% CI [0.29-0.92], and inadequate health literate, OR = 0.49; 95% CI [0.27-0.87], compared to adequate health literate patients (Ojinnaka et al., 2015). Similarly, a cohort of low and high literate patients assessed by the REALM measurement indicated that low health literacy was associated with more barriers for undergoing a colonoscopy, $p = 0.009$ (Peterson, Dwyer, Mulvaney, Dietrich, & Rothman, 2007). Conversely, a blinded-RCT by Calderwood et al. (2011) illustrated no difference between traditional pamphlet instructions versus an animated video format relative to adequate bowel preparation scored by a physician, 91% versus 89%, $p = 0.43$.

CTML

CTML was developed by Dr. Richard Mayer in 1997 (Mayer, 1997). He is a graduate of the University of Michigan, circa 1973. Currently, Dr. Mayer is a professor of psychology at the University of Santa Barbara. Through his research in how humans

learn, he developed CTML. Learning concepts include strengthening responses through associations, information acquisition which adds to information to memory, and knowledge construction fostering cognitive representations (Mayer, 1992). Additionally, learning entails a cognitive, thinking and processing information, and behavioral, actively engaging with the information, process (Bonwell & Elison, 1991). Each of these active learning processes must be performed at a high level to cultivate meaning long-term memory.

CTML was developed using three assumptions for learning:

- Dual coding theory: This theory was developed by Paivio (1971) postulating that individuals learn by absorbing verbal and visual images. These images strengthen the process of learning. However, verbal and visual information is processed within two different channels in the brain. Therefore, each channel constructs a separate code for representing the incoming information. These codes, verbal and imagery, are utilized to recall previous information (Sternberg, 2003).
- Limited capacity: This concept indicates that each learning channel, verbal and visual, has limited memory capacity during a point in time. This construct entails that an individual may only store small amounts of memory at any one time representing portions of the incoming information (Bradley, 1986).
- Active processing: This learning process occurs when humans actively engage cognitive processes creating a mental code for incoming information. This process is fostered by paying attention, organizing incoming material, and

integrating new information with previous knowledge. Cook and Mayer (1988) described this active learning by using comparison techniques, generalizing new material, enumeration codes, and classifying information.

The CTML model is an active process for learning verbal and pictorial information, multimedia, through a dual channel process, visual and auditory. Learners' process words and images utilizing cognitive and sensory channels in the brain. Incoming words may be spoken or text absorbed by either the eyes and/or ears. Pictorial images are processed by the eyes. Next, these stimuli are incorporated into working memory, which encompasses limited storing capacity. Within the working memory phase of multimedia learning, the verbal and pictorial models are generated. Lastly, these models are integrated with stored knowledge producing long term memory (Mayer & Moreno, 2003).

Multimedia instructions include both words, text or spoken, and images, photos, animation, charts, illustrations, and videos, where individuals learn more with both stimuli compared to a singular stimulus (Mayer, 2009). Three types of cognitive processes occur during learning which may affect learning capacity: Extraneous, Essential, and Generative (Mayer, 2009). Extraneous processing is impacted when the extraneous processing and required essential processing exceeds the learner's cognitive capacity. Essential processing is inhibited when the required processing exceeds the learner's cognitive capacity. Lastly, Generative process is obstructed if the learner decides to forego implementing effort for comprehending the incoming information.

There are evidence-based principles reducing the opportunity for reaching cognitive capacity for each of these cognitive principles required for learning.

In essence, CTML provides theoretical principles for reducing learning fatigue capacity. This theory defines the active process of learning by limiting the maximum cognitive capacity using dual comprehension mechanisms (Mayer, 2005). Thus, CTML illustrates that two separate channels, auditory and visual, are necessary for processing information. Each channel has limited learning capacity because active learning requires mechanisms for filtering, organizing, and integrating information (Mayer, 2014). The framework of CTML offers benefits to evaluate improvement of CC health literacy via the animation video versus the tradition method because the video requires both auditory and visual acuity compared to the tradition pamphlet only using visual learning.

Summary

Health literacy research is relative limited because a clear and structured definition has only occurred in the past few decades. Low health literacy proficiency has produced health disparities for underserved populations. The deductive effect of health literacy direct and indirect metrics induces economic burden, employment production, and educational achievement. Over the past few decades, health literacy measurement instruments have been abbreviated and more inclusive to further evaluate the influence of different health literacy levels within society, especially as the western world progresses toward greater personal responsibility to an individual’s health care instead of the traditional medical provider dictating nearly all medical decisions.

Functional bowel disorders are highly prevalent in society. These disorders consume a tremendous amount of personal and societal financial resources annually. These symptomatic disorders are trending upward because more and more American are living longer and being diagnosed with numerous chronic diseases. Within functional bowel disorders, CC is responsible for large number of doctor visits, consume large amount of financial resources, and directly affecting quality of life measurements. Information is nonexistent for CC patients to improve CC health literacy. The majority of gastroenterology health literacy research is performed on colonoscopy bowel preparation assessment. Multiple interventions, prose, written, and animation, have been utilized to optimize educational efficacy for conducting an adequate and correct bowel lavage.

As Mayer (2003) developed and investigated the conceptual constructs of CTML, the evidence depicted that learning neural processes may have load capacity. Therefore, utilizing animated education interventions, which include verbal and pictorial limits the potential for cognitive load capacity. Furthermore, by reducing cognitive load capacity, newly presented information has greater opportunity to employ cognitive principles for generating a higher percentage of memory recall. An abundant of animated health literacy projects using CTML has illustrated statistically significant differences between control and treatment groups. Thus, utilizing the theoretical principles of CTML, animation has the potential to enhance CC health literacy decreasing societal economic burden and empowering individuals suffering from CC symptomology.

Chapter 3: Research Method

Introduction

The purpose of this quantitative study was to (a) examine the difference of using CC animated educational video compared to a CC traditional written educational pamphlet in relation to health literacy level for advancing CC knowledge; and (b) identify relationships between health literacy proficiency levels and demographic and environmental variables within a chronic constipated cohort. The research questions for this study included the following:

1. Is there a statistical mean difference between the CC Pretest Quiz and the CC Posttest Quiz following randomization into either the CC animated education video or the CC traditional written educational pamphlet?
2. What is the relationship between health literacy proficiency level and CC Pretest Quiz scores?
3. What is the relationship between health literacy proficiency level and CC Posttest Quiz scores?
4. What is the effect of the randomized group (CC animated education video vs. CC traditional written educational pamphlet) on CC posttest health literacy score controlling for the following independent variables: CC Pretest Quiz score, age, gender, race/ethnicity, highest level of education achievement, income level, employment description, level of interest toward learning, best type of learning, and challenges related to learning?

The following sections include description of rationale for using a retrospective quantitative parallel-group randomized cross-sectional study design, target population, the sampling procedure, and obtaining archival data.

Research Design

The study employed a cross-sectional design structure (Figure 2). The dependent variable for the paired sample *t*-test analysis was the CC quiz scores. For the Pearson product-moment correlation, the variables of the pretest and posttest constipation quiz scores were correlated with the SAHL-E assessment. The dependent variable in the univariate analysis per the generalized linear model was the posttest score controlling for the following independent variables: age, sex (male vs. female), race/ethnicity, BMI, highest level of education achievement, income status, and health literacy level.

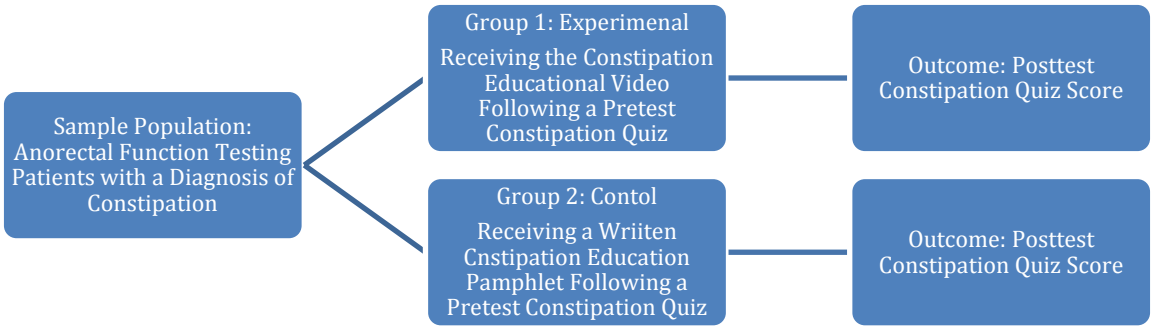

Figure 2. The parallel-group cross-sectional randomized study design for the University of Michigan Chronic Constipation Health Literacy project: CC educational animated video versus traditional CC educational written pamphlet.

For this study, I used a dataset from the University of Michigan in which patients scheduled for anorectal function testing in the gastrointestinal physiology laboratory with the diagnosis of CC were recruited. This secondary dataset included a diverse CC population, age, sex, BMI, and race/ethnicity, cohort experiencing constipation

symptomology. The data were collected using a parallel-group randomized cross-sectional design (Figure 2). This design provided an opportunity to randomize the recruited patients into two groups: the experimental group receiving the CC animated video and the control group obtaining the CC traditional written educational pamphlet. The subject randomization limited selection and researcher bias and permitted rigorous statistical analyses (Kendall, 2003). Using this randomized cross-sectional study design, the expected differences between the experimental and control group would be related to the intervention regardless of prognostic factors.

Similar to the construct of randomized control design studies, this study may have been influenced by additional time allocated for anorectal function testing patients (Sibbald & Roland, 1998). By participating in this study, the constipated patients added approximately 20 minutes to their schedule appointment. The extra cost for conducting randomized design studies was eliminated for this project because of the generosity by the company MyGiHealth permitting the principle investigator to utilize their CC, dyssynergia, animated educational video for no charge (https://go.mygihealth.io/education/symptoms/constipation).

Advancing health literacy knowledge is challenging because various confounding variables may impact outcomes. Randomized controlled trials utilizing animation as the intervention recently have demonstrated positive outcomes for improving health literacy proficiency. Calderón et al. (2014) examined the difference in the Diabetes Health Literacy Survey (DHLS) scores after a group of adult Latinos being randomized into either the control group, easy-to-read written diabetic material, or the experimental group,

watching a cultural specific animated diabetic educational video. The pretest DHLS scores were similar for both groups; however, the experimental group significantly improved their post DHLS scores compared to the control group. Animation as the intervention in randomized controlled trials has depicted positive outcomes for culturally diverse and linguistically varied communities (Hughson et al., 2016). Moreover, this study design provides an opportunity for a quantitative statistical approach, the capability for comparative examination, and to determining the effect size relative to the intervention. This study design was appropriate to advance scientific knowledge toward the impact of animation as a therapeutic clinical tool for improving health literacy proficiency in a diverse and global community experiencing similar disease or symptomology.

Population

The target population for this archived dataset from the University of Michigan composed of individuals experiencing symptomology within the CC spectrum. The CC spectrum ranges from slow gastrointestinal transit, abdominal discomfort, altered stool form, and fecal incontinence (Rao & Meduri, 2011). The dataset consists of CC patients scheduled for anorectal function testing at the University of Michigan's gastrointestinal physiology laboratory from August 2017 to September 2017. The University of Michigan's gastrointestinal physiology laboratory performs 1,000 anorectal function tests per year.

Sampling and Sampling Procedure

The sampling strategy used in this archived dataset was convenience nonrandom sampling. This nonprobability sampling technique focused on the objective to recruit a certain number of CC subjects undergoing anorectal function testing to investigate the impact of a CC animated educational video compared to a CC traditional written educational pamphlet relative to CC health literacy proficiency. Furthermore, this subset of individuals with CC represented approximately 27% to 59% of the entire CC population (Rao & Patcharatrakul, 2016).

The advantages for using a convenience sampling strategy consisted of being easy to execute, inexpensive, and allowing the ability to collect a large amount of data in a reasonable amount of time; conversely, the disadvantages concerning this sampling strategy were limits to generalizability for outcomes onto the global CC community and insufficient power to determine the effect toward minority communities (Bornstein, Jager, & Putnick, 2013). The disadvantage regarding limitation on generalizing outcomes may not represent the entire CC community and instead isolates only individuals with functional CC, pelvic floor dysfunction, and abnormal transit measurements. Next, the University of Michigan resides in Ann Arbor, Michigan where the population consisted of 73% Caucasian (U.S. Census Bureau, 2015). Therefore, minority populations may have been underrepresented primarily due to the community demographics.

The sampling frame for the original study consisted of recruiting subjects from patients scheduled for anorectal function testing at the University of Michigan's gastrointestinal physiology laboratory for the diagnosis of CC. Of the approximately

1,000 anorectal function tests per year scheduled, 700 of this physiological diagnostic pelvic floor evaluation had a diagnosis of CC. The remaining 300 anorectal function tests had a diagnosis of either fecal incontinence, anal pain, and preoperative and postoperative sigmoid and colon evaluation. Therefore, the sample was recruited from the 700 anorectal function tests scheduled for CC. The inclusion criteria for the study consisted of undergoing anorectal function testing for CC, adult age (≥ 18 years of age), ability to read, write, and comprehend English, and capable of signing their own consent form. The exclusion criteria included a diagnosis for any other etiological reason besides CC, pediatrics, individuals who did not speak, write, or comprehend English, unable to provide consent to participate, and visually impaired.

The original University of Michigan's Chronic Constipation Health Literacy project included various covariates to determine the CC patient's opinions related to the two CC interventions: CC animated education video or CC traditional written educational pamphlet. The dependent variable was the intervention, and the primary independent variables were patient perspective questions related to their randomized CC intervention. In addition, data were collected to examine the effect of demographic and environmental variables in relation to patient perspective responses concerning their randomized CC intervention.

I have acquired the following data from the University of Michigan's Chronic Constipation Health Literacy dataset. Pertaining to my dependent variable, I procured the CC Pretest and CC Posttest Quiz scores. The covariates included demographic variables (age, sex, BMI, and race), environments items (socioeconomic status and education), and

health literacy assessment. These variables provided information to answer my research questions related to differences among the two CC health literacy interventions.

A power analysis was conducted using G*Power 3.1 software (Heinrich-Heine-University, Düsseldorf, Germany). A sample size estimation and power analysis for univariate ANOVA was conducted prior to requesting the archival dataset (Faul, Erdfelder, Buchner, & Lang, 2009). The power (1-β) was set at 0.80 and α = 0.05, two tailed. Using the pilot study data pertaining to the CC quiz, the effect size (*d*) was calculated with the following equation by inserting the mean 13-question posttest CC quiz (*N* = 20) for the experimental (*M* = 8.8) and control (*M* = 8.4) groups and the pooled variance (PV) for the entire sample of posttest CC quiz (*SD* = 0.93; Coe, 2002).

$$\text{Effect Size } (d) = \frac{[\text{Mean Experimental Group}] - [\text{Mean Control Group}]}{\text{Standard Deviation}}$$

The effect size (*d* = 0.43) was compared against Cohen's level of effect sizes for *F*-test ANOVA power calculations: small = 0.10, medium = 0.25, and large = 0.40 (1988, pp. 284 – 287). Therefore, with α = 0.05, power 0.80, and *d* = 0.43, the projected sample size required is a minimal of *N* = 97 for between group comparison; thus, each group needed to at least include *n* = 49 (Table 5).

Table 5

*G*Power: ANOVA*

F-test – ANOVA: Fixed effects, special, min effects and interactions Analysis: A priori: Compute required sample size		
Input:	Effect Size (*d*)	0.43
	A err prob	0.05
	Power (1-β err prob)	0.80
	Numerator df	10
	Number of Groups	2
Output:	Noncentrality parameter λ	17.93
	Critical *F*	1.93
	Denominator *df*	95
	Total Sample Size	97
	Actual Power	0.8026965

Procedures for Recruitment, Participation, and Data Collection

Participants were recruited by a single principle investigator at the University of Michigan's gastrointestinal physiology laboratory. The principle investigator identified patients scheduled for anorectal function testing with a diagnosis of CC and fulfilling the inclusion criteria. Each participant was provided a detailed explanation for each section of the study, including the benefits to themselves, time allocation, and potential alterations to the CC health literacy algorithm. Following the investigator's detailed explanation of this study and prior to obtaining informed consent from patients volunteering to participate in the study, the principle investigator applied the teach back method. This confirmation of understanding process provided participants an opportunity to restate the study's objectives, intent, and participation details in their own words (Kripalani & Weiss, 2006). Lastly, the informed consent was obtained by the principle investigator from all participants.

The data collected in the University of Michigan Chronic Constipation Health Literacy project included a demographic and learner assessment intake form, a SAHL-E assessment, CC Pretest and CC Posttest Quiz scores, and a participant perspective CC intervention questionnaire (Figure 3). The demographic and learner assessment intake provided data pertaining to biological variables and environmental elements associated with learning (Appendix A). Next, each participant completed the SAHL-E assessment (Appendix B). Immediately after completing the SAHL-E assessment, each participant took a 13-question CC Pretest Quiz (Appendix C). These three items completed the first phase of the data collection. The participants were randomly selected into the control or

experimental group for their CC health literacy intervention. The control group received a CC traditional written educational pamphlet (Appendix D). The words enclosed in this pamphlet were verbatim to the orated script within the CC animated educational video. The experimental group watched the 2-minute CC animated educational video (Appendix E). Then, the participant proceeded to undergo their anorectal function test approximately 30-minutes: 20-minutes allocated for testing and 10-minutes allotted for cleaning and re-dressing. The second phase of data collection comprised of a 13-question CC Posttest Quiz (Appendix F) proceeded by a participant perspective CC intervention questionnaire (Appendix G). The participant perspective information provided details regarding their beliefs and attitude toward these two CC educational interventions (Boynton, 2004). The CC Posttest Quiz incorporated the exact questions as the CC Pretest Quiz besides the questions were in a different order.

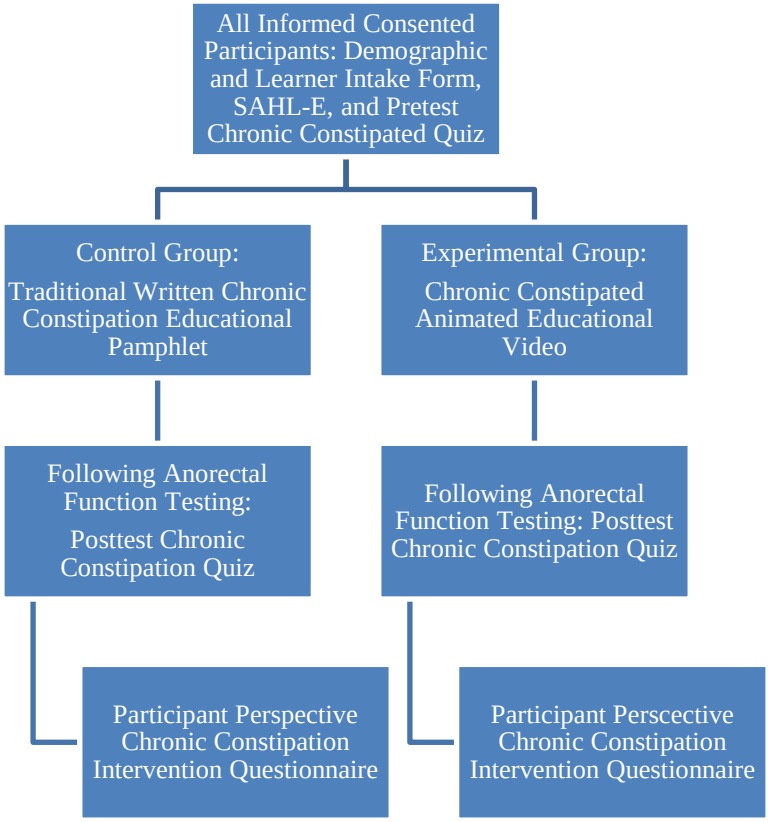

Figure 3. Study flow-chart pertaining to the University of Michigan Chronic Constipation Health Literacy project data collection for the control and experimental CC groups.

I created a letter to the principal investigator at the University of Michigan to inquire the possibility of using their CC dataset for my dissertation (Appendix H). The data were collected under the ethical guidance and approval of the University of Michigan's Internal Review Board: application number HUM00125953. Following approval from Walden University's Internal Review Board, I requested that the University of Michigan's principle investigator to de-identify the CC health literacy dataset and transfer the Microsoft Excel file including the variable key electronically via a Health Insurance Portability and Accountability (HIPAA) secured cloud-based storage system.

Instrument

The SAHL-E was developed by Lee at al. (2010). SAHL-E was constructed using the knowledge of an expert panel through the Delphi process. The Delphi process is a technique for systematically gathering data from a diverse panel of experts to achieve convergence of opinion assembling consensus relative to the particular topic (Hsu & Sandford, 2007). SAHL-E compared to REALM incorporated multiple-choice questions to assess comprehension. The multiple-choice educational achievement technique relative to defining, comprehending or understanding is based-upon accurate identification from previous facts, principles, or concepts (Haladyna, 1999). The SAHL-E was appropriate for the University of Michigan Chronic Constipation Health Literacy project because the time to perform was negligible, health literacy comprehension may be assessed similar to gold-standard health literacy proficiency instruments, and easy to conduct.

Using validated instruments require investigators to obtain permission from the author(s) to utilize within a project; therefore, even though I am using an archived dataset from the University of Michigan, I sent a letter to Dr. Shoou-Yih Daniel Lee at the University of North Carolina, developer of the SAHL-E, for permission to use the health literacy assessment instrument in my dissertation (Appendix I).

The SAHL-E was validated and correlated with two primary instruments utilized in various scientific disciplines for assessing health literacy proficiency: REALM and TOFHLA. The SAHL-E had a very high positive correlation with REALM ($r = 0.94$, $p \leq 0.05$) and a moderate positive correlation with TOFHLA ($r = 0.62$, $p \leq 0.05$) [Mukaka, 2012]. The test-retest reliability for the SAHL-E was 0.80 and 0.89 (Lee, 2010).

Furthermore, the SAHL-E had a high reliability, > $\alpha = 0.90$, for individuals with lower reading levels (Lee, 2010). Overview plots of SAHL-E, REALM, and TOFHLA scores depicted a SAHL-E score between 0 and 14 had a 76%- 85% likelihood of having a low literacy level corresponding to the REALM and TOFHLA instruments (Lee, 2010). Moreover, a cut-off threshold on the SAHL-E of < 14 resembled low health literacy (Lee, 2010).

The SAHL-E has been utilized as a health instrument in various peer-reviewed publications. A recent study by Wolpin et al. (2016) used SAHL-E to measure the effect of health literacy proficiency for utilizing infographics education within a newly diagnosed African American prostate cancer cohort ($N = 26$). They compared the correlation coefficients between the SAHL-E and REALM and TOFHLA; $r = 0.94$, $p \leq 0.05$ and $r = 0.68$ and $p \leq 0.05$ respectively (Lee, 2010). The SAHL-E metric illustrated the lower health literate African- American men newly diagnosed focus longer and quicker toward infographics versus text material (Wolpin, 2016). A study depicted the effectiveness of developing an *Ecological Momentary Assessment (EMA)* mobile application replacing text with icons to report eating and weight loss behavior experiences occurring in the natural environment for low health literate Mexican American females ($N = 41$). Health literacy was measured using the SAHL-E. The internal consistency was determined by a previous validated study: $\alpha = 0.89$ and $\alpha = 0.80$ (Lee, 2010). The results illustrated no differences between usability for the *EMA* mobile application, icons, compared to text prose (Connelly, Stein, Chaudry, & Trabold, 2016).

Researcher Instrument: CC Pretest and Posttest Quizzes

The principle investigator at the University of Michigan constructed CC quizzes: CC Pretest Quiz (Appendix C) and CC Posttest Quiz (Appendix F). These quizzes were identical. The CC quiz questions and multiple-choice answers were from the specific CC educational material: CC traditional written educational pamphlet and CC animated educational video. Because both CC educational platforms utilized verbatim prose, each participant was exposed to the exact same CC educational material regardless of group randomization. Prior to recruiting patients undergoing anorectal function testing for the diagnosis of CC, the principal investigator performed a pilot study using the CC quiz on 20 healthy control individuals; a Microsoft Excel randomization code was applied where 10 received the CC traditional educational written pamphlet and 10 watched the CC animated educational video. Similar to the randomized parallel-group cross-sectional design applied for data collection, each of these pilot study participants completed a CC Pretest Quiz, received a CC education platform, and then 30 minutes later completed a CC Posttest Quiz. The objective for this pilot study was to calculate critical data metrics to compute a power-analysis pertaining to their randomized CC intervention.

The CC animated educational video group pretest and posttest measurements, mean (*M*) and standard deviations (*SD*), were $M = 6.5$ and $SD = 1.8$ and $M = 8.8$ and $SD = 0.97$. The CC traditional written educational pamphlet group CC Pretest Quiz scores were $M = 6.1$ and $SD = 3.5$, and their CC Posttest Quiz values were $M = 8.4$ and $SD = 0.92$. The internal validity of the 13 questions on CC Pretest and CC Posttest Quizzes, $\alpha = 0.68$, trended near acceptable by social experimental threshold of 0.70-0.95; whereas

68% of the variance of a true composite score would be considered internal consistent (Bland & Altman, 1997). A moderate test-retest reliability correlation, $r = 0.64$, for the CC Pretest and CC Posttest Quizzes was depicted (Mukaka, 2012). The test-retest reliability was diminished because there was 70% improvement between the pretest to the posttest after completing the CC educational intervention: CC animated education video ($SD = 1.5$) and CC traditional written educational pamphlet ($SD = 1.4$). This pilot study examining reliability and validity of the CC Pretest Quiz and CC Posttest Quiz provides compelling data verifying the questions were appropriate to measure CC comprehension.

Intervention Study: Independent Variable

The independent variable used in the University of Michigan Chronic Constipation Health Literacy study was the type of CC educational platform: CC animated educational video or a CC traditional written educational pamphlet. The CC animated educational video was designed and constructed by MyGiHealth (https://go.mygihealth.io/education/symptoms/constipation). The CC traditional written educational pamphlet was crafted using the exact same words spoken in the CC animated educational video verbatim. This software was developed by a joint partnership between the University of Michigan, Cedars-Sinai, and the University of California – Los Angeles. The software provides a platform to improve and modernize the method of which doctors and patients communicate. MyGiHealth software tailors an educational prescription related to a patient's gastrointestinal symptomology, utilizes contemporary technology expanding health literacy proficiency, and enhancing the fidelity of clinical office visits.

The computer algorithm for the MyGiHealth software platform, automated evaluation of gastrointestinal symptoms (AEGIS), was compared against standard of care. A cross-sectional study with a paired sample design compared the number of gastrointestinal positive alarm features, melena unintentional weight loss, fever, and decreased appetite, identified by a gastroenterologist and the AEGIS. This design provided an opportunity for the participants ($N = 75$) gastrointestinal medical information to populate in their electronic medical record. Blinded physician reviewers tallied the number of positive gastrointestinal alarm features within the electronic medical record. AEGIS identified a statistically significant more positive gastrointestinal alarm features compared to standard of care, 53% versus 27%, $p \leq 0.001$, and physicians performing usual care methods only documented 30% of the positive gastrointestinal alarm features self-reported by patients using AEGIS (Almario et al., 2015). This contemporary software and highly sophisticated animated gastrointestinal educational videos provide opportunities to invigorate the doctor-patient relationship and improve gastrointestinal health literacy proficiency.

Operationalization: Variable Description

The University of Michigan Chronic Constipation Health Literacy project's dataset includes numerous dependent variables. The demographic variables include sex, age, BMI, and race (Appendix A). Sex is binary (Male or Female), and race is categorized into eight categories (White, African American-Black, Asian, Middle Eastern, American Indian or Alaska Native, Hispanic, Indian, or Native Hawaiian/Other Pacific Islander). Age and BMI are continuous variables. The highest level of educational

achievement and income level ordinal variables are categorized into eight and twelve categories respectively (Table 6 and Table 7). The description type pertaining to the participant's employment was binary, white collar or blue collar.

Table 6

Highest Level of Educational Attainment Categories

1. Grade 8 or less	5. Technical or vocational graduate
2. Grade 12 or less	6. Bachelor's degree
3. High school graduate	7. Master's degree
4. Associate's degree	8. Doctoral degree

Table 7

Income Level (Annual) Categories

1. < $9,999	7. $60,000 - $69,999
2. $10,000 - $19,999	8. $70,000 - $79,999
3. $20,000 - $29,999	9. $80,000 - $89,999
4. $30,000 - $39,999	10. $90,000 - $99,999
5. $40,000 - $49,999	11. $100,000 - $149,999
6. $50,000 - $59,999	12. > $150,000

The three learner assessment ordinal variables measurements are categorized (Appendix A). The first question related to the participant's interest in learning has three responses: Low, Medium, or High. The second question pertaining to the method of which they learn best has four responses: Seeing, Doing, Hearing, or Reading. The last

question concerning issues making it difficult to learn has six responses: Hearing, Vision, Memory, Feeling, Resources, Comfort, or Technology. The participants were instructed to only choose one response for the second and third learner assessment questions.

The SAHL-E instrument evaluates health literacy proficiency as a binary outcome. The SAHL-E has 18 items, common medical terms (Lee, 2010). Each term equates to 1 point, incorrect or correct, in relation to the participant's response toward adjacent medical terms: key (similar), distractor (unrelated), or don't know. The final measurement is calculated by adding all correct responses (key) to common medical terms. Total summation of 0-14 suggest low health literacy and 15-18 indicate adequate health literacy (Lee, 2010).

The CC Pretest Quiz and CC Posttest Quiz include 13 independent questions pertaining to identical CC educational material provided in both the CC animated education video and the CC traditional educational written pamphlet. Each question in the CC quiz equals 1 point. Thus, the CC quiz score has a range of 0 -13 whereas scores closer to 0 equate to lower CC health literacy proficiency and scores near 13 specify higher CC health literacy proficiency. The CC quiz scores are calculated by accumulating all correct responses.

The Participant Perspective CC Intervention Questionnaire includes five independent questions regarding the participant's perception toward their CC health literacy intervention. The first two questions have ordinal responses related to Agreement and Satisfaction (Appendix G). The last three questions provide a binary answer option:

Yes or No. The responses to each question will be included in a regression analysis to predict the participants' likelihood of using the CC intervention in the future.

Data Analysis Plan

The software that will be utilized for analyzing the data is SPSS, Version 24.0 (IBM Corp., Armonk, NY). The data cleaning procedure will encompass identifying incorrect input errors and examine the percentage of missing data points related to each variable. Incorrect input errors will be confirmed by performing a frequency analysis determining if all responses are within the instrument range, available ordinal responses, and outside the two binary answers. These input errors will be eliminated from the University of Michigan Chronic Constipation Health Literacy project's dataset by recoding the variables into a different variable without these errors prior to statistical analyses. Missing data points will be assessed by performing a univariate analysis to establish the extent of missing data. This analysis will compute an indicator variable comparing the percent mismatch between the reported responses and missing responses. According to Enders (2003), educational studies have a missing data rate of 15% to 20%. This CC health literacy study will utilize a conservative missing data rate of 15%. Therefore, if the variable has a missing data rate greater than 15%, the variable will be omitted from analysis. A high percentage of missing data in quantitative research may bias parameter estimates, decrease statistical power, and limit result generalizability (Dong & Peng, 2013).

Research Question 1

Is there a statistical mean difference between the CC Pretest Quiz and the CC Posttest Quiz following randomization into either the CC animated education video or CC traditional written educational pamphlet?

A paired sample *t* test was calculated to depict mean differences between CC knowledge prior to reviewing a CC educational intervention and post CC educational intervention from the same participant. Before performing the paired sample *t* test, normality wasverified by constructing a histogram of the distribution related to differences between the pretest and posttest scores for the entire study cohort. Secondly, boxplots were constructed to asses for bias pertaining to data outliers. The results were interpreted using $\alpha = 0.05$ and the 95% Confidence Intervals.

Research Question 2

What is the relationship between health literacy proficiency level and CC Pretest Quiz scores?

A Pearson product-moment correlation coefficient was computed to measure the strength between the CC Pretest Quiz score and the SAHL-E assessment. Scatter plots were crafted to illustrate the distance between the data points and the line of best fit. The Pearson product-moment correlation coefficient I ranges from +1 to -1. A value of 0 infers no relationship exist between the CC Pretest Quiz and the SAHL-E assessment. Conversely, valuI(*r*) greater than 0 indicate a positive relationship and vIes (*r*) less than 0 depict a negative relationship. All outlier data points were evaluated by constructing Box and Whisker Plots to determine if any values extend beyond the third and fourth quartiles

for the CC Pretest Quiz score and the SAHL-E measurement (Tukey, 1977, pp. 37-41). Any outlier was assessed by reviewing the data input and only omitted if improperly inputted into the dataset (Goodwin & Leech, 2006). The strength of the relationship between the two variables was determined by the size of the correlation coefficient (*r*; Table 8). Additionally, the coefficient of determination, R^2, was calculated to illustrate the proportion of variance shared between the CC Pretest Quiz and SAHL-E measurement. This proportion of variance among the two variables provides evidence for homoscedasticity or heteroscedasticity.

Table 8

Strength of Pearson Product-Moment Correlation Coefficient (r)

Size of Correlation	Interpretation
.90 to 1.00 (-.90 to -1.00	Very High Positive (Negative) Correlation
.70 to .90 (-.70 to -.90)	High Positive (Negative) Correlation
.50 to .70 (-.50 to -.70)	Moderate Positive (Negative) Correlation
.30 to .50 (-.30 to -.50)	Low Positive (Negative) Correlation
.00 to .30 (.00 to -.30)	Negligible Correlation

Note. Rule of thumb for interpreting the size of a correlation coefficient. From "A guide to appropriate use of correlation coefficient in medical research," by M.M. Mukaka, (2012), *Malawi Medical Journal, 24*, p. 71.

Research Question 3

What is the relationship between health literacy proficiency level and CC Posttest Quiz scores?

A Pearson product-moment correlation coefficient was computed to measure the strength of between the CC Posttest Quiz score and the SAHL-E assessment. Scatter plots were crafted to illustrate the distance between the data points and the line of best fit. The Pearson product-moment correlation coefficient (*r*) ranges from +1 to -1. A value (*r*) of 0 infers no relationship exist between the CC Pretest Quiz and the SAHL-E assessment. Conversely, values (*r*) greater than 0 indicate a positive relationship and values less than 0 depict a negative relationship. All outlier data points were evaluated by constructing box-and-whisker plots to determine if any values extend beyond the third and fourth quartiles for the CC Posttest Quiz score and the SAHL-E measurement (Tukey, 1977, pp. 37-41). Any outlier was assessed by reviewing the data input and only omitted if improperly inputted into the dataset (Goodwin, 2006). The strength of the relationship between the two variables were determined by the size of the correlation coefficient (*r*; Table 8). Additionally, the coefficient of determination, R^2, was calculated to illustrate the proportion of variance shared between the CC Posttest Quiz and SAHL-E measurement. This proportion of variance among the two variables provides evidence for homoscedasticity or heteroscedasticity.

Research Question 4

What is the effect the CC animated educational video versus CC traditional written educational pamphlet on the CC posttest health literacy quiz score for a cross-sectional CC population undergoing anorectal functional testing controlling for the following independent variables: CC Pretest Quiz score, age, gender, race/ethnicity,

highest level of education achievement, income level, employment description, level of interest toward learning, best type of learning, and challenges related to learning?

A generalized linear model univariate analysis was conducted exploring the distribution and description of each individual predictor variable pertaining to the CC posttest health literacy quiz. Predictor variables with a $p \leq 0.05$ and ≤ 0.100 will be utilized in the multiple linear regression model. The univariate analysis limited the probability of a covariate significantly effecting the results of the CC posttest health literacy quiz.

A multiple linear regression model was performed to estimate the effect of participant's group on the CC health literacy measured by their CC Posttest Quiz score. Various demographical and environmental covariates were included in the multiple linear regression model based upon the univariate results to control for their effect on the dependent variable CC health literacy because each covariate has been independently demonstrated as an effect on health literacy proficiency and access to health care (Levy & Janke, 2016). The between-subject results were interpreted by assessing the adjustment of R^2 to determine the predictability of the model in the population as a whole. The effect size (η^2) describes the proportion of the variance in the CC health literacy proficiency attributable to the primary factor and covariates. The observed power depicted the probability of rejecting the null hypothesis via replications. An α less than 0.05 will be considered statistically significant.

Threats to Validity

The dataset may include external validity threats pertaining to ecological variables. Anorectal function testing is a mild invasive diagnostic test evaluating an intimate region of the human body. Therefore, the testing environment may influence or alter the participant's behavior. The level of anxiety has been demonstrated to influence simulated defecation responses during anorectal function testing (Rao, Kavlock, & Rao, 2006). To limit this ecological threat, the participant was described each section of the study in thorough detail without anyone in the exam room besides the principle investigator. This interaction method prompted a higher level of trust for the participant to participate in the CC health literacy study. The population external validity threat is negligible because the study design included participant randomization.

Similar to external validity threats, the dataset may comprise two internal validity threats. The subject's motivation to actively participate in their randomized CC health literacy educational intervention. To limit this internal threat, the principle investigator was only research staff member to administer all sections of the study to each participant. Secondly, the CC health literacy quiz is not a validated instrument. Therefore, a test-retest validation assessment was not administered to a large diverse CC sample. To counteract the effect of this internal validity threat, the principle investigator performed a pilot study using the CC health literacy quiz to calculate descriptive statistics and obtain comments related to the CC quiz. The information gained through the CC health literacy quiz pilot study allowed the principle investigator to improve quality and efficacy.

Ethical Procedures

I requested permission to utilize the University of Michigan Chronic Constipation Health Literacy project's data (Appendix H). The University of Michigan has a nationally recognized interdisciplinary bowel disorder program, Michigan Bowel Control Program (https://medicine.umich.edu/dept/michigan-bowel-control-program/). The Michigan Bowel Control Program Director, Dr. William Chey, granted me permission to utilize their CC health literacy proficiency dataset relative to the following conditions:

- I will only use this dataset for my dissertation project.
- I will not provide this data to any other investigator.
- I will cite the institution in my dissertation.
- I will send him a copy of my completed dissertation.

Using secondary datasets are effective in research limiting repetition and wasting of resources especially relative to sensitive topics (Tripathy, 2013). Secondary datasets allow for additional research questions to be answered and peer-reviewed for publication. The primary ethical concern for using the University of Michigan Chronic Constipation Health Literacy project's dataset is to ensure the data was not collected to answer a similar research question. Fortunately, this CC health literacy dataset was constructed to answer a distinctive different research question: patient perspective related to their randomized CC intervention.

The secondary dataset was transferred via a secured electronic vehicle, the University of Michigan's MI-Share, HIPAA compliant, cloud-based system. The University of Michigan's principal investigator sent an invitation via e-mail to access this

encrypted server protected folder. This HIPAA compliant folder temporarily stored the dataset. The data were de-identified and organized in a Microsoft Excel database. I copied the secondary CC health literacy dataset onto an encrypted password protected external hard drive and a HIPAA compliant cloud-based system. For the dissertation project, the student, Dissertation Chair, and Dissertation committee had access to the secondary dataset. Following completion and publication of the dissertation, the secondary dataset will be destroyed from all encrypted and password protected storage areas.

Summary

Chapter 3 provides a methodological description required to answer four independent research questions relative to the effect of two different CC health literacy interventions. This chapter's prose deliberates the definition of key terms, sample population, and dependent and independent variables. Additionally, the chapter provides a description for measurement instruments and data collection procedures. The statistical analyses agenda to examine relationships, correlations, and descriptive differences between a CC health literacy interventions and covariates. Next, internal and external validity threats are explored including methods for counteracting or limiting their impact on the outcomes. Finally, various ethical concerns are addressed highlighting the potential challenges using a secondary dataset and techniques employed to securely protect the secondary CC health literacy dataset.

Chapter 4: Results

Introduction

The purpose of the dissertation was to explore the impact of using animation compared to traditional health literacy methods, written scripts, related to CC health literacy proficiency. The four research questions required examining inferential statistics between the two groups, CC animated educational video versus CC traditional written educational pamphlet, and relationships between demographic and health literacy social determinant predictor variables in relation to CC health literacy proficiency. The devised hypotheses were propositions formulated by scientific reasoning that allowed for the rejection or failure to reject the null hypotheses based upon the statistical rigor of the analyses output.

Chapter 4 includes description the analyses conducted to provide statistical evidence to reject or fail to reject the null hypothesis for all four research questions. Sample descriptive statistics, entire sample and divided by CC health literacy intervention, are displayed first followed by a detailed explanation of the statistical output related to the statistical methodology for research question. This chapter concludes with a succinct summary pertaining to the overall results.

The secondary dataset utilized for this analysis was obtained from the University of Michigan in relation to their University of Michigan Chronic Constipation Health Literacy project from June of 2017 to February of 2018. Following Walden University's IRB approval (01-31-18-0353706), an Unfunded Data Sharing Agreement was crafted and agreed upon by both the University of Michigan and Walden University (Appendix

J). The transferred dataset, via a HIPAA protect cloud server (M-Box), was de-identified excluding all HIPAA identifiers. The dataset included demographics, environmental variables, health literacy levels, and pretest and posttest CC quiz scores.

The statistical software of SPSS, Version 24.0 (IBM Corp., Armonk, NY) was used for employing the statistical methodology to provide evidence to reject or fail to reject the null hypotheses. Prior to conducting the statistical methodology, each variable within the secondary data was compared to the code associated to the variable. This data exploration process provided opportunity to verify that the categorical variables matched the corresponding code. Within each statistical plan pertaining to individual research questions, data outliers were explored for indirectly effecting statistical output.

Statistical Power Criteria

In Chapter 3, a power analysis was performed using G*Power 3.1 software (Heinrich-Heine-University, Düsseldorf, Germany), shown in Table 5. The power (1-β) was set at 0.80 and $\alpha = 0.05$, two tailed. The mean values, standard deviations, and pooled variance metrics were determined by a pilot study measurement. The effect size ($d = 0.43$) was computed using the pilot study measurements. This effect size was denoted as large greater than 0.40 in relation to Cohen's level of effect sizes for *F*-test ANOVA power calculations (Cohen, 1988). The projected same size was at least $N = 97$ ($n = 49$ each group) for between group differences. The secondary dataset, University of Michigan's Chronic Constipation Health Literacy project, included a sample size of $N = 100$ ($n = 50$ each group). Thus, the minimum sample size was fulfilled to determine

differences between the two groups, CC animated educational video versus CC traditional written educational pamphlets.

Study Population Demographics

Participants recruited within this secondary dataset (N = 100) were a cross-section of patients scheduled for anorectal function testing with a diagnosis of CC at the University of Michigan between June 2017 and February 2018. Descriptive statistics were used to assess the basic demographic information on the study population.

Population Demographic Variables

One hundred patients were recruited to participate in the study. The sample consisted of 84 women (84%) and 16 men (16%). The majority of the participants were White (82%; Table 9). The age of participants ranged from 20 to 83 (M = 47.4, SD = 16.0). The upper thresholds for skewness and kurtosis were > 2 and > 7 (West, Finch & Curran, 1996, pp. 56-75). Age was normally distributed with skewness of -0.100 (SE = 0.241) and kurtosis of -0.881 (SE = 0.478) The BMI of the participants ranged from 18.5 to 27.6 (M = 27.6, SD = 6.3). BMI was normally distributed with skewness of 1.25 (SE = 0.25) and kurtosis of 1.57 (SE = 0.50).

Table 9

Study Population Demographics Variables

Characteristic	*N*	*M (SD)/%*
Age	100	47.4 (16.0)
BMI	100	27.6 (6.3)
Gender		
Female	84	84.0%
Male	16	16.0%
Ethnicity		
White	82	82.0%
Black	11	11.0%
Hispanic	5	5%
Asian	1	1%
Indian	1	1%

Note. Means (SD) and Percentages (%) for Participant Population. Source University of Michigan's Chronic Constipation Health Literacy dataset.

Population Socioeconomic Determinants

The highest levels of education achievement among the participants were normally distributed with a skewness of 0.05 (*SE* = 0.24) and kurtosis of -1.38 (*SE* = 0.48). The two highest presented highest level education achievement were high school graduates, *n* = 30 (30.6%) and master's degree, *n* = 30 (30.6%; Figure 4). Income status was normally distributed with a skewness of 0.66 (*SE* = 0.25) and kurtosis of -1.01 (*SE* =

0.49; Figure 5). Income status categories of less than $39,999, *n* = 57, represented 60.7% of the participants. Participants reporting an annual income status of less than $10,000, *n* = 22, denoted 23.4%. Participants described their employment type as white collar, *n* = 54 (67.5%), compared to blue collar, *n* = 26 (32.5%).

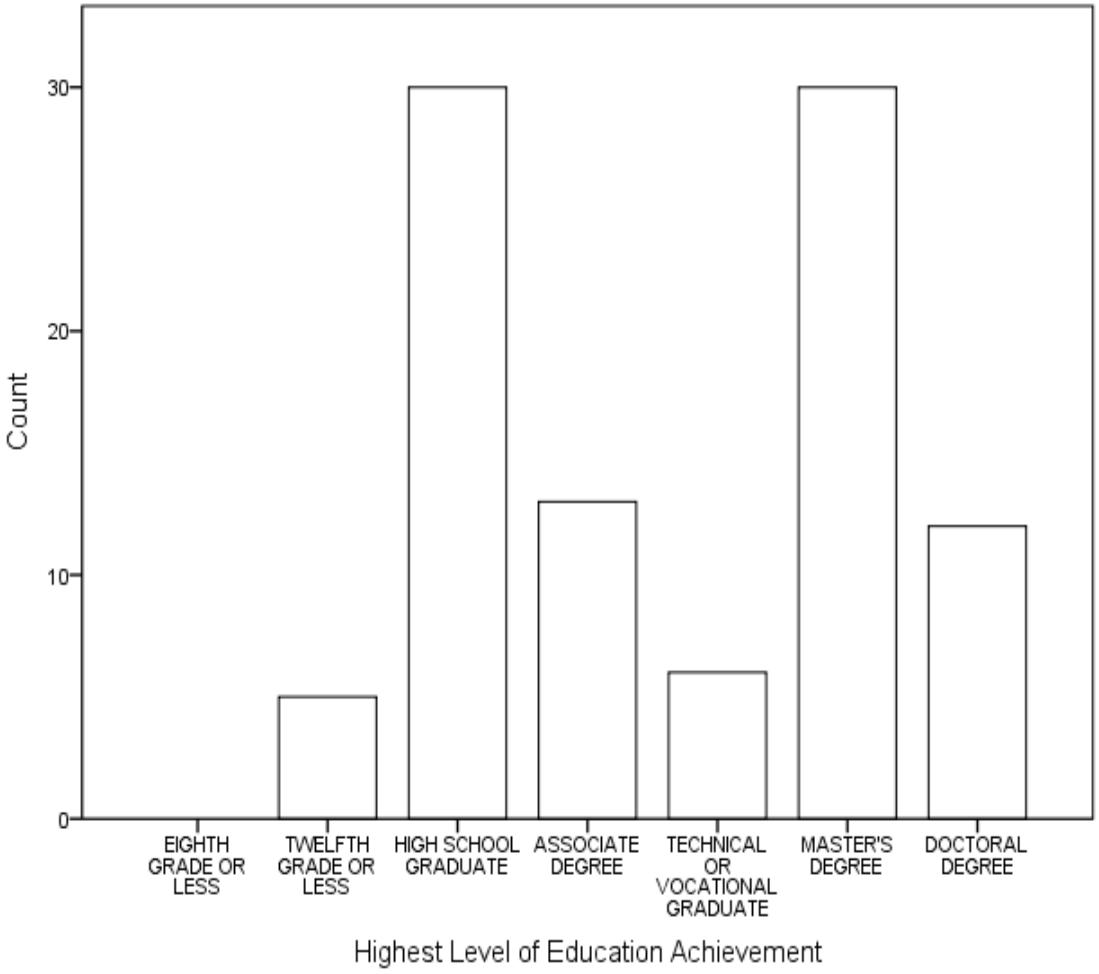

Figure 4. Highest level of education achievement of participant population. Source: University of Michigan's Chronic Constipation Health Literacy dataset.

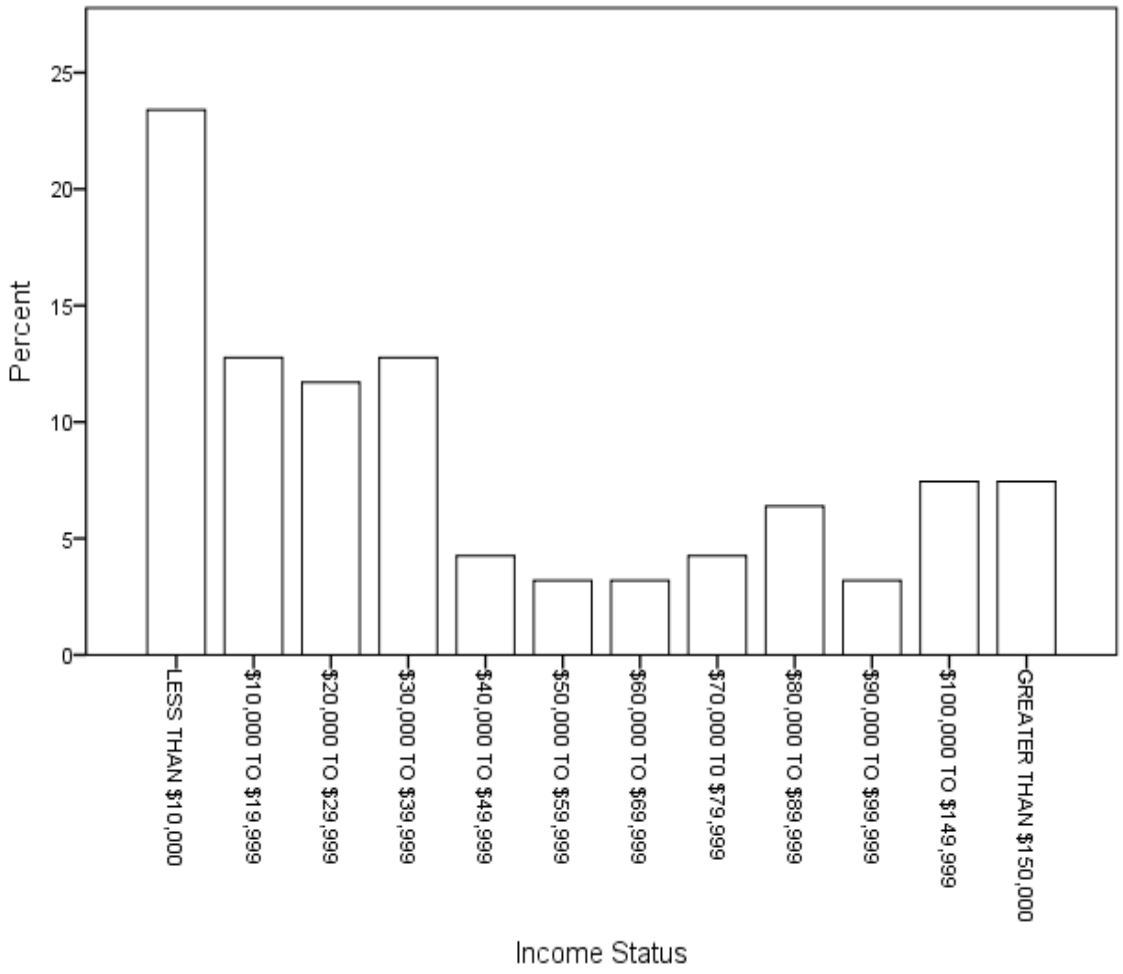

Figure 5. Income status of participant population. Source: University of Michigan's Chronic Constipation Health Literacy dataset.

Population Health Literacy Proficiency

Using the SAHL-E, 91.0% of participants accurately responded to 15 of the 18 items. A score of at least 15 denotes health literacy proficient (Lee, 2010). Thus, the sample was nondistributed with a skewness of -3.10 (*SE* = 0.24) and a kurtosis of 11.5 (*SE* = 0.48; Figure 6).

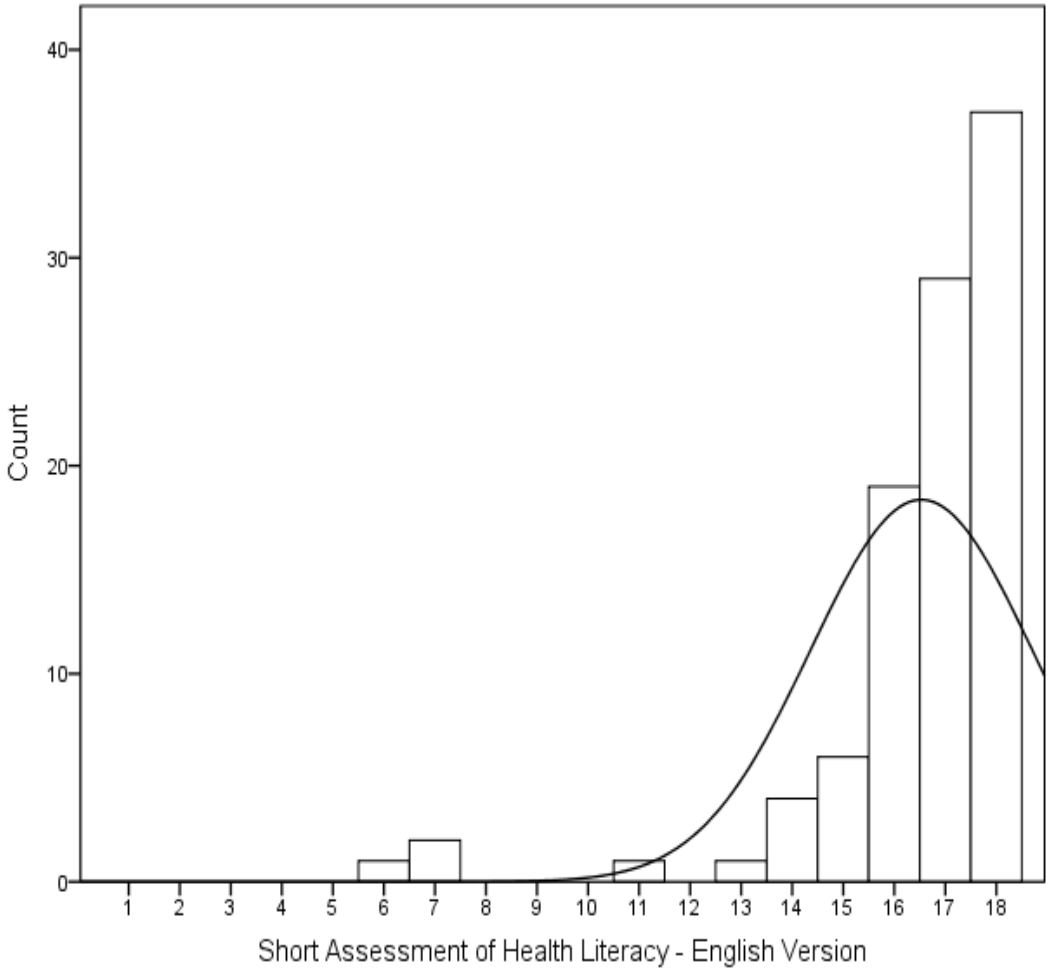

Figure 6. Total scores for the SAHL-E among the participant population. Source: University of Michigan's Chronic Constipation Health Literacy dataset.

Animated Educational Video Versus Traditional Written Educational Pamphlet Group Demographic Variables

An independent-samples *t* test was performed to compare the age for the CC animated education video and CC traditional written educational pamphlet groups. There was no significant differences in age for the CC traditional written educational pamphlet (M = 49.7, SD = 16.3) and the CC animated educational video (M = 45.0, SD = 15.6) groups; $t(98) = 1.461$, $p = 0.15$. The magnitude of the difference in mean age (M

difference = 4.66, 95% CI: -1.67 to 10.9) was minimal ($\eta^2 = 0.03$; Cohens, 1988). Equally, BMI depicted no statistical difference between the CC traditional written educational pamphlet (*M* = 27.3, *SD* = 6.6) and the CC animated educational video (*M* = 28.0, *SD* = 6.1) groups; *t*(90) = -0.53, *p* = 0.60. Negligible difference in mean BMI (*M* difference = -0.70, 95% CI: -3.32 to 1.93, $\eta^2 = 0.003$).

A chi-square test for independence indicated no significant differences in proportion of women and men between the CC traditional written educational pamphlet and CC animated educational video groups, χ^2 (1, *n* = 100) = 0.06, *p* = 0.59. Each group was primarily female: CC traditional written educational pamphlet (*n* = 43, 86.0%) and CC animated educational video (*n* = 41, 82.0%). Likewise, ethnicity demonstrated no differences in proportion among the self-reported ethnicity among the participants in both groups, χ^2 (1, *n* = 100) = 0.17, *p* = 0.56. Both the CC traditional written educational pamphlet (*n* = 41) and CC animated educational video (*n* = 41) groups denoted 82.0% an ethnicity of White followed by Black, CC traditional written educational pamphlet (*n* = 4, 8%) and CC animated educational video (*n* = 7, 14.0%).

Group Socioeconomic Determinants

There was a normal distribution related to highest level of education achievement for both the CC traditional written educational pamphlet, skewness of 1.57 (*SE* = 0.340) and kurtosis of -1.50 (*SE* = 0.67), and the CC animated educational video group, skewness of 0.31 (*SE* = 0.35) and kurtosis of -1.33 (*SE* = 0.68). No significant difference in proportions pertaining to highest level of education achievement between the two groups, χ^2 (1, *n* = 96) = 0.27, *p* = 0.24. However, the CC traditional written educational

pamphlet group had, *n* = 21, self-report a master's degree as the highest level of education achievement (42.9%) compared to the CC animated educational video group, *n* = 9, (19.1%; Figure 7).

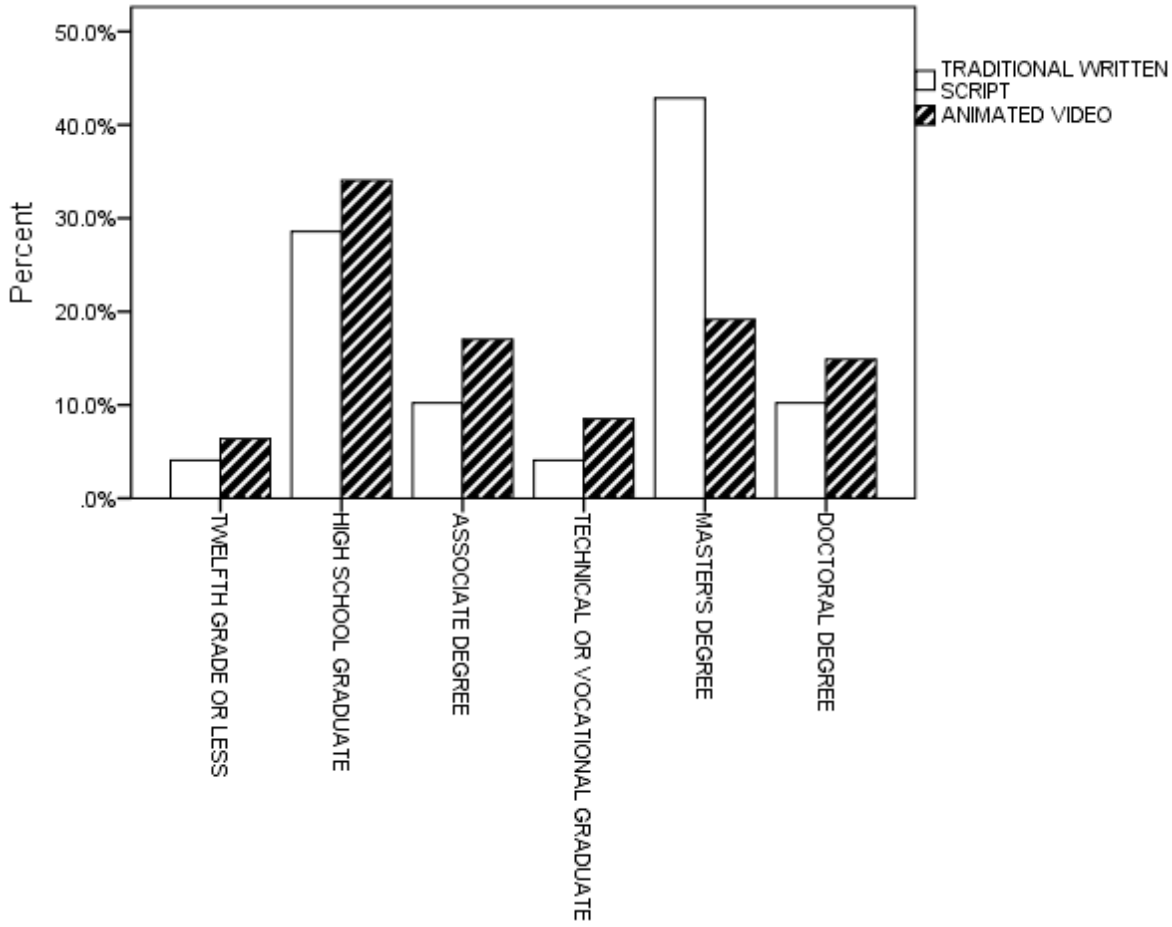

Figure 7. Highest level of education achievement: CC traditional written educational pamphlet versus CC animated educational video.

Income status was normally distributed for both the CC traditional written educational pamphlet and CC animated educational video groups. CC traditional written educational pamphlet group depicted a skewness of 0.57 (*SE* = 0.34) and kurtosis of -1.08 (*SE* = 0.67). Similarly, the CC animated educational video group had a skewness of 0.79

(*SE* = 0.35) and a kurtosis of -0.89 (*SE* = 0.69). There was no significant difference in proportions between the CC traditional written educational pamphlet and CC animated educational video groups in relation to income status, χ^2 (1, *n* = 94) = 0.42, *p* = 0.12. Each group had alike proportions for participants within the University of Michigan's Chronic Constipation Health Literacy dataset who self-reported an annual income of less than $39,999: CC traditional written educational pamphlet (*n* = 28, 56.0%) and CC Animated Educational Video (*n* = 29, 58.0%). CC traditional written educational pamphlet group self-reported their employment category as white collar (*n* = 26, 65.0%) equivalently to the CC animated educational video group (*n* = 28, 70.0%): χ^2 (1, *n* = 80) = 0.05, *p* = 0.63.

Group Health Literacy Proficiency

A chi-square test for independence indicated no significant differences in the proportions of participants in the University of Michigan's Chronic Constipation Health Literacy dataset who correctly answered SAHL-E items (0-18) corresponding as either low health literacy (0-14) or health literate (15-18), χ^2(1, *N* = 100) = 3.053, *p* = 0.08 (Table 10). Though, the CC animated educational video group had greater number of low health literate participants, *n* = 7, (14.0%), compared to the CC traditional written educational pamphlet group, *n* = 2 (4.0%).

Table 10

Health Literacy Proficiency Determined by the SAHL–E: CC Traditional Written Educational Pamphlet versus CC Animated Educational Video

Health literacy proficiency	CC traditional written pamphlet group	CC animated video group	χ^2	*P*
Low health literate (correct response of 0-14)	2 (4.0%)	7 (14.0%)	3.053	0.08
Health literate (Correct responses 15-18)	48 (96.0%)	43 (86.0%)		

Research Question 1

Is there a statistical mean difference between the CC Pretest Quiz and the CC Posttest Quiz following randomization into either the CC traditional written educational pamphlet or the CC animated educational video?

$H_0$1: There is no statistically significant mean difference between the CC Pretest and CC Posttest Quiz scores following randomization into either the CC animated educational video or CC traditional written educational pamphlet intervention.

H_a1: There is a statistically significant mean difference between the CC Pretest and CC Posttest Quiz scores following randomization into either the CC animated educational video or CC traditional written educational pamphlet intervention.

The difference between the pretest and posttest scores among the entire sample was equally distributed with a skewness of 0.15 (*SE* = 0.24) and a kurtosis of 0.13 (*SE* = 0.48; Figure 8). The majority of the score differences, *N* = 74 (74.0%), ranged from 1 to 4. The traditional written educational pamphlet group, *n* = 50, depicted a normal distribution related to CC quiz score differences with a skewness of 0.40 (*SE* = 0.34) and a kurtosis of 0.73 *(SE* = 0.66). The CC quiz score differences ranging between 1 to 4 had a frequency of *n* = 36 (72.0%). Similarly, the CC animated educational video group illustrated normal distribution pertaining to CC quiz score differences with a skewness of 0.006 (*SE* = 0.34) and a kurtosis of -0.48 (*SE* = 0.66). In relation to CC quiz scores differences ranging between 1 to 4, the frequency computed *n* = 38 (76.0%).

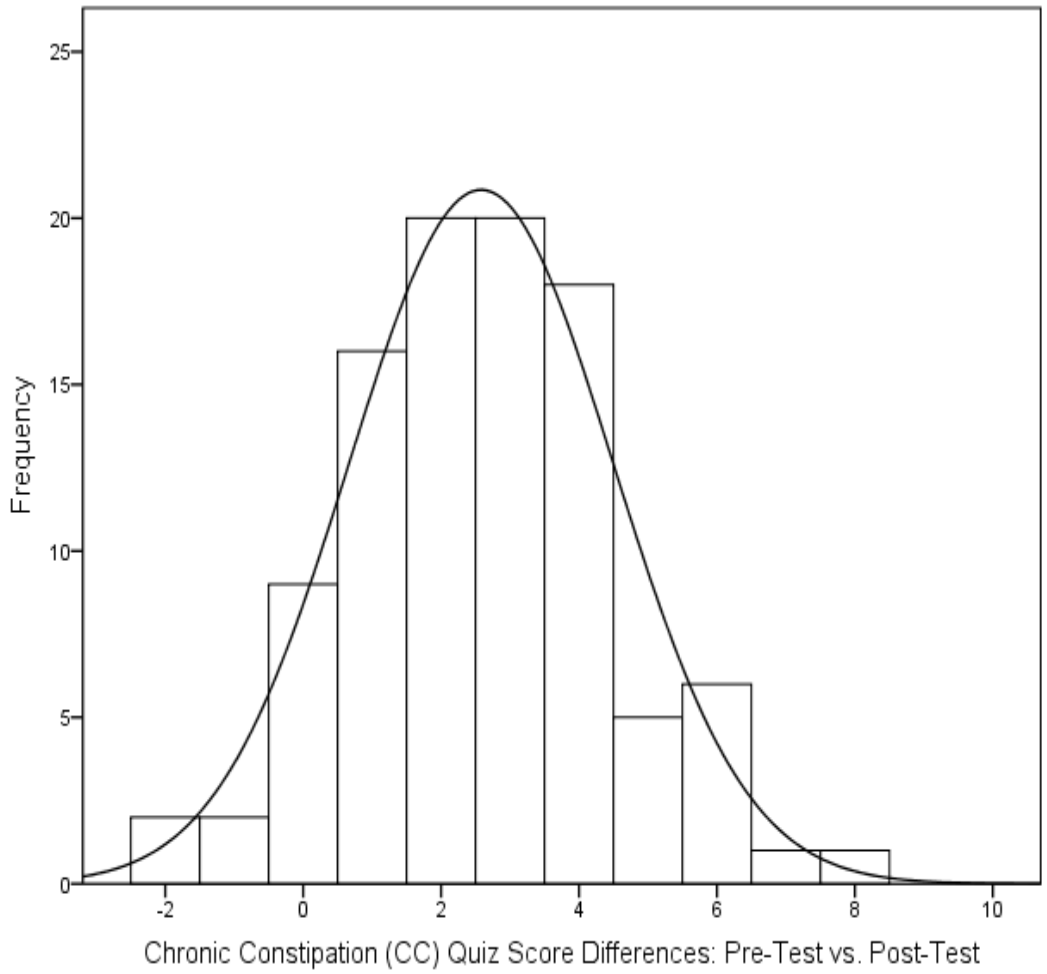

Figure 8. Distribution of quiz score differences between the CC Pretest Quiz and CC Posttest Quiz among the entire University of Michigan's Chronic Constipation Health Literacy project dataset.

The box-and-whisker plot demonstrated minimal bias for data outliers between CC Pretest Quiz and CC Posttest Quiz scores between the CC traditional written educational pamphlet and CC animated educational video groups (Figure 9). The CC traditional written educational pamphlet group CC quiz score difference was a *Mdn* = 2.00. The CC quiz score differences ranged from -2 to 8. Two CC traditional written educational pamphlet group participants had CC quiz score differences greater than the

75th percentile of 3.00. The CC Posttest Quiz score was included in the analyses because the quiz score remained within the possible maximum scoring range of 0 to 13. The CC animated educational video group CC quiz score difference equated to a *Mdn* = 3.00. The CC quiz score differences ranged from -1 to 6. No CC animated educational video group participants scored a CC quiz score difference beyond the 75th percentile of 4.00.

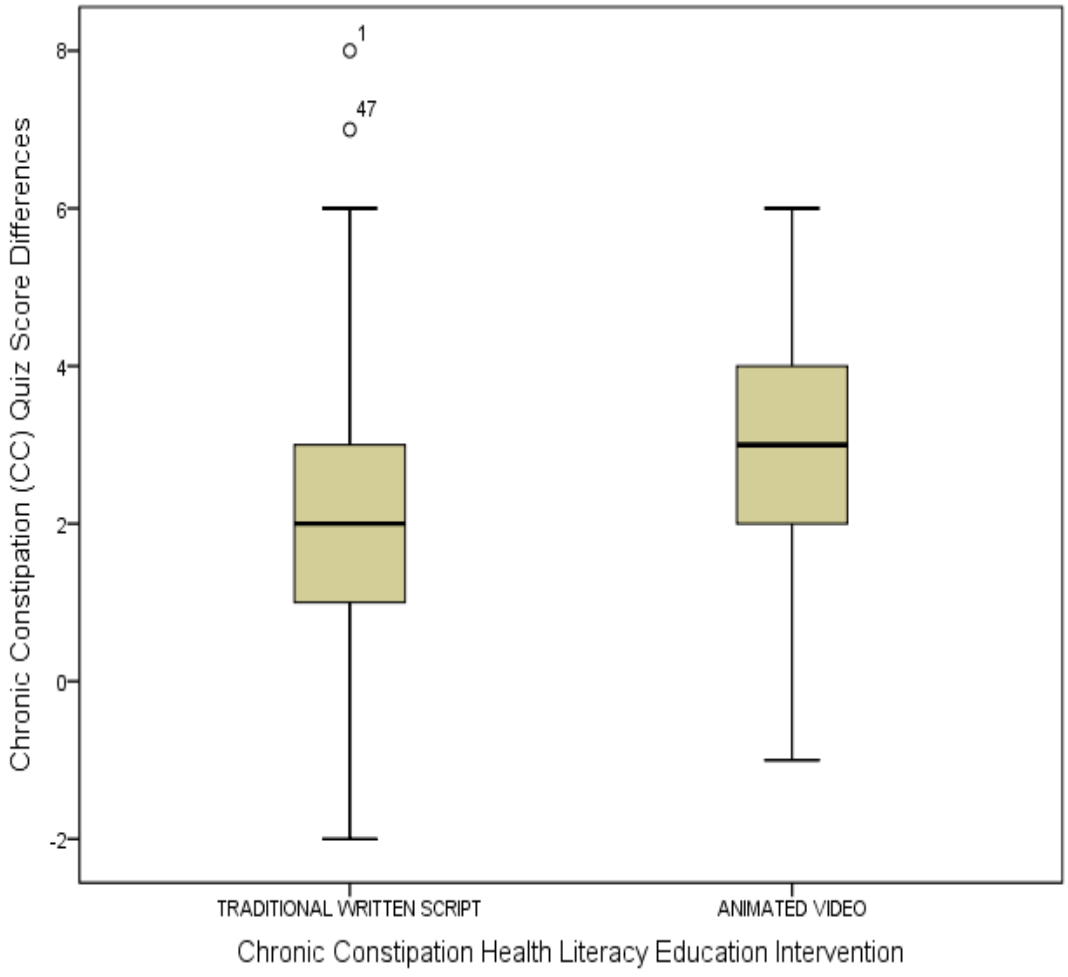

Figure 9. Assessment for data outliers pertaining to differences between CC Pretest Quiz and Posttest Quiz among the CC traditional written educational pamphlet and CC animated educational video groups.

A paired-samples *t* test was conducted to compare the difference between the CC Pretest Quiz and Posttest Quiz scores for the CC traditional written educational pamphlet group. There was a significant difference in CC quiz scores between the CC Pretest Quiz (M = 8.86, SD = 2.19) and CC Posttest Quiz (M = 11.1, SD = 1.83); $t(49) = -7.78$, $p \leq 0.001$, 95% CI: for M difference -2.81 to -1.66, $r = 0.50$. Likewise, a paired-samples *t* test was computed comparing the difference between the CC Pretest and CC Posttest Quiz scores for the CC animated educational video group. There was a significant difference in CC quiz scores between the CC Pretest Quiz (M = 8.28, SD = 2.09) and CC Posttest Quiz (M = 11.2, SD = 1.81); $t(49) = -11.9$, $p \leq 0.001$, 95% CI: for M difference -3.41 to -2.42, $\eta^2 = 0.61$.

An independent-samples *t* test was conducted to compare the pretest scores between the CC traditional written educational pamphlet and CC animated educational video groups. There were no significant difference in CC Pretest Quiz scores for the CC traditional written educational pamphlet group (M = 8.86, SD = 2.19) and CC animated educational video group (M = 8.28, SD = 2.09); $t(98) = 1.36$, $p = 0.18$. Equally, there were no significant differences in posttest scores between the two groups: CC traditional written educational pamphlet (M = 11.1, SD = 1.83) and CC animated educational video (M = 11.2, SD = 1.81); $t(98) = -0.275$, $p = 0.78$. The magnitude of the differences in the mean differences were negligible for both pretest and posttest scores between the two groups: CC Pretest Quiz (M difference = 0.58, 95% CI: -0.26 to 1.43, $\eta^2 = 0.02$) and CC Posttest Quiz (M difference = -0.10, 95% CI: -0.82 to 0.622, $\eta^2 \leq 0.001$).

Therefore, the null hypothesis was rejected in lieu of alternative hypothesis because these results depict that both CC health interventions, CC traditional written educational pamphlet and CC animated educational video, improve CC health literacy.

Research Question 2

What is the relationship between health literacy proficiency level and CC Pretest Quiz score?

$H_0$2: There is no relationship between health literacy proficiency level and CC Pretest Quiz score?

H_a2: There is a relationship between health literacy proficiency level and CC Pretest Quiz score?

Normal distributions were portrayed for both the low health literate group, n = 9, skewness of 0.41 (SE = 0.72) and kurtosis of 0.41 (SE = 1.40), and the health literate group, n = 91, skewness of -0.88 (SE = 0.253) and kurtosis of 0.71 (SE = 0.50) related to the CC Pretest Quiz. The pretest score range for the low health literate was 5-10 was smaller compared to the health literate group 2-13. A Box-and-Whisker plot depicts that the low health literate group had a *Mdn* score of 7.00 versus the health literate group, *Mdn* score of 9.00 (Figure 10). The health literate group had four participants who had a pretest score less than the 25th percentile of 8.00. These outliers were included in the analyses because the pretest scores fell within the CC Pretest Quiz scoring range (0-13).

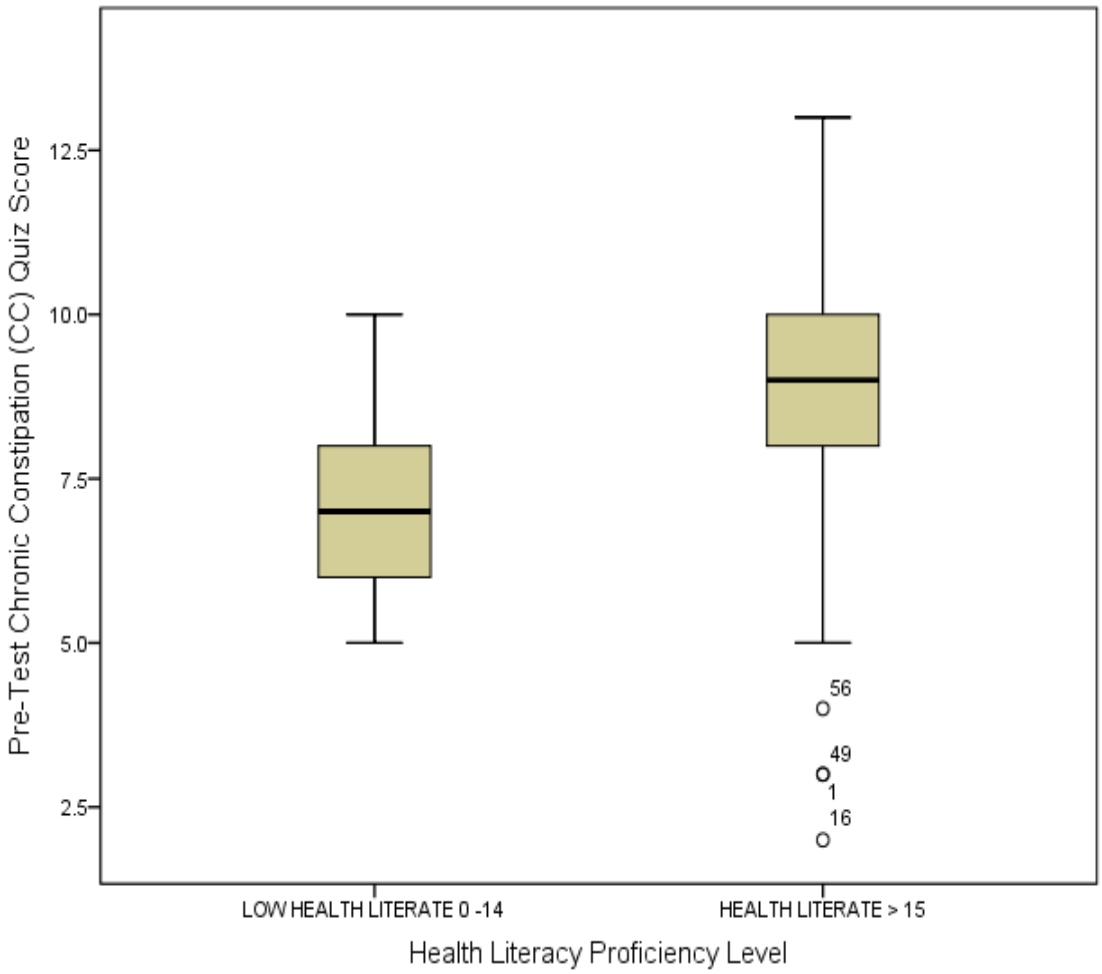

Figure 10. CC Pretest Quiz scores: Low health literate compared to health literate.

A scatter plot illustrated a positive linear relationship between the raw score of the SAHL-E and the CC Pretest Quiz (Figure 11). The relationship provided evidence for the higher SAHL-E score equates to a better CC Pretest Quiz score. The red line inserted into the scatter plot indicates the minimal SAHL-E raw score required for to be categorized as health literate (Lee, 2010). A Pearson product-moment correlation was calculated to determine the relationship between the SAHL-E raw score, evaluating health literacy proficiency, and the CC Pretest Quiz scores. There was a negligible positive correlation

between these two variables which were statistically significant ($r = 0.20$, $n = 100$, $p = 0.05$). The coefficient of determination of $r^2 = 0.03$ indicates that the proportion of variance between the CC Pretest Quiz score and the SAHL-E is negligible. Thus, the SAHL-E raw scores variability is unequal for predicting CC Pretest Quiz scores.

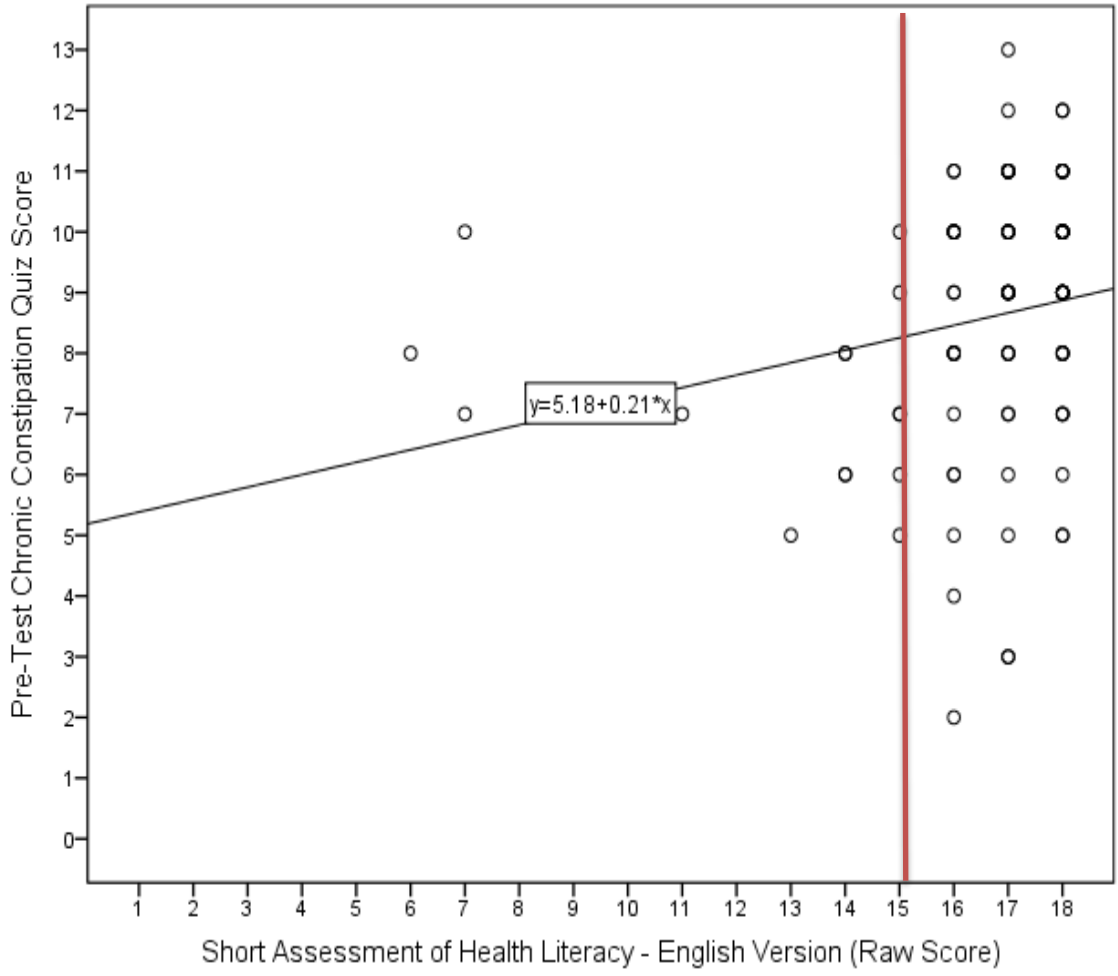

Figure 11. A scatter plot determining the relationship between the raw score of the SAHL-E and the CC Pretest Quiz score.

The statistical analysis examining research question two provided evidence for rejecting the null hypothesis in lieu of the alternative hypothesis. Even though more of trending relationship, the higher SAHL-E raw score elicits greater likelihood of a

participant being categorized as health literate having a higher pretest score compared to low health literate.

Research Question 3

What is the relationship between health literacy proficiency level and CC Posttest Quiz scores?

$H_0$3: There is no relationship between health literacy proficiency level and CC Posttest Quiz scores.

H_a3: There is a relationship between health literacy proficiency level and CC Posttest Quiz scores.

A nonnormal distribution was depicted for the low health literate group, n = 9, skewness of 2.37 (SE = 0.17) and kurtosis of -1.51 (SE = 1.40) in relation to the CC Posttest Quiz. The low health literate group had a positive skewness where the mode, 7.00, was smaller than the Mdn = 10.00. Conversely, a normal distribution was signified for the health literate group, n = 91, skewness of -1.36 (SE = 0.25) and kurtosis of 2.09 (SE = 0.50) related to the CC Posttest Quiz. The posttest score range for the low health literate was 7-13 was smaller compared to the health literate group 5-13. A Box-and-Whisker plot illustrated that the low health literate group had a Mdn score of 10.0 versus the health literate group, Mdn score of 12.0 (Figure 12). The health literate group had four participants who had a posttest score less than the 25th percentile of 11.00. These outliers were included in the analyses because the posttest scores fell within the CC Posttest Quiz scoring range (0-13).

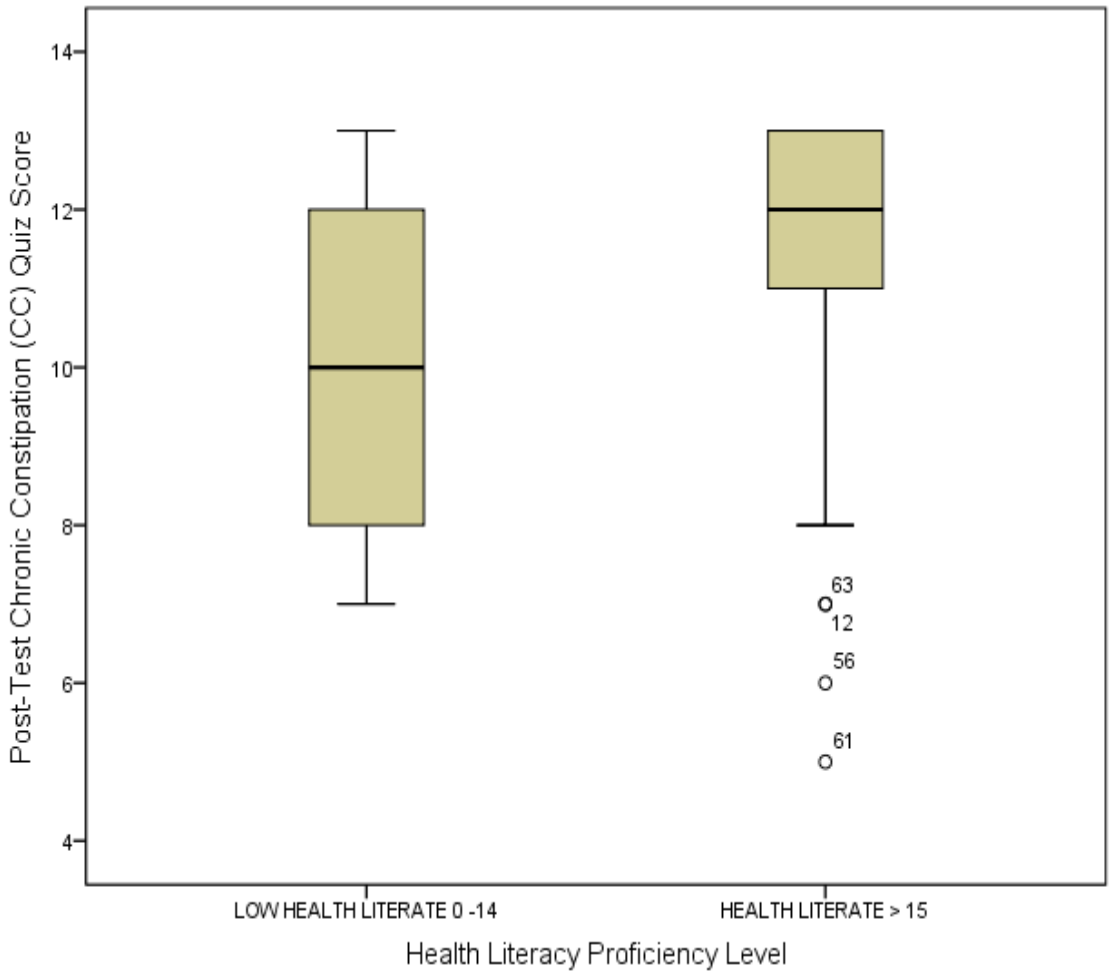

Figure 12. CC posttest Quiz scores: Low health literate compared to health literate.

A scatter plot illustrates a positive linear relationship between the raw score of the SAHL-E and the CC Posttest Quiz (Figure 13). The relationship provides evidence for the higher SAHL-E score equates to a better CC Posttest Quiz score. The red line inserted into the scatter plot indicates the minimal SAHL-E raw score required to be categorized as health literate (Lee, 2010). A Pearson product-moment correlation was calculated to determine the relationship between the SAHL-E raw score, evaluating health literacy proficiency, and the CC Posttest Quiz scores. There was a low positive correlation

between these two variables which were statistically significant ($r = 0.30$, $n = 100$, $p = 0.003$). The coefficient of determination of $r^2 = 0.09$ indicates that the proportion of variance between the CC Posttest Quiz scores and the SAHL-E is negligible. Thus, the relationship between these two variables represent a heteroscedastic relationship.

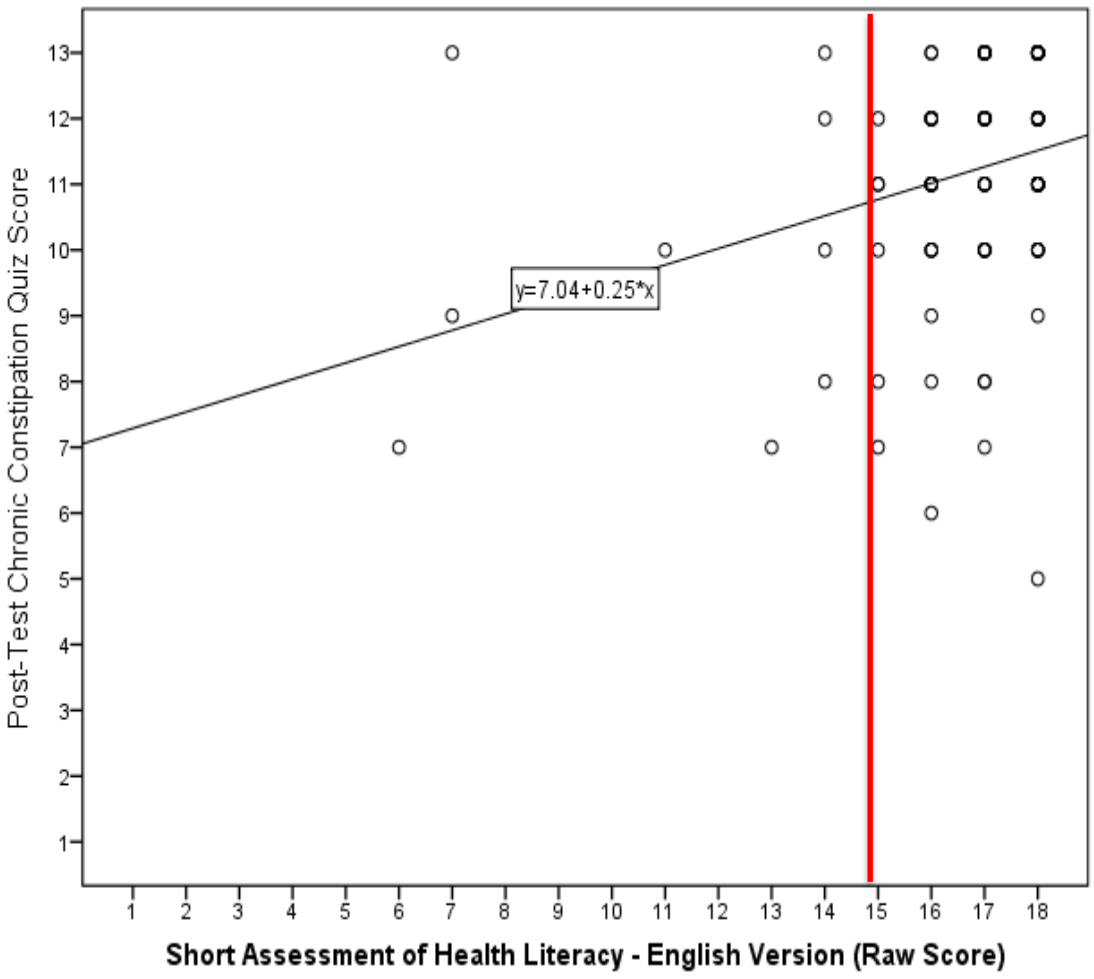

Figure 13. A scatter plot determining the relationship between the raw score of the SAHL-E and the CC Posttest Quiz score.

The statistical analysis examining research question three provides evidence for rejecting the null hypothesis in lieu of the alternative hypothesis. Even though the variance between the SAHL-E is positively low, the higher SAHL-E raw score elicits

greater likelihood of a participant performing being categorized as health literate performing better on the posttest compared to low health literate.

Research Question 4

What is the effect of the CC traditional written educational pamphlet versus CC animated educational video on the CC posttest health literacy quiz score for a cross-sectional CC population undergoing anorectal function testing controlling for the following independent variables: CC Pretest Quiz score, age, gender, race/ethnicity, highest level of education achievement, income level, employment description, level of interest toward learning, best type of learning, and challenges related to learning?

$H_0$4: There is no effect of the randomized group on CC posttest health literacy quiz scores controlling for biological, environmental, and learning motivation variables.

H_a4: There is an effect of the randomized group on CC posttest health literacy quiz scores controlling for biological, environmental, and learning motivation variables.

Prior to performing a multiple linear regression analysis to determine the relationship between the outcome variable, CC Posttest Quiz scores, and the covariates fulfilling the one-way ANOVA univariate analysis criteria ($p \leq 0.05$ or $p \leq 0.10$), CC educational intervention, CC Pretest Quiz score, highest level of education achievement, age, and learning interest, outliers pertaining to the outcome variable, CC Posttest Quiz score, were assessed. Standardized Predicted and Residual values were plotted for homoscedasticity. Outliers were defined by values less than -3.30 and greater than 3.30 (Tabachnick & Fidell, 2007 p.128). The CC Posttest Quiz standardized predicted and residual values ranged from -2.39 to 1.73 and -3.11 to 1.90 respectively (Figure 14).

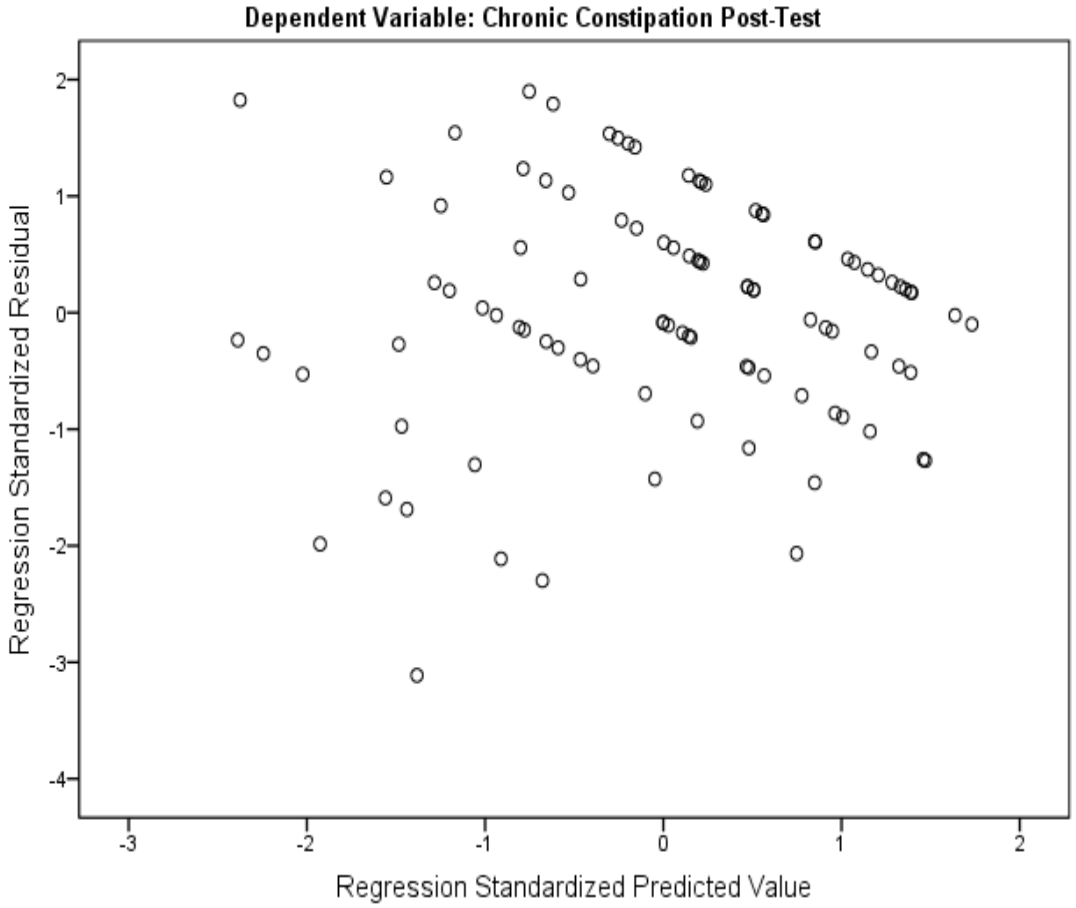

Figure 14. Standardized predicted and residual values assessing for outliers pertaining to the dependent variable: CC Posttest Quiz score.

The one-way ANOVA univariate analyses concluded that four covariates met the criteria of either $p \leq 0.05$ or $p \leq 0.10$ have a significant relationship on the dependent variable, CC Posttest Quiz scores (Table 11). The four covariates included CC Pretest Quiz score, $F(1,98) = 41.19$, $p \leq 0.001$; age, $F(1,98) = 2.77$, $p = 0.09$; highest level of education achievement $F(1,6) = 3.51$, $p = 0.004$; level of learning interest $F(1,2) = 3.05$, $p = 0.05$.

Table 11

One-Way ANOVA Univariate Analysis: Demographics, Environmental Variables, Health Literacy Proficiency, and CC Pretest Assessment in Relation of CC Posttest Results

Variable	Type III Sum of Squares	*df*	Mean Square	*F*	Sig	η^2
CC Quiz						
CC Pretest	96.10	99	96.10	41.19	.00*	.30
Demographics						
Age	8.42	99	8.42	2.61	.10****	.03
Gender	.012	1	.012	.004	.95	.00
Race/ethnicity	17.77	4	4.44	1.37	.25	.06
Body mass index (BMI)	5.82	92	5.82	1.81	.18	.02
Environmental variables						
Highest educational achievement	60.85	6	10.14	3.51	.004**	.19
Income status	24.67	11	2.24	.64	.79	.08
Employment category	4.64	1	4.64	1.73	.19	.02
Learning variables						
Learning interest	19.39	2	9.69	3.054	.05***	.02
Best learning method	8.437	3	2.81	1.02	.39	.04
Difficulty learning	16.30	6	2.72	.89	.51	.06

*$p \leq 0.001$, **$p = 0.01$, ***$p = 0.05$, ****$p = 0.10$

A normal probability plot of the standardized residual evaluating normality related to the dependent variable, CC Posttest Quiz scores, was constructed (Figure 15). A Shapiro-Wilk test was computed using a $p = 0.05$ as significance. The distribution of the posttest scores had a highest score range of 13, $n = 11$, and lowest score of 42, $n = 7$. Therefore, the Shapiro-Wilk test had an alpha value of < 0.001 indicating that the distribution of the outcome variable is nonlinear (Chantarangsi et al., 2015).

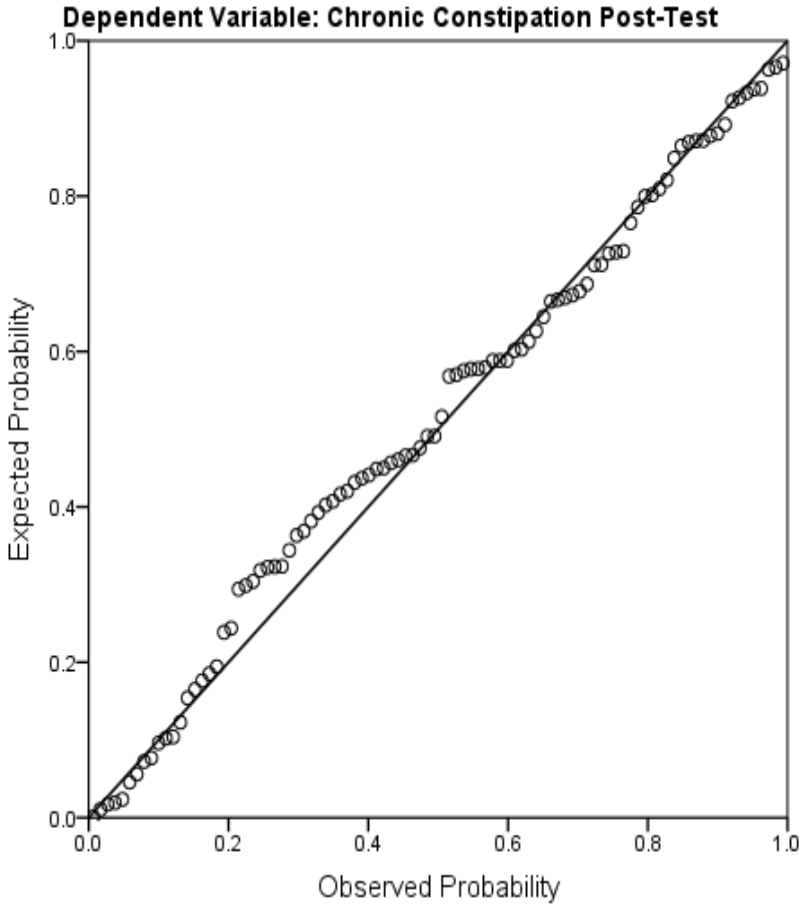

Figure 15. Distribution assessment for normality pertaining to the dependent variable: CC Posttest Quiz score.

Multicollinearity was evaluated among the covariates fulfilling the generalized linear model univariate analysis. A variance inflation factor of greater than 10 indicated multicollinearity among the covariates (O'brien, 2007). The variance inflation factors ranged from 1.0 to 1.5. Therefore, the independent variables did not illustrate multicollinearity.

Multiple linear regression analysis was used to determine if the CC Pretest Quiz score, CC educational intervention, age, highest level of educational achievement, and

learning interest, significantly predicted greater CC Posttest Quiz scores. The results of the regression analysis indicated three predictors explained 38.1% of the variance (r^2 *=.41*, $F(5,90) = 12.68$, $p \leq 0.001$. Ranking the effect size, sr^2, order for the variance of the posttest score given for each independent variable denoted that the CC Pretest Quiz score had the highest effect size, $sr^2 = 0.45$ (Table 12).

Table 12

Effect Size Order Among the Variance of the CC Posttest for Each Individual Predictor Variable

Predictor variable	*B*	*SEB*	β	sr^2	*t*	Sig
CC Pretest	.43	.08	.50	.45	5.70	.000*
Age	-.02	.01	-.18	-.18	-2.28	.03**
Highest level of education achievement	.22	.01	.20	.18	2.23	.03**
CC animated educational video	.38	.30	.11	.10	1.29	.20
Learning interest	.38	.30	.11	.10	1.27	.21

*$p \leq 0.001$, **$p = 0.05$

The effect size provides evidence pertaining to the strength of independent variables for the variance in the dependent variable, CC Posttest Quiz scores. The effect size, $sr^2 = .10$, of the CC educational intervention indicates a 10.0% variance in posttest scores. However, the effect size of the CC educational intervention with adequate power and controlling for random significant predictor variables did not surpass an alpha level of less than a $p = 0.05$. Therefore, the null hypothesis may not be rejected.

Summary

Specific health literacy information related to CC was explored to determine the impact for improving CC health literacy in a cohort undergoing anorectal function testing with a diagnosis of CC. The secondary analysis of the University of Michigan's Chronic Constipation Health Literacy project provided statistical evidence for using specific symptom-based disorder health literacy information to improve health literacy targeting a particular health disorder. The CC educational intervention improved CC Posttest Quiz scores compared to CC Pretest Quiz scores. Thus, these subjects exhibited additional knowledge pertaining to CC regardless of the CC educational intervention following viewing CC animated educational video or reading the CC traditional written educational pamphlet.

Assessment of the subject's health literacy proficiency was useful for predicting CC Pretest and CC Posttest Quiz results. The validated instrument, SAHL-E, indicated that the higher the SAHL-E raw score predicted higher CC Pretest and CC Posttest Quiz score. Moreover, using the binary categorical variable of high health literate and low health literate from the SAHL-E results, the higher health literate group scored higher the CC Pretest and CC Posttest Quizzes compared to the low health literate group.

Using a rigorous regression model, where upon, a two-stage process eliminating predictor variables impacting the posttest score by chance from over-compensating the model strengthening effect size of predictor variables fulfilling the model's parameters. The primary predictor variable for influencing the variance for the posttest score was the pretest score. Age negatively affected the posttest scores. Thus, older subjects had a

lower score on the CC Posttest Quiz compared to younger subjects. Educational Achievement was moderately significant for producing higher CC Posttest Quiz results. The CC education intervention, CC animated education video, elicited a slightly higher CC Posttest Quiz score compared to the CC traditional written educational pamphlet. However, these two groups had similar *M* and *SD* CC Posttest Quiz scores. Subject self-reported interest in learning had limited effect on the posttest, yet, the higher level of interest learning exhibited slightly higher posttest scores.

Chapter 5 detail how these results may generalize to the greater CC community rather than the CC cross-sectional cohort of individuals seeking anorectal function health care related to their CC. Furthermore, this chapter postulate the social impact of these results for a growing community seeking CC health care advice and guidance.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

This study was conducted to examine the impact of a contemporary medium for improving CC health literacy. CC specific health literacy mediums, traditional or contemporary, are sparse. Within the medical discipline of gastroenterology, health literacy research primarily has targeted colonoscopy preparation. Traditional written pamphlets have demonstrated limited improvement in colonoscopy preparation (Smith et al., 2012). Conversely, cartoons have demonstrated greater quality of colonoscopy preparation measured by a validated colonoscopy preparation instrument (Tae et al., 2012). With a CC prevalence rate of up to 27%, this specific symptom disorder affects individuals, health care utilization, and financial resources (Higgins & Johanson, 2004). However, limited educational specific mediums have been available to address CC health literacy.

Using CTML as framework, the study explored whether CC patients undergoing anorectal function testing knowledge increases after reviewing CC education material: traditional education written pamphlets or animation. Comparisons between pre- and posttest assessments were performed, and a model was constructed to determine the relationship between the CC Posttest Quiz and a priori variables. This is the first study explicitly investigating the impact of the type of CC educational medium as a function for improving CC health literacy proficiency. The main finding of this study was that pretest CC knowledge, age, and highest level of education achievement had a significant impact on CC health literacy proficiency. Furthermore, the contemporary medium, CC animated

educational video, provided improvement in CC Posttest Quiz scores compared to the CC traditional written educational pamphlet controlling for significant predictor variables.

Interpretation of the Findings

Research Question 1

The first research question related to the mean difference between the CC Pretest and CC Posttest Quiz scores following randomization to receive the CC traditional written educational pamphlet or the CC animated educational video. The hypothesis consisted of a difference between the CC Pretest and CC Posttest Quiz scores after reviewing either CC educational medium. Each group produced statistically significant improvement between the pretest and posttest: CC traditional written educational pamphlet (*M* improvement of 20.1%) and CC animated educational video (*M* improvement of 26.1%). Moreover, the mean times from a participant completing the CC Pretest Quiz to finishing the CC Posttest Quiz were nearly identical between both groups: CC traditional written educational pamphlet, $M = 27.6$ minutes, and CC animated educational video, $M = 27.7$ minutes. Thus, because similar latencies between the pretest and posttest transpired, CC-specific educational mediums produced greater CC health literacy proficiency. The CC animated educational video group retained slightly higher CC information indicating that a combination of visual and auditory channels was superior to a singular channel learning cognitive process. This outcome was in support of concepts within the CTML limiting cognitive overload as a function for comprehension (Dikiltas & Duvenci, 2009).

Research Question 2

Research Question 2 investigated the relationship between health literacy proficiency and CC Pretest Quiz scores. The working hypothesis depicted that a positive relationship between health literacy proficiency and pretest scores. The low health literate group exhibited a lower mean pretest score by 22.2% compared to the health literate group. Similar to other chronic diseases such as hypertension and diabetes, inadequate health literacy proficiency deters exhibiting sufficient health care knowledge (Williams, Baker, Parker, & Nurss, 1998).

Because only 6.7% of the study cohort had a measurement of low health literate, the sample elicited an unequal distribution between the two groups. Hence, the variance between the SAHL-E raw score and CC Pretest Quiz score was negligible. The medical words used in the SAHL-E are common medical terms. Conversely, the verbiage expressed in the CC Pretest Quiz is specific terminology. This contrast from common medical words to specific medical terminology may explain the large range of pretest scores within the health literate group, 2-13.

Research Question 3

Analogous to Research Question 2, Research Question 3 explored the relationship between health literacy proficiency and the posttest scores. The hypothesis stated that a relationship exists between a participant's health literacy proficiency and posttest score. The low health literate group produced lower median scores compared to the health literate group by 16.7%. Parallel results were discovered with higher health literacy proficiency eliciting greater colonoscopy preparation comprehension (Smith et al., 2012).

Hence, greater health literacy proficiency significantly impacts comprehension of specific medical information.

A weak positive linear relationship was illustrated between the raw score of the SAHL-E and the CC Posttest Quiz score. Data were undistributed between the two groups: low health literate and health literate. The posttest score range was smaller for the low health literate group, 7-13, versus the health literate group, 5-13. These results highlight the complexity of health literacy pertaining to a specific symptom-based disorder, CC. Several models have depicted health care knowledge comprehension depends on more than a singular variable such as health literacy proficiency; instead, numerous social determinants must be included in the model for greater clarity toward comprehension improvement (Masayoshi & Nakayama, 2017).

Research Question 4

Research Question 4 focused on the impact of the CC educational intervention in relation to the CC Posttest Quiz score. Hence, a two-step regression model was constructed to emphasize the a priori and key predictor variables that impact the posttest score enhancing the model's efficiency and accuracy and eliminating significant relationships between the dependent variable and predictor variables by random chance (Palmer & O'Connell, 2009). Step 1 of the regression model consisted of performing univariate analysis for each a priori and key predictor variables using a conservative $p \leq 0.05$ or $p \leq 0.10$ to be included into the linear regression model. The criterion threshold varies among models; however, as a sum of 11 a priori and key predictor variables were identified within the literature impacting health literacy proficiency, the model was

developed to maximize rigor, statistical stability and generalizability, between the CC Posttest Quiz scores and a priori and key predictor variables (Bursac, Gauss, Williams, & Hosmer, 2008).

The univariate analyses depicted three covariates less than $p \leq 0.05$: CC Pretest Quiz score, highest level of education achievement, and level of learning interest. The relationship between CC knowledge determined by the CC Pretest Quiz score and CC Posttest Quiz evaluation emulates health literacy research. Individuals categorized with higher health literacy proficiency demonstrate greater understanding for specific health diseases. Subsequently, 93% of the CC cohort registered as health literate using the SAHL-E. Various social determinants impact health. However, education achievement markedly influences individual health and societal health regardless of race/ethnicity and socioeconomic status (Hahn & Truman, 2015). The CC cohort's highest level of education achievement was approximately 3 times larger than the United States reported average (Figure 16). According to the U.S. Census Bureau (2015), only 12% of the U.S. population reported achieving advanced degrees, master's, doctoral, or professional. Learning is strongly correlated to motivation and self-interest (Tse & Xiao, 2014). As such, 72.7% of CC cohort recounted a high level of learning interest compared to 25.3% medium level of learning interest and 2.0% low level of learning interest.

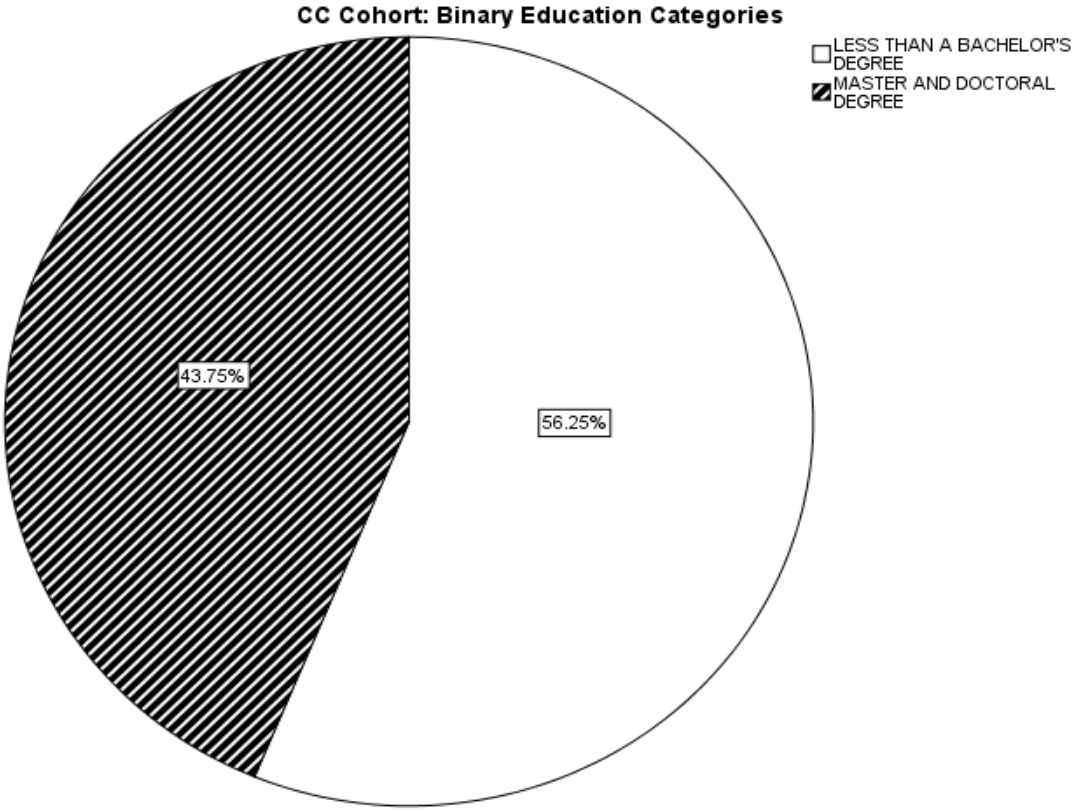

Figure 16. CC cohort divided into binary highest level of educational achievement categories: Less than a bachelor's degree and master's and doctoral degrees.

The predictor variable of age was the sole covariate with a $p \leq 0.10$. A systematic review detailed the negative impact of aging related to health literacy proficiency, learning, and health care knowledge comprehension (Chesser, Woods, Smoothers, & Rogers, 2014). The univariate analysis represented a similar trend for a lower CC Posttest Quiz score with each increasing age. The majority of the CC cohort, 75%, were within the age range of 18-59 years compared to 25.0% greater than the age of 60 years. Even though the prevalence of CC increases with age, as a function of comorbidities, pharmacologic side-effects, and functional pathophysiology, in the absence of these CC associated factors, the prevalence of CC is increasing in younger adult populations

(Ribas, Saldana, Mauti-Rague, & Clave, 2011; Sanchez & Bercik, 2011). Thus, the CC cohort was a representative of a growing trend of individuals seeking CC health care advice and pelvic floor diagnostic test.

The linear regression model including only the specific a priori and key predictor variables meeting the rigorous criteria indicated that greater CC knowledge measured by the pretest signified the largest effect for higher posttest scores. Additionally, only highest level of education achievement and age were statistically significant for higher posttest scores. Conversely, the CC educational intervention and learning interest variables had mild effect on posttest scores without significantly improving posttest scores. With regards to the variable CC Pretest Quiz score, as increasing utilization of the World Wide Web among all age groups, especially younger individuals, patients are becoming more informed of diseases and disorders and available health care resources (Murray et al., 2003). Thus, as the prevalence of CC grows among all age groups, the model represents a similar inclination to other chronic diseases depicting the CC cohort's awareness for common CC attributes.

Higher levels of education achievement produced higher posttest scores. This positive relationship provides additional insight for enhancing working memory and recollection capabilities in relation to advanced academic achievement. Working memory enables an individual to store information for later utilization (Gathercole, Pickering, Camilla, & Zoe, 2003). Using principles of CTML, increasing working memory aptitude by dual-channel learning, visual and/or auditory, each advanced level of education achievement equated to 0.22 points higher on the CC Posttest Quiz. This beta value

represents a 1.76 mean difference between the lowest and highest reported level of education achievement within a 13-question CC Posttest Quiz. Thus, the variable highest level of education achievement significantly impacts the posttest score by 1.7% to 13.5%.

Aging is associated to cognitive changes as a function of time such as diminish working memory function and cognitive process speed (Salthouse, 1996). The literature provided evidence for older adults experiencing greater challenges compared to younger individuals in performing numeracy and comparison mental exercises (Salthouse, 1992). Hence, decreasing cognitive speed linked to comprehension influences age-related cognitive working memory capacity for retaining new information (Salthouse, 1996). The a priori variable, aging, delineated a significant negative effect related to the posttest score. The beta metric in the linear regression model, B = -0.02, equated to a potential 9.7% mean difference in posttest scores between the youngest participant to the oldest: age range of the CC cohort 20-83. This finding was equivalent to a large body of literature detailing the impact of age on learning using animation as the primary educational intervention (Bouchiex, 2015).

The specific CC educational intervention had a small effect regarding posttest scores. The CC animated education video group elicited a 10% mean difference in posttest scores compared to the CC traditional written pamphlet group. These results were contrary to other health literacy research utilizing animation as the intervention. Diabetic health literacy proficiency was significantly improved using an animated intervention compared to a control group (Calderón et al., 2014). Furthermore, animated health information depicted considerable development for minorities to identify health

information gaps and enhanced communication with health care professionals (George et al., 2013). Conversely, my data provided additional support for older adults improving less than younger individuals in a specific aptitude test following an animated educational intervention (Bouchiex, 2015).

Self-reported interest in learning, categorized as high, medium, or low, had a small effect on mean posttest scores. Similar to the CC educational intervention, each categorical increase pertaining interest learning equated to 10% mean difference in posttest scores. These data conflicted with the learning literature. Internal learning interest and motivation significantly impacts overall learning and perceived health competency (Jung, Jo, & Oh, 2016). Aging denotes a decline in learning interest specifically for challenging subjects (Dörnyei, 1994). These data indicated the overall internal interest for learning about an intimate and embarrassing subject, CC, for this particular CC cohort.

The five a priori and key predictor variables used within the linear regression model collectively elicited a statistically significant relationship, $p \leq 0.001$, impacting the posttest score. Enhancing health literacy proficiency pertaining to a specific and convoluted health symptom-based disorder should include these particular variables. However, because improving health literacy proficiency is multifaceted including a multitude of social determinants, life experiences, and learning motivation, statistical models may need to be less rigorous to better understand the impact of the diverse collection of predictor variables.

Limitations of the Study

The study consisted of four limitations. Themes of limitations included secondary analysis, a single point in time, cohort motivation, and highly educated community. First, secondary analysis of a dataset involves potential bias for the primary investigator collecting the primary dataset and the data may not represent a wider CC community. Furthermore, a secondary review of a data eliminates awareness to study specific graduations throughout the primary data collection process which may provide additional insight for data interpretation. To mitigate the limitations using a secondary dataset, I populated frequency tables for all demographic, environmental, interventional, and CC Pretest and CC Posttest Quiz score variables and cross-tabulated the output with the dataset's code (Cheng & Phillips, 2014). This statistical process identified any discordant documented variables from the master variable code. Fortunately, the cross-tabulation process did not expose any discordant input errors or missing data points.

The CC health literacy dataset was collected utilizing a cross-sectional study design. This type of study was prone to response bias pertaining to the participant's behavior and mental mindset at that particular point in time. As undergoing anorectal function testing nonsedated may involve anxiety, humility, and embarrassment, the response to the CC Pretest Quiz and CC Posttest Quiz may be affected by the participant's mental state during the data collection phase. Furthermore, this study design only provides an evidence for increased CC health literacy proficiency at this point in time compared to longitudinal CC knowledge comprehension through temporal data collection (Sedgwick, 2014). Recognizing the limitations related to the cross-sectional

study design, the outcomes were presented as an association, depicted by the effect size of the rigorous identified a priori and predictor variables, not causation, to infer among the CC cohort seeking health care advice for pelvic floor dysfunction.

Next, individual experiencing CC accompanies a negative social stigma. A systematic review examining the impact of CC subtypes illustrated lower self-reported quality of life metrics (Belsey et al., 2010). These quality of life metrics included psychosocial discomfort in addition to physical and mental distress. Likewise, CC patients self-report significantly more anxiety compared to the general population (Hosseinzadeh, Poorsaadati, Radkani, & Forootan, 2011). Hence, this CC cohort may exhibit greater motivation toward learning additional CC knowledge compared to the general CC population on basis for their willingness to undergo anorectal function testing. The potential motivation factor may produce self-enhancing bias by their internal incentive for improving their pelvic floor dysfunction and identify anorectum attributes contributing to CC (Miller & Ross, 1975). Therefore, the results provided insight for using a contemporary medium to enhance CC knowledge rather than concentrating on longitudinal CC outcomes resulting from the CC specific educational platform.

Lastly, according to the U.S. Census Bureau (2015), only 12% of the U.S. population has successfully completed a professional and/or advanced degree. Conversely, the CC cohort within the University of Michigan Chronic Constipation Health Literacy project displayed 42% with completion of an advanced degree (master's or doctorate). Therefore, this skewness in education achievement difference may provide reasons for limited score differences between the CC Pretest Quiz and CC Posttest Quiz.

Furthermore, using the same CC health literacy intervention model, the pretest and posttest variation may exhibit greater significant results. This education discrepancy posits that the University of Michigan CC patient population may not be representative of a greater CC community. Academic achievement has demonstrated predictability for self-regulated learning features (Kitsantas, Winsler, & Huie, 2008). Because anorectal function testing is a specialized gastroenterological practice, these limited functional anorectal practices are generally located within large tertiary medical centers. According to the Council on Graduate Medical Education (1998), tertiary health care centers with specialties services are largely located in urban geographical locations compared to rural areas. Within the United States, urban areas exhibit 33% of adults with at least a bachelor's degree compared to rural locations, 19% (U.S. Department of Agriculture, 2017). These recent education achievement percentages between geographical regions provide discernment to the study's results for CC patients seeking anorectal function testing at these specialty centers.

Recommendations

Animation has been used to enhance learning in a wide range of age populations within the U.S. health care system from pediatrics to gerontology. The CTML maximizes the benefits for using animation as a learning medium, auditory and verbal cognitive channels. However, animation should be viewed as a dynamic medium rather than a static intervention; whereas, the color, verbiage (content), tone, and speed, of the animated intervention should be developed targeting a specific age population. Therefore, integrative frameworks have demonstrated effective animated learning models to isolate

particular cognitive processing skills (Wouters, Pass, & van Merriënboer, 2008). The older population, over the age of 65 years, is projected to more than double by 2050 from currently 40.2 million to 88.5 million Americans (Vincent & Vincent, 2010). Consequently, aging produces normal declining cognitive process such as vocabulary recognition, conceptual reasoning, memory, and processing speed (Harada, Love, & Triebel, 2013). As the a priori variable, age, revealed a significant negative effect for posttest scores following the CC intervention, animators should tailor health proficiency related animated videos to age specific populations. This customized animation may provide enriched learning comprehension advantages for among a variety of age-brackets.

Secondly, internal motivation for learning using animation pertaining to a CC population should be explored especially given the sensitivity and societal factor related to bowel dysfunction. Because anxiety and lower quality of life metrics are readily portrayed by individuals experiencing CC, the dynamic movement demonstrated in animated educational mediums may prompt greater distraction interfering with cognitive processing. Animation may produce two distinct different interest: emotional and cognitive (Kim, Yoon, Whang, Tversky, & Morrison, 2009). Therefore, a CC animated education medium may elicit an emotional response, yet the minimal cognitive interest may diminish the relationships and associations connecting the new CC information to fundamental CC knowledge (Kintsch, 1980). Future investigations need to further understand the impact of individuals' internal motivation for expanding their CC

knowledge by measuring emotional versus cognitive interests related to CC animation mediums.

Social Implications

Technology is transcending health care by consolidating electronic medical records, securing privacy, and empowering patients by providing relevant health care information. CC directly impacts the health care system by consuming a considerate amount of health care resources. CC consumes approximately $106 to $238 billion annually and responsible for 2.5 million physician visits per year (Chang et al., 2010; Vernon et al., 2007). Therefore, by developing a contemporary CC educational medium, CC patients may be empowered to further understand attributes contributing to CC. The Pew Research Center (2018) recently conducted a survey investigating the percentage of Americans who own a smartphone; in 2011, 35% of Americans self-reported owning a smartphone compared to 2018 where 77% of Americans state smartphone ownership. The paradigm transition for accessing health information, paper to electronic to virtual, is prompting a social change for disease/disorder health literacy. Utilizing electronic mediums, especially animation and virtual reality via the internet and applications, to enhance specific diseases/disorder health literacy proficiency prompts social change by challenging culturally accepted health literacy social institutions, physician directed and educational pamphlets. Therefore, publishing CC animated education videos on the internet offer CC patients the opportunity to explore pelvic floor anatomy and physiology abnormalities repeatedly strengthening comprehension and augmenting privacy for an intimate symptom-based disorder. Increasing CC education may decrease health care

utilization cost by empowering the CC patient to implement preventative measures subsiding symptomology.

Absenteeism and loss of work productivity significant impacts employer output. CC symptomology especially severe symptoms have similar absenteeism rates and loss of work productivity output compared to ankylosing spondylitis and major depression (Neri et al., 2014). Developing a strategy for identifying symptoms of chronic disease provides opportunities to mitigate the illness (Grady & Gough, 2014). Moreover, improving CC health literacy proficiency expand approaches for inserting an adequate and effective strategy plan to counteract CC symptomology. This effective CC symptom plan utilizing a simplistic understanding of the pelvic floor anatomy and physiology may decrease CC individual's absenteeism and loss of work productivity.

Thirdly, CC is directly associated to lower quality of life metrics (Belsey et al., 2010). Managing quality of life and CC is a health care challenge. The primary effective method for improving quality metrics in a chronic disease/disorder is developing a strategy plan limiting the impact of CC symptomology. By expanding CC health literacy proficiency, individuals with CC can triage which quality of life metrics, physical, psychosocial, mental, or global, are more effected by CC symptomology.

Conclusion

CC is highly prevalent in the United States and globally. As society ages, the likelihood of CC will continue to rise directly and indirectly impacting health care utilization, health care economics, and quality of life metrics. Health literacy proficiency is a large public health problem; especially as the U.S. health care system transitions to a

patient-centered program. Therefore, patients are increasingly responsible for their own preventative and disease management health care. Traditional methods for educating patients regarding diseases/disorders are relatively ineffective. Developing contemporary mediums, animation and Internet-based programs, specifically exploring aspects of a diseases/disorders suchlike CC provides opportunities to improve disease/disorder specific health literacy proficiency. These contemporary mediums need to concentrate on covariates that directly influence health literacy proficient barriers pertaining to a specific disease/disorder. Enhanced CC education offers strategy options to prevent symptom exacerbation. Implementing a different approach, animation, to improve CC health literacy inspires social change for appropriate methods to improve health literacy and maintaining a connection to the cultural shift for greater importance to electronic mediums. By improving CC health literacy utilizing contemporary individuals with medium CC may devise a productive strategy for limiting work absenteeism and loss of work productivity.

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Appendix A: Health Literacy Demographic Form and Learner Assessment

1. Gender: Male or Female
2. Age: _____
3. Height: _____ and Weight: _____
4. Please specify your Race:
    a. White
    b. African- American or Black
    c. Asian
    d. Middle Eastern
    e. American Indian or Alaska native
    f. Hispanic
    g. Indian
    h. Native Hawaiian or Other Pacific Islander
5. Highest Level of Education Achievement:
    a. Eighth Grade or Less
    b. Twelfth Grade or Less
    c. High School Graduate
    d. Associate Degree
    e. Technical or Vocational Graduate
    f. Bachelor's Degree
    g. Master's Degree
    h. Doctoral Degree

6. What is your income level?

    a. Less than $10,000 g. $60,000 to $69,999

    b. $10,000 to $19,999 h. $70,000 to $79,999

    c. $20,000 to $29,999 i. $80,000 to $89,999

    d. $30,000 to $39,999 j. $90,000 to $99,999

    e. $40,000 to $49,999 k. $100,000 to $149,999

    f. $50,000 to $59,999 l. Greater than $150,000

6. How would you describe your employment?

    a. Blue Collar

    b. White Collar

7. My interest in learning is:

    a. Low

    b. Medium

    c. High

8. I learn best by:

    a. Seeing

    b. Doing

    c. Hearing

    d. Reading

9. Issue that make it difficult to learn:

    a. Hearing b. Vision c. Memory

    d. Feelings e. Technology f. Comfort

Appendix B: SAHL-E

Stem	Key or Distractor		Don't Know
1: kidney	_urine	_fever	_don't know
2: occupation	_work	_education	_don't know
3: medication	_instrument	_treatment	_don't know
4: nutrition	_healthy	_soda	_don't know
5: miscarriage	_loss	_marriage	_don't know
6: infection	_plant	_virus	_don't know
7: alcoholism	_addiction	_recreation	_don't know
8: pregnancy	_birth	_childhood	_don't know
9: seizure	_dizzy	_calm	_don't know
10: dose	_sleep	_amount	_don't know
11: hormones	_growth	_harmony	_don't know
12: abnormal	_different	_similar	_don't know
13: directed	_instruction	_decision	_don't know
14: nerves	_bored	_anxiety	_don't know
15: constipation	_blocked	_loose	_don't know
16: diagnosis	_evaluation	_recovery	_don't know
17: hemorrhoids	_veins	_heart	_don't know
18: syphilis	_contraception	_condom	_don't know

Short Assessment of Health Literacy – English. Adapted from "Short Assessment of Health Literacy – Spanish and English: A comparable test of health literacy for Spanish and English," by Lee, S.Y.D., Stucky, B.D., Lee, J.Y., Rozier, G., & Bender, D.E., (2010), *Health Services Research, 45*, p. 1113.

Appendix C: CC Pretest Quiz

Please answer each question:

1. Where is the anal sphincter located?
    a. Inside the Colon
    b. At the end of the anus
    c. Inside the stomach
    d. At the end of a piece of stool
2. (Circle all that apply) What are the different names for constipation?
    a. Dyssynergic Defecation
    b. Anismus
    c. Incontinence
    d. Pelvic Floor Dysfunction
3. What occurs when the puborectalis relaxes?
    a. The rectum becomes tighter
    b. The rectum straightens
    c. The rectum curls
    d. The anal sphincter spasms
4. What is the main purpose for the anal sphincter remaining closed?
    a. Keep stool from coming out or leaking when not supposed to
    b. Keep air from entering the body
    c. Keep contents from entering the body
    d. Stop infection

5. Passing stool is an uncoordinated effort
    a. True
    b. False
6. What occurs when the abdominal muscles contract while having a bowel movement?
    a. Stomach cramps
    b. Vomiting
    c. Increase pressure in the rectum
    d. Rectal itching
7. What muscle wraps around the lower end of the rectum?
    a. Internal anal sphincter
    b. Pylorus
    c. Puborectalis
    d. Triceps
8. True or False: Do these items listed below represent how stool is passed?
    a. Abdominal muscles increases pressure in the rectum
    b. Puborectalis relaxes and straightens
    c. The anal sphincter and pelvic floor muscles relax
    d. Stool is passed

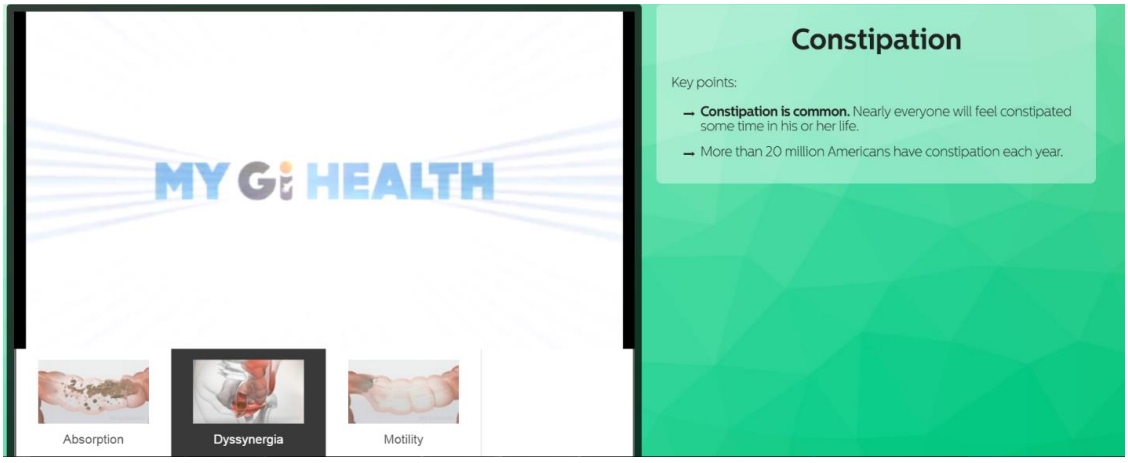
9. Which of the following may not contribute to constipation?
    a. A lack of abdominal muscle pressure into the rectum
    b. The puborectalis contracting
    c. Deep breathing
    d. The anal sphincter not opening or contracting
10. Abdominal and Rectal muscles are required to pass stool?
    a. True
    b. False
11. Which muscle is not located in the pelvic floor?
    a. Puborectalis
    b. Deltoid
    c. Anal Sphincter
12. The rectum is not required to straighten to pass stool?
    a. True
    b. False
13. What type of muscle is the puborectalis?
    a. Loop
    b. Circular
    c. Sheet
    d. Oval

Appendix D: CC Traditional Written Pamphlet

The anal sphincter is a muscular ring at the end of the anus. The anal sphincter stays closed to keep stool from coming out or leaking when it is not supposed to. To pass stool, several muscles must work in a coordinated way. Muscles in the abdominal wall contract which increases pressure in the rectum. The puborectalis is a loop of muscle that wraps around the lower end of the rectum. When the puborectalis relaxes, it allows the rectum to straighten. The anal sphincter and pelvic floor muscles also relax. This all happens at the same time to allow stool to pass. When these muscles do not work as they should, a person may become constipated. For example, the abdominal muscles may not contract to push stool through the anus. The puborectalis may not relax or may even contract, this means the rectum cannot straighten to let stool pass. The anal sphincter may not open or may even contract. This type of constipation has many names: Dyssynergia, Dyssynergic Defecation, Pelvic Floor Dyssynergia, Pelvic Floor Dysfunction, and Anismus.

Appendix E: MyGiHealth CC Animated Educational Video

MyGiHealth is partnership between the University of Michigan, Cedars-Sinai Medical Center, and the University of California Los Angeles. Their partnership has created an application providing a virtual tool to improve the communication between physicians and patients (https://go.mygihealth.io/). Additionally, they have produced various gastrointestinal animated learning videos to enhance patient understanding concerning highly prevalent gastrointestinal disorders. The URL for the animated educational constipation video is: https://go.mygihealth.io/education/symptoms/constipation.



Appendix F: CC Posttest Quiz

Please answer each question:

1. The rectum is not required to straighten to pass stool?
    a. True
    b. False
2. (Circle all that apply) What are the different names for constipation?
    a. Dyssynergic Defecation
    b. Anismus
    c. Incontinence
    d. Pelvic Floor Dysfunction
3. Passing stool is an uncoordinated effort
    a. True
    b. False
4. Which of the following may not contribute to constipation?
    a. A lack of abdominal muscle pressure into the rectum
    b. The puborectalis contracting
    c. Deep breathing
    d. The anal sphincter not opening or contracting

5. Where is the anal sphincter located?
    a. Inside the Colon
    b. At the end of the anus
    c. Inside the stomach
    d. At the end of a piece of stool
6. True or False: Do these items listed below represent how stool is passed?
    a. Abdominal muscles increases pressure in the rectum
    b. Puborectalis relaxes and straightens
    c. The anal sphincter and pelvic floor muscles relax
    d. Stool is passed
7. What occurs when the abdominal muscles contract while having a bowel movement?
    a. Stomach cramps
    b. Vomiting
    c. Increase pressure in the rectum
    d. Rectal itching
8. What muscle wraps around the lower end of the rectum?
    a. Internal anal sphincter
    b. Pylorus
    c. Puborectalis
    d. Triceps

9. What occurs when the puborectalis relaxes?
    a. The rectum becomes tighter
    b. The rectum straightens
    c. The rectum curls
    d. The anal sphincter spasms
10. Abdominal and Rectal muscles are required to pass stool?
    a. True
    b. False
11. What type of muscle is the puborectalis?
    a. Loop
    b. Circular
    c. Sheet
    d. Oval
12. What is the main purpose for the anal sphincter remaining closed?
    a. Keep stool from coming out or leaking when not supposed to
    b. Keep air from entering the body
    c. Keep contents from entering the body
    d. Stop infection
13. Which muscle is not located in the pelvic floor?
    a. Puborectalis
    b. Deltoid
    c. Anal Sphincter

Appendix G: Participant Perspective CC Intervention Questionnaire

1. Do you agree or disagree with the following statement: my chronic constipation intervention was useful for improving my chronic constipation health literacy level?
    a. Strongly Agree
    b. Somewhat Agree
    c. Neither Agree nor Disagree
    d. Somewhat Disagree
    e. Strongly Disagree
2. How satisfied or dissatisfied were you with the chronic constipation health literacy intervention?
    a. Very Satisfied
    b. Somewhat Satisfied
    c. Neither Satisfied nor Dissatisfied
    d. Somewhat Dissatisfied
    e. Very Dissatisfied
3. Do you think that the chronic constipation health literacy intervention was useful for a chronic constipation population?
    a. Yes
    b. No

4. Would you recommend the chronic constipation health literacy intervention to other constipated individuals?
    a. Yes
    b. No
5. Would you use the chronic constipation health literacy intervention in the future for chronic constipation education?
    a. Yes
    b. No

Appendix H: Permission Letter for the University of Michigan Chronic Constipation Health Literacy Dataset

02/01/2017

Name: Jason Baker

Institution: Walden University

Department: College of Health Sciences, Public Health

Address: 100 Washington Avenue South

City/State/Zip: Minneapolis, MN 55401

Dear Dr. William D. Chey:

I am a doctoral study from Walden University writing my dissertation titled *Does Animation Improve Constipation Health Literacy Proficiency Greater than Traditional Written Pamphlets?* under the mentorship of my dissertation committee chair Dr. Raymond Panas. Dr. Panas can be reached by contacting Walden University.

I would like your permission to use the Chronic Constipation Health Literacy Proficiency dataset for my dissertation project under the following conditions:

- I will only use this dataset for my dissertation project.
- I will not provide this data to any other investigator.
- I will cite your institution in my dissertation.
- I will send you a copy of my completed dissertation.

If these conditions are acceptable, please indicate by replying to me through email: xxxxxx@waldenu.edu

Sincerely,

Jason Baker, M.S. (Doctoral Student)

Appendix I: Permission Letter for the SAHL-E

03/26/2017

Name: Jason Baker

Institution: Walden University

Department: College of Health Sciences, Public Health

Address: 100 Washington Avenue South

City/State/Zip: Minneapolis, MN 55401

Dear Dr. Shoou-Yih Daniel Lee:

I am a doctoral study from Walden University writing my dissertation titled *Improving Chronic Constipation Health Literacy Proficiency: Animation versus Traditional Written Pamphlets*, under the mentorship of my dissertation committee chair Dr. Raymond Panas. Dr. Panas can be reached by contacting Walden University.

I would like your permission to use the *Short Assessment of Health Literacy - English* instrument for my dissertation project under the following conditions:

- I will only use this instrument for my dissertation project.
- I will not provide this instrument to any other investigator.
- I will cite your manuscript in my dissertation.
- I will send you a copy of my completed dissertation.

If these conditions are acceptable, please indicate by replying to me through email: xxxxxx@waldenu.edu

Sincerely,

Jason Baker, M.S. (Doctoral Student)

Jason,

Please feel free to use the instrument in your diss research. Good luck.

Daniel

Shoou-Yih Daniel Lee, MS, PhD
Professor, Department of Health Policy and Management
Co-director, Consortium for Implementation Science
Gillings School of Global Public Health
The University of North Carolina at Chapel Hill
135 Dauer Drive
Chapel Hill, NC 27599-7411
Tel: (xxx) xxx-xxxx
Fax: (xxx) xxx-xxxx
E-mail: xxxxxxx@email.unc.edu

Appendix J: Unfunded Data Sharing Agreement

eRESEARCH | PROPOSAL MANAGEMENT

Date: Thursday, January 11, 2018 2:12:42 PM

Print Close

View: Display UFA Summary

Unfunded Agreement

Project Title: Does Animation Improve Constipation Health Literacy Proficiency Greater Than Traditional Written Pamphlets?

UFA Category: Data Use Agreement

UFA No.: 18-UFA02125

UFA Type: Outgoing DUA

EXTERNAL ENTITY INFORMATION

External Entities:

External Entity Description
Walden University

Target Agreement Execution Date: 1/15/2018

Target Agreement Execution Date Reason: This date provides adequate time for Jason Baker to complete, defend, and publish his dissertation in time for the July 2018 graduation.

External Entity PI (if applicable):

PI Name	PI Email
Raymond M. Panas, PhD	raymond.panas@mail.waldenu.edu

External Entity Contact Information:

Name	Email	Street Address	Telephone	Fax
Libby Munson	irb@mail.waldenu.edu	Walden IRB Contact Office of Research Ethics and Compliance Walden University, 100 Washington Avenue South, Suite 900, Minneapolis, MN 55401	612-312-1283	626-605-0472

Routing and Processing Instructions:

PROJECT PERSONNEL

Contact Participant: Jason Baker , 734-936-5567, jrb@med.umich.edu

Primary Research Administrator: Jeffery Holden , 734-936-6400, jholden@umich.edu

Administrative Home Department: Int Med-Gastroenterology , (239500)

Personnel:

Name	Role	UFA Edit Rights	Appointments
William Chey Phone: 734-936-4775 E-Mail: wchey@umich.edu	PI or Responsible Faculty Member	yes	239500, Int Med-Gastroenterology

Name	Role	UFA Edit Rights	Appointments
Jason Baker Phone: 734-936-5567 E-Mail: jrb@med.umich.edu	Other Investigator or Participant	yes	239500, Int Med-Gastroenterology
Karen Szemak Phone: 734-647-2938 E-Mail: szemak@umich.edu	Administrative Contact	yes	
Rachel Oeffner Phone: 734-615-9045 E-Mail: rachoeff@umich.edu	Administrative Contact	yes	
Jeffery Holden Phone: 734-936-6400 E-Mail: jholden@umich.edu	Administrative Contact	yes	

Is there measurable personnel effort for the project that is related to the unfunded agreement? No

MATERIAL TRANSFER INFORMATION

Experimental plan for the material:

PLEASE INDICATE WHAT TYPE(S) OF MATERIALS ARE BEING TRANSFERRED:

Human Derived Materials (tissue, samples, specimens, cells, DNA, etc.)	No
Cells (other than those derived from human subjects or patients)	No
Plasmid/Vector/DNA/RNA	No
Mouse/Rat	No
Other Model Organism (yeast, zebrafish, drosophila)	No
Antibody	No
Protein	No
Chemical compound	No
Software/code	No
Device	No
Other material	No
Will the materials be used with other proprietary materials provided by a third party outside of UM, either academic or commercial?	

MATERIAL SAFETY:

Are materials dangerous to handle, store, or use?

Hazardous materials description:

Is this a hazardous chemical that has a capacity constraint?

Capacity constraint description:

DATA USE INFORMATION

Please describe the data being transferred:

The data is being used as the source for Jason Baker's PhD dissertation from Walden University. The primary objective for the dissertation is to examine the impact of animation on chronic constipation health literacy proficiency. The approved and defended proposal abstract is as follows (See attachment).

Please describe the activity for which the data are being used or upload a document below:
See attachment

Are any data, results, information or other deliverables required?	No
Deliverables description:	

OUTGOING DATA DETAILS:

Are there any specific security, data handling, or data management requirements that need to be incorporated into this agreement?

IT - Encryption, passwords, disaster recovery, etc.

Data security plan from recipient

Other

Publication Restrictions:
There are no items to display

Authorized users of the data:

If "Other" is selected, please describe the restrictions: UM can send the data through M-Box, a HIPAA compliant, cloud system by inviting Dr. Raymond Panas and Jason Baker access to the HIPAA compliant and U of M protected cloud server system.

May recipient re-disclose data to third parties, such as collaborators or repositories? No

Do the data being shared contain human subjects identifiers? No

Please list the human subjects identifiers contained in the data set to be shared:

ADDITIONAL PROJECT INFORMATION

Is there a cost or fee for this data/material?	No
Fee Details:	**Amount** **Funding Source** **Department** There are no items to display
Are there any specific security requirements?	Yes
Please indicate the type of security required:	IT - Encryption, passwords, disaster recovery, MiShare, etc.
Security requirements description:	UM can send the data through M-Box, a HIPAA compliant, cloud system by inviting Dr. Raymond Panas and Jason Baker access to the HIPAA compliant and U of M protected cloud server system.

MTA: Does the research you will be conducting with the materials involve possible export controls, classified research, or security clearances?
DUA, Other, or Master: Will you be engaged in any activity under this agreement that involves classified research or possible export controls?No

RESEARCH ACTIVITY

Please note that not all questions will apply to all agreement categories.

DOES THE PROPOSED ACTIVITY INVOLVE ANY OF THE FOLLOWING:

Human research?			Yes			
Please indicate the related HUM(s):	**HUM ID**	**Status**	**Approval Date**	**Original Approval Date**	**Expiration Date**	**Comments**

HUM ID	Status	Approval Date	Original Approval Date	Expiration Date	Comments
HUM00125953	Approved	6/1/2017	6/1/2017	5/31/2018	

Use of radioactive material or the radiation from radioactive material in or on humans?	
RDRC/SHUR approval number:	

Use of cadavers, human body parts (e.g., organs, tissues), or human body substances (e.g., blood products, body fluids, cells/cell lines, and pathology materials)?

Human body substances description:	

Use or derivation of human induced pluipotent stem cells (iPSC) or human embryonic stem cells (hESC)?

Is HPSCRO approval pending?	
Date of HPSCRO approval:	

Use of recombinant or synthetic nucleic acid molecules (rDNA or SNA)?

Please specify the containment level for the rDNA or SNA work in this project:	
Has the rDNA or SNA work in this project been submitted to the Institutional Biosafety Committee (IBC) for review and approval?	

Related IBC Registration(s):

IBC Number	State	PI Last Name	PI Uniqname	Last Approval Date	Expiration Date	Biosafety Level(s)
There are no items to display						

Related IBC Application(s):

IBCA Number	State	PI Last Name	PI Uniqname	Last Approval Date	Expiration Date	Covers rDNA	Highest Biosafety Level
There are no items to display							

Use of biological agents infectious or hazardous to humans, animals, or plants?

Infectious agents or biological toxins description:	
Is the material on the Federal Select Agent and Toxin list?	

Use of radioactive materials for (non-human)

research?	
Radiation Policy Committee (RPC) Approval Number:	
Use of unbound engineered nanoscale particles or nanofabrication technology?	
Particles/nanofabrication technology description:	
Is this agreement related to another unfunded agreement?	No
Please indicate which UFA(s) relate to this research:	**ID State Category PI Last Name** There are no items to display
Legacy SSP number(s) and description(s):	**SSP Number Description** There are no items to display
Is SSP number unknown?	
Unknown SSP description:	
Is this agreement related to an existing sponsored project?	No
Please indicate which PAF(s) provide support for this research:	**ID Title PI State Admin Home** There are no items to display
Other externally funded sponsor project description:	
Please describe how any previous agreements are related to this agreement:	
Is there an invention on file with the Office of Technology Transfer that relates to this agreement?	No
OTT File Number:	**OTT File Number** There are no items to display
Will this activity result in intellectual property whether or not patentable or disclosed?	No
Intellectual property description:	

SUPPORTING DOCUMENTS

Draft Documents

Document	Version	Type	Last Modified
Jason_Baker_Data_Description_Utilization.pdf(0.01)	0.01	Statement of Work - SOW	1/9/2018 4:01 PM

PI SIGNATURES

Do you (or your family members) or any of the key investigators (or their family members) have a conflict of interest with the external entity or any other entity related to this project (e.g. equipment vendor, subcontractor, vendor of a product being evaluated by the project)? Conflicts occur when the investigators have stock or other financial interest in, receive income from, consult with, or serve as an officer, director, or advisor to the external entity or project-related entities.

PI's Response to Conflict of Interest Question:

The undersigned, to the best of their knowledge and belief:

1. Certifies that the information submitted within the agreement is true, complete, and accurate.
    a. Certifies that any false, fictitious, or fradulent statement or claims may subject the PI to criminal, civil, or administrative penalties (**DHHS only**).
2. Certifies the proposed work is consistent with University unit objectives and all faculty involved in the proposal have agreed to participate.
3. Certifies that no Federal appropriated funds have been or will be paid to influence or attempt to influence the granting of this agreement.
4. Accepts the obligations and commitments described in the agreement.
5. Agrees to perform the work in accordance with University and sponsor policies, which includes maintaining safe practices for the conduct of the project, reporting safety incidents, using properly commissioned lab space (if applicable), and properly disposing of or removing hazardous materials or equipment (if applicable).
6. Agrees to accept responsibility for the scientific or programmatic conduct of the activities described in this agreement and to provide any required progress reports if an agreement is executed.
7. Certifies that the Conflict of Interest Statement above is true, complete, and accurate, and agrees to disclose any new outside interests or changes to existing outside interests during the term of the proposed project following the instructions at Disclosure Process.

Required Participant Signatures:

Person	Title
Jason Baker	Research Area Specialist Lead

Received Participant Signatures:  Research Area Specialist Lead

Person	Title
There are no items to display	

Ad Hoc Reviewer Comments (if applicable):

Date Reviewed	Reviewer	Dept Name	Reviewer Comments
There are no items to display			