LIVING WITH FIBROMYALGIA (FM): THE SALIENCE OF CLINICAL SUBGROUPS

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Fibromyalgia (FM) is an elusive syndrome that affects 2% of the United States population, with health care costs exceeding $20 billion in 1998. FM alters lives with its symptoms and by interfering with everyday life. This dissertation explored the association between subgroups of women with FM and their functional status. The first study examined the effectiveness of an Internet-based health promotion intervention to improve the clinical outcomes for two subgroups of women with FM: those with high Fibromyalgia Impact Questionnaire (FIQ) scores (n = 5) and those with low FIQ scores (n = 5). Single subject design and grouped data revealed that the intervention had mixed results for the two subgroups. The clinical response to the intervention depended on the method of analysis (individual versus group) and the target behavior of interest. The second study examined the associations among objective and subjective measures, and two target outcomes: physical activity and functional status (FIQ total score), and then used the data to classify FM subgroups (n = 72). Using Exhaustive Chi-square Automatic Interaction Detector (Exhaustive CHAID), we developed two models. Model I, with the target outcome of physical activity, yielded 9 distinct subgroups, whose members had characteristics that were significantly associated with very unfavorable to very favorable physical activity outcomes. Model II, with

the target outcome of the FIQ total score, yielded 5 distinct subgroups whose members had characteristics that were significantly associated with very unfavorable to very favorable functional status outcomes. The third study used qualitative and quantitative methods to identify clinically relevant triggers of FM flares, experienced by three subgroups women with low (n = 6), average (n = 5), and high (n = 4) FM impact, to explore the effect of triggers on their functional status. Using mixed methods, we were able to substantiate, quantify, and qualify the affects of FM on the lives of persons with FM and the direct consequences of those affects on activities. Overall activity, FM symptoms, and weather were the most prominent triggers. Findings from these studies suggest that the influence of FM on functional status affects women differently based on subgroup membership.

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PREFACE

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1. INTRODUCTION

Fibromyalgia (FM) is an enigmatic rheumatic syndrome of unknown etiology with an umbrella of chronic and multidimensional symptoms that alter lives. According to the 1997 National Arthritis Data Workgroup report (Lawrence et al., 1998), FM affects 2% of the United States (US) population; specifically 3.4% women and 0.5% men (i.e., 7:1 ratio). Fifteen to 20 percent of all new rheumatology referrals met the 1990 American College of Rheumatology (ACR) diagnosis criteria for FM (Doron, R. Peleg, A. Peleg, Neumann, & Buskila, 2004). Thus, fibromyalgia may currently be the most common rheumatic diagnosis of female rheumatology patients, with annual health costs that exceed a staggering $20 billion (*Fibromyalgia syndrome: Hearing before the Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies*, House of Representative, (1998) [testimony of Ronald C. Kramis]). Pain, fatigue, poor sleep quality, gastric irritation or irritable bowel syndrome (IBS), and psychological distress constitute the constellation of signs and symptoms associated with fibromyalgia (Wolfe et al., 1990). In the 1995 National Health Interview Survey, persons with chronic conditions, such fibromyalgia were among the 39 million Americans who reported activity limitations (NCHS, 1998). Therefore, in addition to significant health costs, fibromyalgia alters lives with its physical and cognitive symptoms and by interfering with everyday lifestyles and routines (i.e., household and leisure activities, social relationships, and work related activities).

The management of FM occurs through two primary types interventions: pharmacological and non-pharmacological (Forseth & Gran, 2002; Goldenberg, Burckhardt, & Crofford, 2004; Hadhazy, Ezzo, Berman, Creamer, & Bausell, 2002; Okifuji & Ashburn, 2001; Oliver, Cronan, & Walen, 2001; Rossy et al., 1999; Sim & Adams, 2002; Wolfe et al., 1996). Pharmacotherapy focuses on the management of pain, fatigue, and poor sleep quality (Buskila, 1999; Lautenschläger, 2000; Nørregaard, Volkmann, & Danneskiold-Samstøe, 1995; Rao & Bennett, 2003; Simms, Felson, & Woolf, 2004). The three principal classes of drugs used alone or in combination to manage FM are: (1) anti-inflammatory, (2) analgesic agents, and (3) antidepressant (Forseth & Gran, 2002; Okifuji & Ashburn, 2001; Rossy et al., 1999; White & Hart, 1996). The range of non-pharmacological interventions employed alone or in combination are physical training, mainly aerobic or non-aerobic exercise (Jentoft et al., 2001; Martin et al., 1996; Rooks, Silverman, & Kantrowitz, 2002), education (Goossens et al., 1996; Nicassio et al., 1997; Vlaeyen et al., 1996), psychological interventions (e.g. cognitive behavioral) (Goossens et al., 1996; Nicassio et al., 1997; Williams, 2003; White & Nielson, 1995; Vlaeyen et al., 1996), physical modalities (Berman, Ezzo, Hadhazy, & Swyers, 1999; Buckelew et al., 1998), self-help strategies (Sim & Adams, 2002; Williams, 2003), and complementary and alternative medicine (CAM) (Bell et al., 2004; Ebell & Beck, 2001; Nicassio, Schuman, Kim, Cordova, & Weisman, 1997). However, the results of both interventions have yielded inconsistent results or short-term improvements.

The challenges of FM management reinforce the need to gain additional understanding of how fibromyalgia influences the functional status of persons with this syndrome. With a national push toward health-promoting interventions (Public Health Service, 1998) and

recommendations to use empirical data to guide clinical priorities (Institute of Medicine, 1999, 2001), clinical research on FM is becoming more common.

Central to understanding of how fibromyalgia influences the functional status of persons with FM, one must acknowledge that functional status is complex in that it affects the whole person. Functional status refers to the ability of a person to engage in daily activities and participate in personal and societal roles (National Committee on Vital and Health Statistics [NCVHS], 2002). Many multimodal technological advances are currently available to gather objective real-time data (Balas et al., 1997; 2004; Kop et al., 2005, Korszun et al., 2002; Landis et al., 2003; Robinson, Patrick, Eng, & Gustafson, (For the Science Panel on Interactive Communication and Health), 1998), in addition to the more typical subjective self-report data (Bierman, 2001; Ruggieri, 2003) about the symptoms and functional status of persons with FM. Changes in functional status often occur because of the natural and dynamic impact of physical, emotional, or environmental factors (NCVHS, 2002). Therefore, a clear need exists for effective strategies that will enable persons to cope with and manage fibromyalgia based on the variability of its manifestation.

Research findings have increasingly confirmed that FM is a heterogeneous, rather than a homogeneous syndrome (Gatchel et al., 2002; Turk, Okifuji, Sinclair, & Starz, 1996; Turk, Okifuji, Sinclair, & Starz, 1998; Turk & Rudy, 1988; Walen, Cronan, Serber, Groessl, & Oliver, 2002), and subgrouping of persons with fibromyalgia has gained interest based on chronic pain models or from various techniques used to demonstrate the ability to identify relevant clinical subgroup differences such as pain thresholds, physical performance, and psychological function. To date the clinical relevance for developing and implementing appropriately tailored evidence-based intervention and management protocols based on FM subgroups remains unclear

(Giesecke et al., 2003; Masi & Yunus, 1990; Turk et al., 1996; Turk et al., 1998). An examination of function-related factors, namely objective and subjective functional status data may enhance the understanding and the clinical relevance of FM subgroups. However, subjective and objective data may lead to different estimations of the functional status of the cohort, for instance results from the Fibromyalgia Impact Questionnaire (Burckhardt, Clark, & Bennett, 1991), which in turn can impact the ability of clinicians and researchers to more effectively target interventions and assess functional outcomes.

Numerous quantitative studies have described fibromyalgia related to its etiology (Geenen & Jacobs, 2001; Staud & Smitherman, 2002), the diagnosis criteria (Katz, Wolfe, & Michaud, 2006; Wolfe et al., 1990), and the management and interventions strategies (Karjalainen et al., 2004; Sim & Adams, 2002). However, there has been less use of qualitative methods such as narratives, diaries, video interpretation, and interviews that probe personal histories and experiences of persons with fibromyalgia to query the experiences, meaning, and consequences of life with fibromyalgia (Cudney, Bulter, Weinert, & Sullivan, 2002; Henriksson et al., 1992; Schaefer, 2005; Söderberg, Lundman, & Norberg, 1999). Persons with the syndrome face the stigma associated with an elusive diagnosis (Åsbring & Närvänen, 2002) and are required to adjust participation levels due to pain and fatigue (Gaston-Johansson, Gustafsson, Felldin, & Sanne, 1990; Henriksson, 1994). Several researchers have combined quantitative and qualitative methods to gain insight into how persons with fibromyalgia cope with chronic pain, and the effects of social and health care support related to quality of life (Kelley & Clifford, 1997; Schoofs, Bambini, Ronning, Bielak, & Woehl, 2004).

Given that fibromyalgia will continue to alter the lives, influence functional status, and possibly grow into a greater public health concern, there is a need to examine and develop

clinically relevant subgroups so as to more effectively target FM interventions. Hence, the overall purpose of this dissertation was to explore the association between subgroups of women with FM and their functional status. The specific aims were to:

1. examine the effectiveness of a self-monitored cognitive-behavioral and interactive technology-based intervention to improve the clinical outcomes for two subgroups of women with fibromyalgia: those with low and high FM impact,
2. examine the associations among symptoms of FM and objective and subjective functional status measures, and then use the functional status data to classify FM clinical subgroups, and
3. use mixed methods to identify clinically relevant triggers of fibromyalgia flares, experienced by three subgroups women with low, average, and high fibromyalgia impact, and explore the effect of triggers on their functional status.

Chapters 2, 3, and 4 address Aims 1, 2, and 3, respectively. Chapter 5 summarizes the findings of the three studies.

2. THE EFFECTIVENESS OF AN INTERNET-BASED HEALTH PROMOTION INTERVENTION ON THE CLINICAL OUTCOMES OF TWO SUBGROUPS OF WOMEN WITH FIBROMYALGIA

2.1. INTRODUCTION

Persons with fibromyalgia syndrome (FM) deal with the challenges of its unknown etiology, impact, and trajectory. Despite the syndrome's complex manifestation, namely, widespread pain, fatigue, psychological, and behavioral symptoms, a clear need exists for effective strategies that will enable persons to cope with and manage fibromyalgia. Among the priorities of Healthy People 2010 are establishing and implementing health-promotion interventions to prevent functional decline and facilitate healthy living (Public Health Service, 1998). With this national push toward health-promoting interventions, attempts to test these strategies in clinical research are becoming more common.

Because of the many technological advances currently available, researchers and health care professionals are well equipped to gather objective real-time data (Balas et al., 1997; Balas & Iakovidis, 1999; Dittmar, Axisa, Delhomme, & Gehin, 2004; Kop et al., 2005, Korszun et al., 2002; Landis et al., 2003; Robinson, Patrick, Eng, & Gustafson, (For the Science Panel on Interactive Communication and Health), 1998), in addition to the more typical subjective self-report data (Bierman, 2001; Ruggieri, 2003) about the symptoms and functional status of persons with FM. Multimodal technologies are also readily available to enhance service delivery and

promote health in real-time. Personal computers (PC), the Internet, E-mail, and electronic documents (E-docs) devices are among these multimodal technologies. Body-monitoring devices (e.g., SenseWear® Pro_2 Armband, BodyMedia®, 2003) are technologies that detect and record objective real-time data, and they enhance the ability to diagnose, manage, and prevent health conditions (Dittmar et al, 2004; Kop et al., 2005, Korszun et al., 2002; Landis et al., 2003; Lilja & Nordic, 2005; Sung, Marci, & Pentland, 2005; Tractenberg, Singer, Cummings, & Thal, 2003). Moreover, the objective lifestyle (i.e., participation time in physical activities and sleep quantity) and physiological (i.e., galvanic skin response and body temperature) functional status data collected by the body-monitoring devices can be used to complement and corroborate self-report data offered by the wearer. These technologies have a novel appeal and hold promise for providing accessible and reliable health information to empower health care consumers (Balas et al., 1997; Robinson et al., 1998; Sung et al., 2005).

Additionally, the Internet has added an innovative dimension to the access of health information, the facilitation of health care service delivery, monitoring, and support, and the conduct of health research. According to the March 2004 Nielsen//NetRatings report, 204.3 million (75%) Americans have access to the Internet from the comfort of their homes. The prevalence of Internet use to access health information among adults in the United States varies from 35% to 80% (Baker, Wagner, Singer, & Bundorf, 2003; Fox et al., 2000; Horrigan & Rainie, 2002; Pennbridge, Moya, Rodgrigues, 1999; Taylor, 2002). The Internet has been reported to be "the primary source of health information for consumers" (WebMD Corporation, 2003), and the 1999 Harris Poll (Ferguson, 1999) found that Web sites related to rheumatic conditions were among the most often accessed. Despite the fact that these data support the use

of the Internet as a "virtual" pathway to health information, the rate of accessing health information does not translate directly into changed outcomes.

To examine the effectiveness of Internet-based interventions and to identify associated changed and unchanged outcomes a literature review was conducted. Using a keywords search *Internet-based interventions* on PubMed yielded 180 scholarly articles. The content of these interventions included topics as diverse as education and counseling (e.g., nutrition, smoking cessation, groups, obesity), prevention (e.g., HIV/AIDS, hearing loss, cancer), rehabilitation (e.g., alcoholism, spinal cord injury, traumatic brain injury), health promotion (e.g., addiction, empowerment, physical activity, psychosocial impact), and health or disease management (e.g., arthritis, asthma, chronic headaches, diabetes, back pain, mental health issues, weight loss, cardiovascular disease) (Baker et al., 2003; Nguyen, Carrieri-Kohlman, Rankin, Slaughter, & Stulbarg, 2004). Of the 180 articles located through PubMed, 15 addressed the needs of persons with chronic conditions: cancer (Chang, Collins, & Kerrigan, 2001), diabetes (Barrera, Glasgow, McKay, Boles, & Feil, 2002; Hejlesen, Plougmann, & Cavan, 2000; McCoy, Couch, Duncan, & Lynch, 2005; McKay, King, Eakin, Seeley, & Glasgow, 2001; Plougmann, Hejlesen, & Cavan, 2001), headaches (Devineni, & Blanchard, 2005), heart disease (Brennan et al., 2001; Gordon et al., 2001), HIV/AID (Flatley-Brennan, 1998), obesity (Tate, Wing, & Winett, 2001; Winett, Tate, Anderson, Wojcik, & Winett, 2005), asthma (Finkelstein, O'Connor, & Friedmann, 2001), back pain (Lorig et al., 2002), and physical inactivity (Napolitano et al., 2003).

However, no studies related to rheumatic conditions, including fibromyalgia, were identified. The following overview includes selected studies that used interactive Internet technology and examined interventions and outcomes relevant to "The Efficacy of Computer and

SenseWear® Technologies for Promoting Health in People with Fibromyalgia: A Randomized Clinical Trial" (FIBRO-RCT), from which the current study was derived.

Of the 15 studies that addressed chronic conditions, the 4 studies reviewed were chosen because they focus on the effectiveness of Internet-based interventions with physical activity, behavioral, and educational components, which were relevant to the FIBRO-RCT. Empirical data promote physical activity as the most effective intervention for fibromyalgia, followed by behavioral and educational interventions (Oliver, Cronan, & Walen, 2001; Rossy et al., 1999; Sim & Adams, 2002). Additionally, the four reviewed studies identified outcomes that changed and those that did not change following these interventions. See Table 2.1 for the summarized characteristics and results of the selected Internet-based interventions.

Table 2.1: Overview of Selected of Internet-Based Interventions

N	Subjects/Group Characteristics	Intervention (by group)	Outcome Measures	Main Results p-values ≤ .05 are significant
Citation: McKay et al., 2001 **Study Design:** Randomized pilot study				
N = 78	Average subject: 52.3 years old, white female, with college education, working full-time, diagnosed with diabetes > 1 year, taking insulin, and 1 or more co-morbid chronic disease Experimental Group (Exp): n = 38 Control Group (Information Only – IO): n = 40	Experimental: • Diabetes Network (D-Net) Active Lives physical activity – 8-week personalized Internet-based physical activity (PA) intervention: action planning, personalized feedback, peer support via E-mail, diary Control Group: • Information Only - Internet information – diabetes, physical activity; glucose tracking	• Self-reported (SR) moderate-vigorous activities • SR minutes walking/day • Depression (Center for Epidemiologic Studies Depression scale)	• **Physical activity, walking, depression** • Between groups - no group differences for moderate-vigorous activities, walking, or depression • **Physical activity and walking** • Within groups - both groups increased total PA and walking time ($p < .001$) • **Program usage (Web site logons)** • Within groups - decreased Web site usage for both groups during 8-week program • **Participant outcomes** • Between groups - ≥ 3 logins yielded greater changes in moderate-vigorous physical activity levels compared to those who logged in less than 3 times, but only for the Experimental group ($p = .049$)

Table 2.1 (continued).

N	Subjects/Group Characteristics	Intervention (by group)	Outcome Measures	Main Results p-values ≤ .05 are significant
Citation: Tate et al., 2001 **Study Design:** Randomized, controlled trial				
N = 91	Hospital employees – weight management Internet Behavior Therapy (IBT): n = 46 Average IBT subject: 41 years old, married, white female, with college degree Internet Education (IE): n = 45 Average IE subject: 41 years old, married, white female, with some college	Repeated measures (0, 3, and 6 months) IBT: • 24-weeks of behavioral weight loss lessons and personalized feedback on nutrition, exercise, self-monitoring strategies via E-mail, online resources, and an E-behavior diary (tracking diet and exercise) IE: • Internet educational resources, E-behavior diary (diet and exercise)	• Weight (measured in light street clothing, without shoes, and on a calibrated scale) • Waist circumference (measured with a Gulick steel tape measure) • Depression (Centers for Epidemiological Studies Depression Scale) • Dietary intake (Block Food Frequency Questionnaire) • Physical activity (self-report format of the Paffenbarger activity Questionnaire)	• **Body weight and weight circumference** • Between groups - IBT lost more weight than IE at 3 and 6 months (t = 3.4, p = .001; t = 2.1, p = 0.04, respectively) • Between groups - more IBT subjects lost ≥ 5% body weight than IE (45% vs. 22%, χ^2 = 4.03, p = 0.05) • Between groups - IBT reduced waist circumference more than IE at 3 (p = .001) and 6 months (p = 0.009) • **Overall Web site login** • Between groups - IBT group login frequency was greater than IE group during the first 3 months, with a mean (SD) 19 (10.9) times compared to 8.5 (10.4) times (p < .001); login frequency decreased for both groups by the sixth month (p < .001); yet the IBT group continued to log in more often at 6-months than the IE group (6.8 (6.2) vs. 1.0 (3.0), p < .001) • Within groups - IBT and IE groups' 6-month weight loss correlated significantly with login frequency (IBT, r_s = -.43, p = .003; IE, r_s = -.33, p = .03) • **Dietary intake and exercise** • Within- and between groups - IBT and IE groups' dietary intake (p < .001) and physical activity (p = .03) improved over time; but no group differences • IBT – weight loss was significantly associated with total number of E-behavior diaries submitted (r_s = -.50, p = .001) • **Depression** • No results presented

Table 2.1 (continued).

N	Subjects/Group Characteristics	Intervention (by group)	Outcome Measures	Main Results p-values ≤ .05 are significant
Citation: Zabiniski et al., 2001 **Study Design:** Randomized, controlled trial				
N = 62	Average subject: High-risk eating disorder;19.3 year old, white female, college freshman or sophomore; mean body mass index (BMI) 24.9 Experimental Group (Exp): n = 31 Control Group (Waitlist Control – WC): n = 31	Repeated measures (Baseline, posttest, and 10-week follow-up) Experimental: • 8-week Student Bodies program – interactive software program modeled after self-help groups and psycho-educational treatments for eating disorders and an electronic support message board Control Group: Waitlist controls	• Body Shape Questionnaire (BSQ) • Eating Disorder Inventory (EDI): Drive for Thinness (DT) and Bulimia (BUL) subscales • Eating Disorder Examination Questionnaire (EDE-Q): restraint, eating, shape & weight subscales • Weight • On-line social support scale	• **Intervention effects** • Between groups - no significant group differences for the outcome measures at posttest and 10-week follow-up • Between groups - no significant 2-way interactions for group by time with any outcome measure • Both groups - baseline to posttest effect sizes ranged from 0.00 (EDE-Q Shape) to 0.56 (EDI Drive for Thinness) • Both groups - baseline to follow-up effect sizes ranged from -0.14 (EDI Bulimia) to 0.46 (EDI Drive for Thinness) • Significant time effects for both groups: (better outcomes from baseline to posttest and maintained at 10-week follow-up except BMI) 1. BSQ – $F(2, 108) = 7.76$, $p < .002$; 2. EDE-Q Global – $F(2, 108) = 8.08$, $p < .002$; 3. EDE-Q Shape – $F(2, 108) = 10.76$, $p < .001$; 4. EDE-Q Weight – $F(2, 108) = 5.27$, $p < .01$; 5. BMI – $F(2, 108) = 6.20$, $p < .005$ (posttest to 10-week follow-up) • **Compliance** • No significant correlations between compliance and outcome

Table 2.1 (continued).

N	Subjects/Group Characteristics	Intervention (by group)	Outcome Measures	Main Results p-values ≤ .05 are significant
Citation: Lorig et al., 2002 **Study Design:** Randomized, controlled trial				
N = 580	Chronic back pain Treatment (TG): n = 296 <u>Average TG subject:</u> 46 years old, married male with 16.5 yrs of education Control (CG): n = 284 <u>Average CG subject</u>: 45 yr old married male with 16.6 yrs of education	Repeated measures – all completed online (baseline; 6 and 12 months) <u>TG</u>: • Closed/ moderated E-mail discussion group (not real time); a copy of *The Back Pain Helpbook*; and videotape (*Taking Control of Your Back Problem*) that modeled an active lifestyle with back pain <u>CG</u>: • Usual care plus non-health related magazine subscription	• Quality of life (pain – visual analogue scale; disability – Roland-Morris Scale; role function – Illness Intrusiveness Scale; and health distress) • Health care use (tracked provider visits and days in hospital) • Exercise endurance (no measure reported) Self-care orientation(Self-Care Orientation Scale) • Self-efficacy (measured by combining previous instruments)	• **Health status and health care utilization** • <u>Between groups</u> - TG demonstrated better outcomes compared to the CG at 12 months: 1. Disability (p = .01); 2. Health distress (p = .01); 3. Pain interference (p = .05); 4. Role functioning (p = .007); 5. Self-care orientation (p = .014); and 6. Self-efficacy (p = .003) • <u>Between groups</u> - no group differences for doctors visits (p = .07), but TG used health care services less than CG • <u>Between groups</u> - TG self-care orientation & self-efficacy significantly enhanced (both 9%) compared to CG (4% and -2%) (p = .01 and p = .003, respectively) • 6-month changes in self-efficacy were significantly associated with 12-month health status: 1. Disability (r = -.20, p < .001); 2. Health distress r = -.33, p < .001); 3. Pain interference (r = -.18, p < .001); and 4. Role function (r = .26, p < .001) • **Exercise endurance** 1. No results presented

2.1.1. Internet-based Interventions with Chronic Population Samples

2.1.1.1. Physical Activity Component

Physical activity has been identified as the most effective intervention for fibromyalgia (Oliver, et al., 2001; Rossy et al., 1999; Sim & Adams, 2002) and it was also one of the key components of the experimental arm of the FIBRO-RCT (see p. 20). In an 8-week randomized pilot study, McKay and colleagues (2001) developed two Internet-based interventions for people with diabetes. The experimental arm of the study focused on increasing physical activity and provided personalized feedback, and the control arm of the study provided information only on diabetes, physical activity, and depression. The expected strengths of the personalized Internet intervention did not yield significant group differences for moderate-vigorous activities, walking, or depression. Nonetheless, both groups did increase their walking time and total amount of physical activity ($p < .001$). However, those in the experimental arm of the study who logged on to the Internet more showed greater changes in moderate-vigorous activities ($p = .049$) (see Table 2.1). In summary, the interactive Internet technology intervention contributed to increases in physical activity for those who logged in more frequently.

2.1.1.2. Behavioral Component

A cognitive-behavioral intervention with the option of personalized feedback was incorporated into the experimental arm of the FIBRO-RCT. Cognitive-behavioral interventions (also labeled as behavioral medicine interventions, cognitive-behavioral therapies, or cognitive-behavioral approaches) have been utilized with numerous populations for education, prevention, health

promotion, and health management and focus on changing thinking to change behavior. In a 24-week RCT study design, Tate et al. (2001) evaluated the outcomes of a weight loss intervention. The experimental arm of the study consisted of an Internet-based behavioral (IBT) condition that included lessons on weight loss with personalized feedback, and the control arm consisted of an Internet-based educational (IE) condition that included Internet educational sites, with self-monitoring. Subjects in the experimental arm, who received the personalized feedback during the IBT, lost significantly more weight than the subjects in the control IE group, at both 3 (p = .001) and 6 months (p = .04) (4.0 kg vs. 1.7 kg and 4.1 kg vs. 1.6 kg, respectively). A statistically significant relationship emerged between login frequency and weight loss from baseline to 6-months (IBT, r_s = -.43, p = .003; IE, r_s = -.33, p = .03) for both groups. Login frequency also declined for both groups by the sixth month of the study (p < .001). However, the IBT group continued to log on more frequently than the IE group at 6 months (p <.001). Furthermore, the IBT intervention results indicated that the weight loss amount was significantly correlated to the total number of electronic diaries submitted (r_s = -.50, p = .001) (see Table 2.1). In summary, the interactive Internet technology intervention contributed to weight loss, especially for those who logged in more frequently.

2.1.1.3. Education Component

Education is a common component of non-pharmacological treatment protocols used to manage fibromyalgia (Oliver et al., 2001; Rossy et al., 1999; Sim & Adams, 2002). Education was also another primary component of both the experimental and control arms of the FIBRO-RCT. Zabiniski and colleagues (2001) examined the effects of an 8-week interactive education and support intervention designed to improve body image, eating patterns, and shape/weight

preoccupation among college women with high-risk eating disorder behaviors. The experimental arm of the Web-based intervention used an interactive software program titled Student Bodies, which was modeled after psychoeducational and self-help eating disorders groups as well as an electronic discussion board. The control arm of the study was the study waitlist, which received no treatment. The results of the RCT did not support the hypothesis that the women in the intervention group would have a greater awareness of a positive body image compared to the control group. No group differences for body image occurred at the posttest or the 10-week follow-up. However, significant time effects indicated better outcomes on the Body Shape Questionnaire, Eating Disorder Examination Questionnaire – global, Eating Disorder Examination Questionnaire – shape, and Eating Disorder Examination Questionnaire – weight ($p < .01$) between baseline and posttest; and body mass index from posttest to 10-week follow-up ($p < .005$). Effect sizes for baseline to posttest for the experimental and control groups ranged from 0.00 to 0.56, whereas baseline to follow-up effect sizes ranged from -0.14 to 0.46. The Eating Disorder Drive for Thinness scale resulted in a moderate effect size for both groups for the baseline to posttest ($d = 0.56$) interval and Eating Disorder Examination Questionnaire for the baseline to follow-up interval ($d = 0.53$) (see Table 2.1). In summary, the interactive Internet technology intervention did not contribute to reduction in obsessiveness with thinness or positive body image changes.

2.1.1.4. Cognitive-Behavioral and Education Components

Just as the FIBRO-RCT experimental arm combined cognitive-behavioral and educational interventions, so did a study by Lorig and colleagues (2002). Lorig et al. (2002) sought to establish that the Internet could improve the health status and health care utilization for people

with chronic back pain in a repeated measures RCT. The experimental arm of the study consisted of a closed, moderated discussion and education group as well as the provision of a cognitive-behavioral book and videotape promoting self-efficacy in managing and coping with symptoms of back pain. The control arm of the study received usual care and a subscription to a non-health-related magazine. Data confirmed the hypotheses that persons with chronic back pain who participated in the experimental supportive E-mail discussion intervention demonstrated significantly better outcomes for disability and health distress (both, $p = .01$); role functioning ($p = .007$); pain ($p = .05$); and self-care orientation ($p = .014$) at the 1 year follow-up compared to the usual care control group. Self-efficacy for health management outcomes were also significantly better for the treatment group compared to the control group at the 1 year follow-up ($p = .003$). Participants in the experimental arm of the study also reduced health care utilization; however, no significant group differences were found (see Table 2.1). In summary, the interactive Internet technology intervention significantly contributed to decreased disability, health distress, and pain and increased role functioning, self-care orientation, and self-efficacy for health management. Although the reduction was not significant, health care utilization was also reduced.

2.1.2. Summary of Internet-based Interventions with Chronic Population Samples

Implementation of the emerging Internet-based interventions with multimodal delivery formats remains a novel approach in health service delivery with chronic populations. Researchers who investigate the effectiveness of interactive Internet technologies face the challenge of identifying and selecting appropriate outcome measures (Gustafson, Robinson, Ansley, Adler, & Brennan, 1999). The influence of these interventions on health-related outcomes with health conditions

populations suggests moderate improvements among particular subsets (Lorig et al., 2002; McKay et al., 2001; Tate et al., 2001; Zabiniski et al., 2001). However, the improvements may be statistically significant, these results warrant cautious interpretation. All the studies reviewed relied on self-report data for their outcomes; even though real-time technologies were available to objectify and possibly enhance the self-reported data. In the studies surveyed, the interactive Internet-based interventions significantly improved outcomes in the following categories: symptoms, physical activity, weight loss, waist circumference, dietary intake, quality of life, self-efficacy, disability, and self-care orientation (Lorig et al., 2002; McKay et al., 2001; Tate et al., 2001; Zabiniski et al., 2001). Outcomes that did not demonstrate significant changes due to the Internet-based interventions fell into the following categories: body image, eating disorder behaviors, and depression.

In conclusion, the evidence presented examined the impact of interactive Internet-based cognitive-behavioral and educational interventions on health-related outcomes of participants with chronic health conditions. However, the identified interventions and outcomes deserve additional inquiry before asserting generalizations related to the effectiveness of Internet-based interventions. For women with FM, one objective of the FIBRO-RCT was to compare the efficacy of an experimental arm that consisted of a cognitive-behavioral, educational, and interactive technology-based intervention that utilized a personal computer, the Internet, E-mail, E-docs, and the SenseWear® Pro_2 Armband with a control arm consisting of usual care and educational materials. The current study examined the effectiveness of the interactive Internet technology experimental condition to improve the clinical outcomes for two subgroups of women with FM: those with low Fibromyalgia Impact Questionnaire (FIQ) scores and those with high Fibromyalgia Impact Questionnaire (FIQ) scores.

2.1.3. Hypotheses

We hypothesized that an interactive-Internet intervention would decrease fatigue and pain and increase sleep and physical activity duration in persons with fibromyalgia, with both low and high impact scores on the FIQ. However, we also hypothesized that improvement would be greater in the low FIQ subgroup than in the high FIQ subgroup.

2.2. METHODS

2.2.1. Study Design

A single-subject ABA′ withdrawal, multiple baseline design was employed with female participants diagnosed with FM enrolled in the experimental arm of a prospective intervention study, FIBRO-RCT. A single-subject study design was chosen to assess the change in four target behaviors during an 8-week study. The study included 3 phases:

1. Phase A (Baseline): Phase A consisted of 7-days of usual care.
2. Phase B (Intervention): A 6-week self-monitored, cognitive-behavioral, and interactive technology-based intervention, and
3. Phase A' (Withdrawal/Return-to-Baseline): Phase A' consisted of 7-days of return to usual care.

Multiple Baselines: The multiple baseline target behaviors examined were fatigue, pain, sleep, and physical activity.

2.2.2. Participants

Participant data analyzed in this study were derived from the FIBRO-RCT. To be included in the FIBRO-RCT, participants (a) were female and at least 18 years of age; (b) met the 1990 American College of Rheumatology FM diagnosis (Wolfe et al., 1990); (c) were diagnosed with FM at least 1-year prior to study participation; (d) had requisite vision to read newsprint for computer use; (e) spoke English; and (f) had an operable telephone line in the home. Exclusion criteria were: (a) disability due to a medical diagnosis other than FM (e.g., stroke, Parkinson disease) and (b) residence further than 40-miles from the Oakland campus of the University of Pittsburgh. However, to ensure homogeneity of the sample, to be included in the current study, participants were: at least 45 years of age and menopausal. Subjects were recruited from clinical rheumatology practices at the University of Pittsburgh Medical Center (UPMC) - Arthritis and Internal Medicine Associates and from other physician practices that see a high percentage of fibromyalgia patients. All participants provided informed consent.

2.2.2.1. Clinical Subgroups Subject Selection

The Fibromyalgia Impact Questionnaire (FIQ) (Burckhardt, Clark, & Bennett, 1991) was used to stratify subjects in the experimental arm of the FIBRO-RCT into two subgroups, based on the median split of the total FIQ score (Median = 55.94) without the work status items included (i.e., maximum score of 80) for the data analyses. The low FIQ group consisted of subjects with an

FIQ score of $\leq$ 55.93 and the high FIQ group consisted of subject with an FIQ score $\geq$ 55.94. The FIQ is a reliable and valid 10-item self-report questionnaire (Burckhardt et al., 1991). It is the most commonly used disease-specific instrument for measuring the functional status of persons with fibromyalgia. The FIQ measures health status outcomes over the past week believed to affect: (1) physical functioning (e.g., home management, community involvement, mobility); (2) well-being (e.g., days they felt well); (3) work attendance; and (4) FM symptoms. Higher scores suggest a greater extent of fibromyalgia impact. Ten women, five from the low FIQ subgroup (low FM impact), and five from the high FIQ subgroup (high FM impact) were randomly selected using the online program, Research Randomizer (Urbaniak, 1997) to select the study participants.

2.2.3. Experimental Condition

The four components of the FIBRO-RCT intervention were self-management, cognitive-behavioral strategies, interactive technology-based education, and education, which will be described, respectively.

2.2.3.1. Self-management Component

The emphasis on self-management (e.g., self-monitoring of behaviors and symptoms, coping skills, and problem solving techniques) in the experimental condition centered on the process of taking individual responsibility and making lifestyle changes and decisions that influence health. Data the participants used for making such decisions were derived from the Internet and the armband technology (SenseWear® Pro_2 Armband). The focus of self-management was (1)

disease management (e.g., proper use of medications); (2) behavior modification (e.g., pacing activity to regulate symptoms); (3) coping with and adjusting to the effects of the disease (e.g., social, economic, and emotional consequences) and, (4) learning effective strategies to share health information (e.g., accurate interpretation and reporting of one's condition) (Holman & Lorig, 2004). The specific self-management strategies that were encouraged during the study were active management of FM, prioritizing daily activities, monitoring symptoms and then adjusting behaviors or diet accordingly, and guided-education by printed material and Internet links (e.g., National Sleep Foundation, Harvard Medical School's consumer health information – InteliHealth). The experimental condition used a cognitive-behavioral therapy approach to facilitate self-management skills among participants.

2.2.3.2. Cognitive-behavioral Component

Cognitive-behavioral therapy (CBT) evolved from the social cognitive theory (Bandura, 1986) and psychotherapy, and purports that a person's thoughts may directly change or influence behaviors (Goossens, Vlaeyen, Hidding, Kole-Snijders, & Evers, 2005; Willams, 2003). CBT is a common component of fibromyalgia interventions. Psychological/behavioral interventions offer an effective means of managing fibromyalgia with an educational component added to enhance the program (Oliver et al., 2001; Rossy et al., 1999; Sim & Adams, 2002). The experimental condition of the FIBRO-RCT integrated CBT strategies (e.g., activity pacing, coping skills, sleep hygiene, attribute changes) to facilitate positive lifestyle changes for fibromyalgia management. Throughout the study, a certified and licensed occupational therapist presented CBT strategies to each subject in an educational format beginning with the in-home computer training session. To facilitate the CBT skills training, strategies were reviewed during

a subsequent in-home visit and E-mail communications. The CBT strategies also focused on the potential of interactive technology-based educational components to provide participants with objective feedback on their progress (e.g., physical activity, sleep hygiene, activity pacing), as well as how to use written and Internet-based FM information for self-management.

2.2.3.3. Interactive Technology-based Educational Components

The interactive technology components of this study were the SenseWear® Pro_2 Armband (body monitor), the InnerView™ Research Software ("InnerView™ Research Software (IRS) [body monitor Computer software]", 2003) and the interactive Internet-based Healthy Daily Routine (HDR), personalized E-mail feedback, and online educational resources.

2.2.3.4. Educational Component

The educational elements of the study were designed to combine self-management and CBT strategies to promote wellness using Internet resources and innovative technology (e.g., IRS, HDR, SenseWear® Pro_2 Armband). Participants could access established online resources on reputable Web site links such as www.mayoclinic.com, which were provided by the Fibromyalgia Study team and saved into a favorite's folder on their Internet Explorer Browser. The online resources provided educational information on the primary health promotion components of the FIBRO-RCT such as stress management, sleep, daily activity, planning and pacing, healthy lifestyle choices; and nutrition. Other Web sites were www.sleepfoundation.org, www.intelihealth.com, www.navigator.tufts.edu, and demo.getfitonroute66.com

The IRS, a Java-based computer software application was used with the SenseWear® Pro_2 Armband and the electronic HDR data during the intervention phase of the study. The study participants received the book, *Get Balance! The Guide to Living a Balanced Healthy Lifestyle* (Liden, 2001) that concentrated on practical tenets for wellness. In addition, participants received three Arthritis Foundation (2001) brochures – Fibromyalgia Syndrome, Managing Your Pain, and Managing Your Fatigue. Another available resource was the option to contact and participate in local support and educational group for FM. Furthermore, the research study coordinator initiated and maintained a personalized E-mail dialogue with each experimental group participant related to self-management, CBT, and the armband and HDR technology. Thus, based on the daily feedback from their armband data (e.g., quantity of physical activity, sleep, rest, number of steps taken), the electronic HDR data (e.g., self-perceived well-being, nutrition, activity performance, symptom influence), and their personal motivation to gain control of fibromyalgia, participants received educational support to enable appropriate lifestyle changes consistent with managing FM and its impact.

2.2.4. Instrumentation

The instrumentation for Phases A and A′ was the SenseWear® Pro_2 Armband and the paper version of the HDR. During Phase B, the instrumentation was the SenseWear® Pro_2 Armband, the Internet-based HDR, and the IRS.

2.2.4.1. SenseWear® Pro_2 Armband

The SenseWear® Pro_2 Armband is a body-monitoring device sensitive to movement, worn on the upper right arm, over the triceps muscle body. It contains 11 data collection channels to record physiological and lifestyle data, over time, in the home, community, and/or work environments 24-hours a day, except while bathing. The SenseWear® Pro_2 Armband calibrated data with demographic characteristics (e.g., age, gender, height, weight) based on BodyMedia® proprietary algorithms. Physiological data are longitudinal and transverse accelerometers, galvanic skin response (GSR), heat flux, near-body temperature, and skin temperature. Lifestyle data are timestamps, total energy expenditure, active energy expenditure, number of steps, lying down, sleep duration, and physical activity duration.

Data collection channels are three longitudinal and three transverse accelerometer channels which use 2-axis accelerometers with a micro-electro-mechanical sensors (MEMS)) that detect (a) static and dynamic motion, (b) galvanic skin response (GSR) or skin conductivity affected by the sweat from physical activity and emotional stimuli, and (c) heat flux, or heat exchange between a participant's arm and the environment. Additional data collection channels are near-body temperature (i.e., the temperature of the metal cover exposed to air on one side of the armband), skin temperature (i.e., the temperature of the skin under the armband), and step counter (i.e., pedometer reading of number of steps taken). Moreover, the SenseWear® Pro_2 Armband has a timestamp button to record the number of times pressed, which for the FIBRO-RCT was to record pain medication usage. Total energy expenditure calculates the number of calories burned and an off-body estimate of resting energy expenditure. Active energy expenditure calculates the calories burned during physical activity. Lying down time is

calculated as the cumulative amount of time lying down and being sedentary. Sleep time is calculated as the cumulative amount of time spent sleeping (i.e., lying down and not moving). Physical activity data are the cumulative time spent engaged in physical activity, such as walking, housework, and gardening as well as activities that are more vigorous. The IRS, a Java-based computer software application, allowed the participants to retrieve and view their armband data in a numerical summary and graphical display.

2.2.4.2. Healthy Daily Routine

The IRS computer software application allowed participants to complete an Internet-based HDR daily during the intervention phase of the study. The IRS system requirements are a personal computer with a Pentium II processor or higher, Windows 98/2000/XP/ME operating system, and 128 MB RAM or higher (IRS, 2003).

The Healthy Daily Routine is a study-specific tool created to assess the subjective experiences of well-being (see Figure 1, Step 1 of 3), the nutritional value of meals (see Figure 2, Step 2 of 3), and the daily impact of fibromyalgia (see Figure 3, Step 3 of 3) on activity performance. The five aspects of the HDR well-being rating scales are physical, fatigue, sleep quality, emotional/psychological, and spiritual. The four meals rated on the HDR nutrition scales are breakfast, lunch, dinner, and snack, plus servings of fruits/vegetables and amount of water. Participants rated their well-being and the nutritional value of meals daily using a 5-point rating scale, where 1 represented very poor and 5 represented very good. Finally, the HDR activity performance items are rating scales for the participants' assessment of the impact of fibromyalgia on activity performance (e.g., participation, difficulty, satisfaction with

performance, fatigue, and pain) for each of 11 required and optional activities on the "How did you spend your day?" portion of the questionnaire. Participants rated activity performance items using a 5-point rating scale, where 1 represented strongly agree and 5 represented strongly disagree.

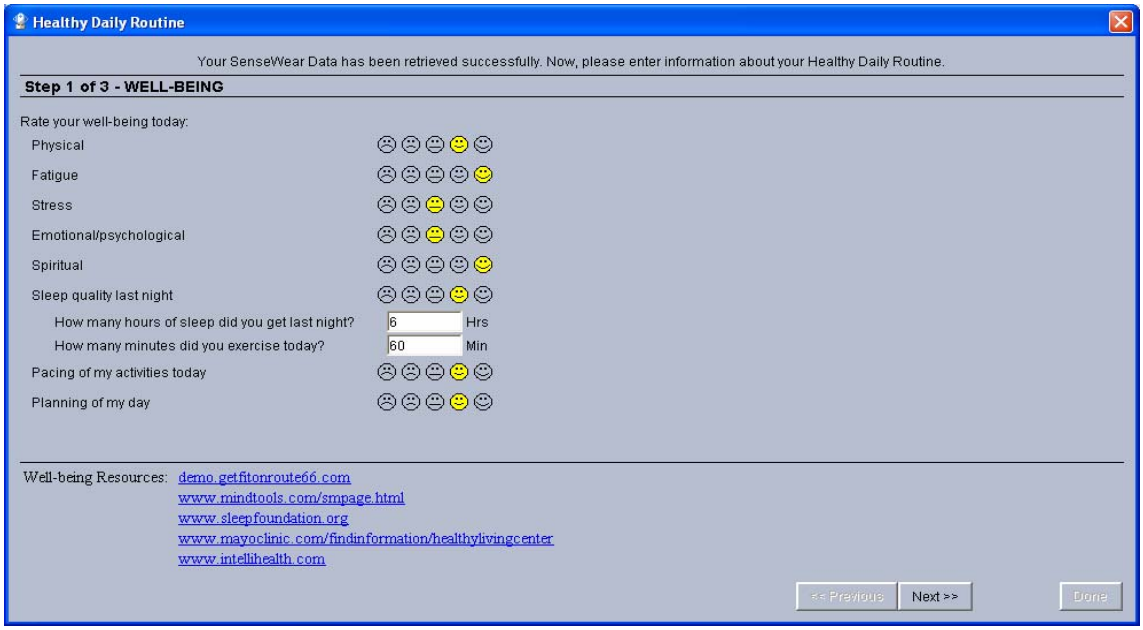

Figure 1: Sample of Electronic HDR Well-Being Form with HDR Fatigue Item

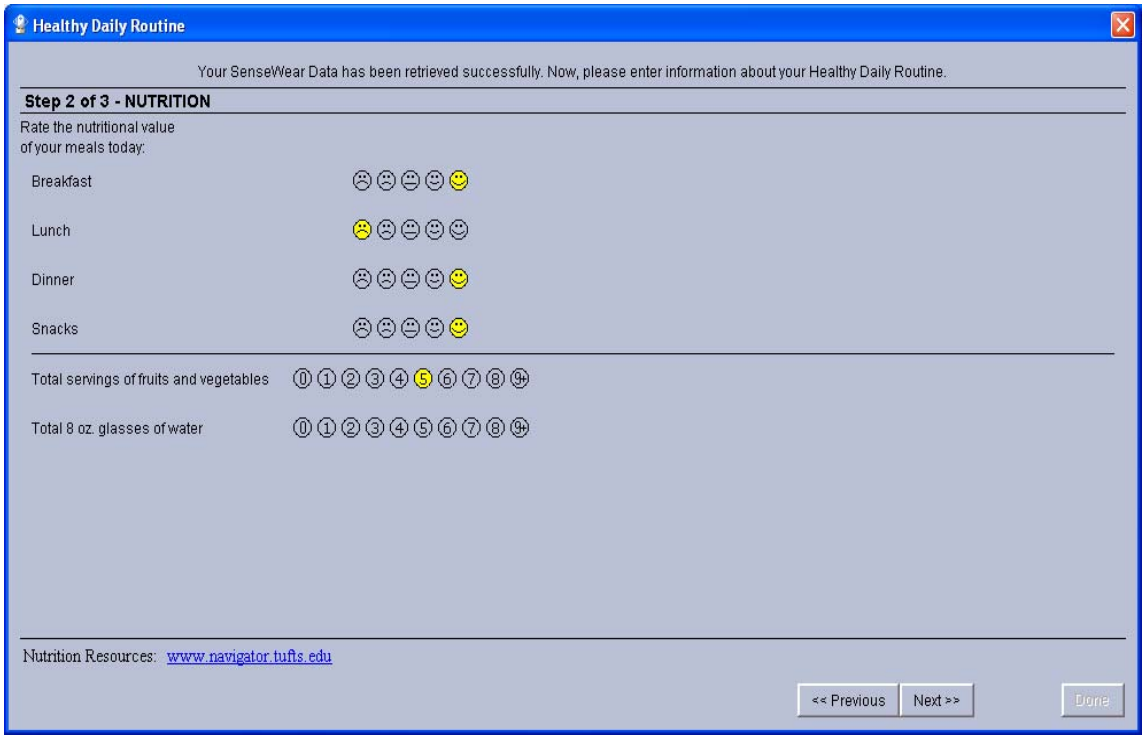

Figure 2: Sample of Electronic HDR Nutrition Form

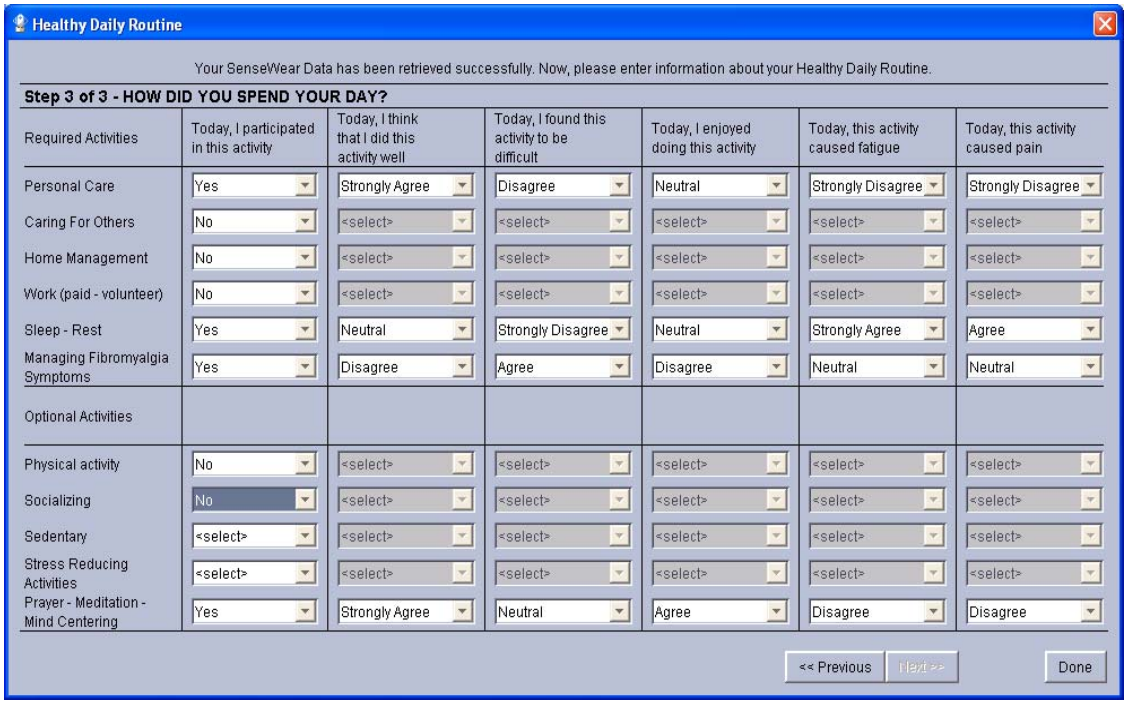

Figure 3: Sample of Electronic HDR Activity Performance Form with HDR Pain Items

2.2.5. Target Behaviors

The four target behaviors assessed at Phase A (baseline), during Phase B (the intervention), and again during Phase A' (the return-to-baseline) were fatigue, pain, sleep, and physical activity.

Fatigue. The HDR well-being form, "Rate your well-being today," has 1 fatigue item. The ordinal rating scale ranged from 1 to 5 points; 1 represented very poor and 5 represented very good. The participants rated their fatigue daily (see Figure 1).

Pain. The pain rating was derived from the pain item for 11 required and optional activities on the HDR activity performance form, for which participants were asked to rate "Today, this activity caused pain". The ordinal rating scale ranged from 1 to 5 points; 1 represented strongly agree and 5 represented strongly disagree. An average of the 11 ratings yielded the daily pain score (see Figure 3).

Sleep. Sleep is the cumulative amount of time spent sleeping (i.e., lying down and not moving) at night. Sleep data were derived from a combination of heat flux, skin temperature, GSR, and longitudinal and transverse accelerometer SenseWear® Pro_2 Armband data based on BodyMedia® proprietary algorithms. Sleep data were totaled daily from 10:00 p.m. to 7:59 a. m. and recorded in minutes.

Physical activity. Physical activity is the cumulative amount of time spent engaged in physical activity, such as walking, housework, and gardening as well as activities that are more vigorous. Physical activity data were derived from a combination of heat flux, skin temperature, GSR, and longitudinal and transverse accelerometer SenseWear® Pro_2 Armband data and are

based on BodyMedia® proprietary algorithms. Daily physical activity data were the total amount of time engaged in activity during each 24-hour and recorded in minutes.

2.2.6. Procedures and Data Collection

Before participating in the FIBRO-RCT study, participants signed an informed consent approved by the University of Pittsburgh's Institutional Review Board for the protection of human subjects. Socio-demographic and functional status data (e.g., age, weight, marital status, education, employment status, occupation, salary, current medications, Fibromyalgia Impact Questionnaire total score) were collected during the FIBRO-RCT to describe the sample.

The IRS was installed on the participants' personal computers if they had one or they used a study computer that had the software already installed. Prior to the baseline phase (A), the research study coordinator trained each participant on how to wear the armband correctly and how to complete the paper version HDR. For all participants randomized to the experimental arm of the FIBRO-RCT, the research study coordinator conducted an in-home training session on how to retrieve and view armband data, how to complete the electronic HDR, how to E-mail data, and how to access the established online resources, prior to beginning the intervention. Participants also received a self-study user's guide at this time that addressed each of the computer tasks required while participating in the study. Further, participants demonstrated competency in the use of the computer for the study purposes, during the in-home training session.

2.2.6.1. Intervention Description

Phase A (Baseline). Phase A was a 7-day period of usual care. Participants wore the body-monitoring armband 24-hours a day except while bathing, and completed the paper version of the HDR daily. During Phase A participants were also provided with three educational brochures developed by the Arthritis Foundation (2001) – Fibromyalgia Syndrome, Managing Your Pain, and Managing Your Fatigue; and, information on local support and educational groups.

Phase B (Intervention). Phase B for the participants of the FIBRO-RCT consisted of a 6-week self-managed program during which participants continued to wear the body-monitoring armband that recorded physiological and lifestyle data 24-hours a day except while bathing. The participants completed an Internet version of the HDR daily that focused on their overall well-being, nutritional habits, and involvement in daily activities. Participants downloaded and reviewed the collected lifestyle data from the armband; they read the book, *Get Balance! The Guide to Living a Balanced Healthy Lifestyle* (Liden, 2001), and they accessed established online resources as needed to foster empowerment for health promotion and living well with fibromyalgia. The research study coordinator supported the participants throughout the intervention with the CBT strategies of activity pacing, relaxation, personal modeling, and behavior modification based on printed and Internet-based educational material (Arthritis Foundation, 2001a, 2001b, 2001c; Liden, 2001; Lorig, 2004; Mayo Foundation for Medical Education and Research, 1998; Sleep Foundation, 2002; Williams, 2003). The interactive intervention emphasized the integration of the armband data, the written and Internet-based FM and educational components, and the participants' perception of their overall well-being for the development and application of the skills learned to achieve a healthy lifestyle. Each evening

during Phase B, the participants retrieved their data from the armband, completed the Internet version of the HDR, and E-mailed it to the research study coordinator. The research study coordinator interacted with the participants via E-mail and telephone as needed during Phase B.

Phase A′ (Return-to-Baseline). Phase A′ was a 7-day period of return to usual care. Participants continued to wear the body-monitoring armband 24-hours a day except while bathing. Participants also completed the paper version of the HDR daily.

2.2.7. Data Analyses

The outcomes of the current study were analyzed using multiple data analytic strategies. For Phase A and Phase A′ all 7 days of data were extracted and recorded. For Phase B, fatigue and pain data were extracted and recorded every third day from the HDR. Likewise, for Phase B, sleep and physical activity data were also extracted and recorded from the SenseWear® Pro_2 Armband every third day. See Appendix A for a sample of the data extraction form (e.g., Form 1). Data were maintained in a database and analyzed using Microsoft Excel and SPSS 12.0.1 for Windows. Missing data were handled using the missing value analysis in SPSS. Specifically, the expectation maximization (EM) method estimates missing values with an iterative process. During iterations, an expected value (i.e., E) or the best lower bound is calculated from the available data and the maximum likelihood estimates (i.e., M) as well (Dellaert, 2002; Dempster, Laird, Rubin, 1977; Velicer & Colby, 2005). The EM method of handling missing data was chosen over data deletion, mean substitution of the data series, and the mean of adjacent data. Data deletion reduces data observations thereby reducing the power of the analyses. Mean substitution does not consider the order of the data; hence, disregarding the possibility of serial

dependency. Similarly, utilizing the mean of the adjacent data was not employed because this method may disguise autocorrelated data or inappropriately level the data. The semi-statistical and statistical procedures used for data analyses were: Barlett's test of autocorrelation coefficients to test serial dependency in the Phase A data (Ottenbacher, 1986), celeration line analysis, the *C* Statistic (Tryon, 1982), coefficient of variation (*CV*), and the Mann-Whitney *U* Test tests. Data analysis was carried out according to a hierarchical scheme (see Figure 4), based on the statistical rigor of single subject design, after an examination of autocorrelation coefficients. However, prior to autocorrelation testing, graphic presentations of levels and trends data (see Appendix B: Sample 1 and 2) allowed for visual inspection of the data to determine if any target behaviors differed between Phase A and Phase B.

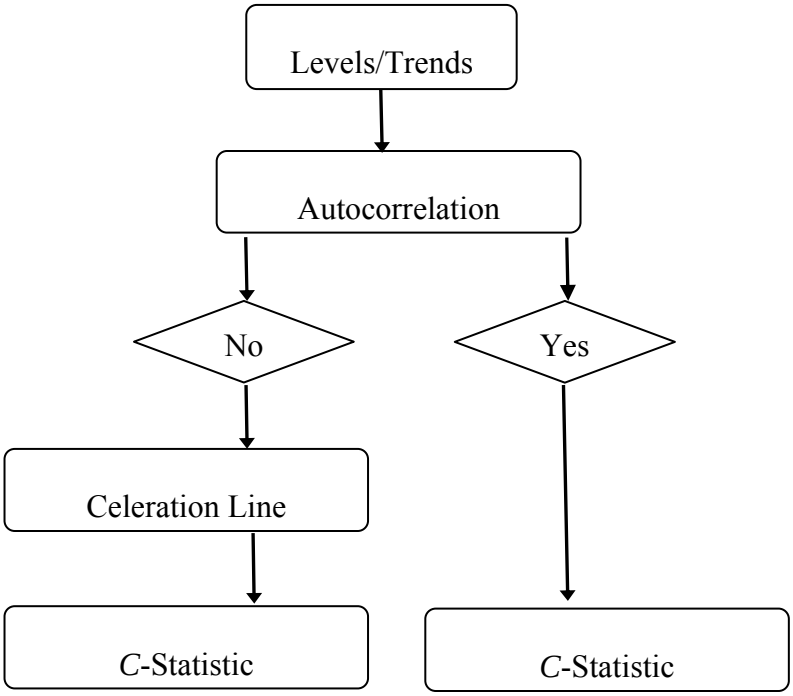

Figure 4: Single Subject Design Statistical Analyses Hierarchy

Potential autocorrelation coefficients for target baseline behaviors were calculated on baseline data of each participant to verify if data points in the given series were significantly correlated with each other (Ottenbacher & Hinderer, 2001). Bartlett's test was used to determine if autocorrelations were statistically significant. Significant autocorrelations of baseline data would prompt an examination of the data using only the *C*-Statistic to evaluate the effects of the intervention because the *C*-Statistic is an acceptable statistical procedure to examine serially dependent data (Tryon, 1982) (see Figure 4). Tryon suggests that the *C*-Statistic is the most rigorous method of analysis used with single subject data. Non-significant autocorrelations were a cue to examine the data using the celeration line and the *C*-Statistic methods.

The trend line, a visual aid to the graphical interpretation of data based on the split-middle method is the most basic semi-statistical procedure, and provides insight into the target behavior trends and the degree of change associated with each behavior during Phase B when autocorrelations are non-significant. The celeration line, calculated from the Phase A baseline data, facilitates visual inspection of the predicted path of the target behaviors without the intervention. A modified Bloom probability table was then used to establish the statistical significance of the number of treatment observations above the celeration line at an alpha of $p <$ .05 (Ottenbacher, 1986). The combined application of the celebration line and the modified Bloom probability table provided a one-tailed test of significance for behavioral change. The final level of analyses for non-serially dependent data was the *C*-Statistic. It is the most statistically rigorous method of data analyses for single subject design research. Additionally, coefficients of variation and Mann-Whitney *U* Test tests were computed on the four target behaviors for the two FIQ subgroups across all phases. The coefficient of variation is a parametric statistical measure of variability, indicating the spread of data points in a data series around the mean (Portney & Watkins, 2000). The CV was applied to the target behaviors of individual participants to compare the relative variation of data, in percentages, for the two subgroups for all target behaviors. The independent samples Mann-Whitney *U* Test tests were used to compare the subgroups (low FIQ: high FIQ) on the four target behaviors.

We hypothesized that an interactive-Internet intervention would decrease fatigue and pain and increase sleep and physical activity duration in persons with fibromyalgia with both low and high impact scores on the FIQ. However, we also hypothesized that improvement would be greater in the low FIQ subgroup than in the high FIQ subgroup. Therefore, all data were analyzed using one-tailed tests of significance.

2.3. **RESULTS**

The 10 white female participants had a mean age ± standard deviation of 52.00 ± 6.7 years, and were, primarily married, and college-educated with a household income of $40,000 - $69,999. Fibromyalgia impact was moderate with an endorsement of an average of 48.9 on the FIQ and a mean Manual Tender Point Fibromyalgia Intensity Score of 6.72. The two subgroups did not differ significantly in their demographics expect on age. Participants in the low FIQ subgroup were older than the high FIQ subgroup. See Table 2.2 and Table 2.3 for an overview of the characteristics specific to the two FIQ subgroups. Presented in Table 2.4 are descriptive data, by FIQ subgroups, and the four target behaviors for all participants, across all study phases. The Bartlett test evidenced no significant level of autocorrelation during Phase A for the four target behaviors for any participant. The graphed celeration lines with an alpha of $p < .05$ in Phase B indicate the statistically significant change from Phase A, which is determined by the number of treatment observations above or below the celeration line, compared to Phase A (Bloom, 1975).

Table 2.2: Characteristics of Low FIQ Subgroup

Variable (score range)	*M*	*SD*
Age, years	56.00	7.00
Ethnic Background, %		
White	100	
Education, %		
High School graduate	40	
College graduate (associates or bachelors)	40	
Graduate/professional training	20	
Marital Status, %		
Married	60	
Living with significant other/partner	20	
Separated	20	
Employment Status, %		
Work part-time (≤ 35 hours/week)	20	
Disabled	40	
Retired	40	
Household Income, %		
$40,000 - $69,999	60	
$80,000 or more	20	
Unknown or refused	20	
Fibromyalgia Impact Questionnaire (0 – 80[†])	43.06	2.23
Manual Tender Point Fibromyalgia Intensity Score (0-10[‡])	6.47	0.96

Note. *M* = Mean and *SD* = Standard deviation for age, Fibromyalgia Impact Questionnaire, and Manual Tender Point Fibromyalgia Intensity Score. Other variable data are reported in percents (%). [†] Higher score indicates greater impact. [‡] Higher score indicates greater pain intensity.

Table 2.3: Characteristics of High FIQ Subgroup

Variable (score range)	*M*	*SD*
Age, years	48.00	3.32
Ethnic Background, %		
White	100	
Education, %		
High School graduate	40	
College graduate (associates or bachelors)	60	
Marital Status, %		
Married	100	
Employment Status, %		
Work full-time (≥ 35 hours/week)	20	
Work part-time (≤ 35 hours/week)	40	
Disabled	20	
Other (medical leave)	20	
Household Income, %		
$ 40,000 - $ 69,999	40	
$ 80,000 or more	40	
Unknown or refused	20	
Fibromyalgia Impact Questionnaire (0 – 80[†])	54.64	6.84
Manual Tender Point Fibromyalgia Intensity Score (0-10[‡])	6.98	1.41

Note. *M* = Mean and *SD* = Standard deviation for age, Fibromyalgia Impact Questionnaire, and Manual Tender Point Fibromyalgia Intensity Score. Other variable data are reported in percents (%). [†] Higher score indicates greater impact. [‡] Higher score indicates greater pain intensity.

Table 2.4: Descriptive Data of Target Behaviors

Participant/ Target Variable	Phase A			Phase B			Phase A'		
	M	*SD*	*CV*	*M*	*SD*	*CV*	*M*	*SD*	*CV*
Low FIQ Subgroup									
Participant 1:									
HDR fatigue	2.57	1.27	0.49	2.86	1.03	0.36	2.43	0.79	0.32
HDR pain	2.59	0.67	0.26	3.43	0.74	0.22	2.88	0.46	0.16
Armband sleep	413.29	46.10	0.11	374.50	162.08	0.43	416.86	47.67	0.11
Armband physical activity	421.86	211.72	0.50	184.79	160.58	0.87	234.29	250.10	1.07
Participant 2:									
HDR fatigue	2.43	1.13	0.47	2.93	1.00	0.34	3.43	0.98	0.28
HDR pain	2.16	0.36	0.17	3.00	0.44	0.15	2.38	0.27	0.11
Armband sleep	343.71	43.63	0.13	316.64	36.39	0.11	295.71	139.60	0.47
Armband physical activity	230.86	24.48	0.11	211.36	64.78	0.31	168.71	135.97	0.81
Participant 3:									
HDR fatigue	3.00	0.58	0.19	2.71	0.73	0.27	2.86	0.53	0.16
HDR pain	2.98	0.75	0.25	3.51	0.52	0.15	2.53	0.63	0.25
Armband sleep	412.14	52.00	0.13	421.50	54.62	0.13	396.71	78.57	0.20
Armband physical activity	263.14	109.27	0.42	274.64	115.79	0.42	321.29	181.44	0.55

Table 2.4 (continued).

Participant/ Target Variable	Phase A			Phase B			Phase A'		
	M	*SD*	*CV*	*M*	*SD*	*CV*	*M*	*SD*	*CV*
Low FIQ Subgroup									
Participant 4:									
HDR fatigue	2.86	0.90	0.31	3.57	0.76	0.21	3.43	0.53	0.16
HDR pain	3.24	0.83	0.26	2.49	0.49	0.20	3.31	0.54	0.16
Armband sleep	403.86	96.10	0.24	423.64	56.32	0.13	449.57	49.79	0.11
Armband physical activity	238.29	51.77	0.22	217.00	59.28	0.27	192.86	75.53	0.39
Participant 5:									
HDR fatigue	1.86	0.90	0.48	2.14	0.77	0.36	2.71	0.76	0.28
HDR pain	2.60	0.43	0.17	2.91	0.38	0.13	3.36	0.20	0.06
Armband sleep	298.43	81.75	0.27	250.36	112.45	0.45	389.43	46.42	0.12
Armband physical activity	64.57	20.04	0.31	70.71	45.82	0.65	91.00	19.36	0.21
High FIQ Subgroup									
Participant 6:									
HDR fatigue	1.86	0.38	0.20	2.64	0.50	0.19	2.00	0.00	0.00
HDR pain	2.38	0.25	0.11	3.44	0.29	0.08	2.45	0.18	0.07
Armband sleep	316.14	73.50	0.23	327.50	109.02	0.33	345.71	38.53	0.11
Armband physical activity	67.00	44.54	0.66	14.79	25.44	1.72	30.57	19.38	0.63

Table 2.4 (continued).

Participant/ Target Variable	Phase A			Phase B			Phase A'		
	M	*SD*	*CV*	*M*	*SD*	*CV*	*M*	*SD*	*CV*
High FIQ Subgroup									
Participant 7:									
HDR fatigue	1.86	0.69	0.37	2.07	1.00	0.48	1.29	0.49	0.38
HDR pain	4.18	0.68	0.16	2.23	0.87	0.39	3.54	0.64	0.18
Armband sleep	304.86	84.77	0.28	320.50	101.44	0.32	343.57	109.28	0.32
Armband physical activity	142.14	48.68	0.34	174.29	91.33	0.52	160.71	79.88	0.50
Participant 8:									
HDR fatigue	2.71	0.49	0.18	2.64	0.63	0.24	3.00	0.82	0.27
HDR pain	2.86	0.24	0.08	2.98	0.28	0.09	2.98	0.29	0.10
Armband sleep	425.00	63.43	0.15	386.71	114.33	0.30	414.29	34.94	0.08
Armband physical activity	198.14	45.81	0.23	189.21	38.14	0.20	202.14	70.95	0.35
Participant 9:									
HDR fatigue	2.57	0.79	0.31	2.36	0.93	0.39	2.71	0.76	0.28
HDR pain	3.08	0.29	0.09	3.21	0.49	0.15	2.64	0.59	0.22
Armband sleep	352.14	59.17	0.17	348.43	115.92	0.33	348.29	62.66	0.18
Armband physical activity	144.71	94.28	0.65	116.50	70.23	0.60	80.00	35.35	0.44

Table 2.4 (continued).

Participant/ Target Variable	Phase A			Phase B			Phase A'		
	M	*SD*	*CV*	*M*	*SD*	*CV*	*M*	*SD*	*CV*
High FIQ Subgroup									
Participant 10:									
HDR fatigue	1.57	0.53	0.34	1.71	0.73	0.42	1.71	0.49	0.28
HDR pain	2.22	0.31	0.14	3.76	0.30	0.08	2.16	0.22	0.10
Armband sleep	406.57	61.05	0.15	253.64	151.92	0.60	92.00	105.42	1.15
Armband physical activity	109.86	40.13	0.37	112.64	55.69	0.49	150.57	73.69	0.49

Note. Phase A was the baseline phase, Phase B was the intervention phase, and Phase A' was the return-to-baseline phase. Healthy Daily Routine (HDR) ratings 1 = very poor to 5 = very good. Armband sleep and physical activity recorded in minutes.

2.3.1. Healthy Daily Routine Fatigue Rating

Healthy Daily Routine fatigue ratings range from 1 = very poor to 5 = very good.

2.3.1.1. Low FIQ Subgroup

Participants 1, 2, 3, 4, and 5 constituted the members of the low FIQ subgroup.

PARTICIPANT 1

Participant 1 reported decreasing levels of fatigue, resulting in an accelerating trend line (see Figure 5). Celeration line analysis of Phase B compared with Phase A indicated that Participant 1 did not perceive significant changes in fatigue (see Figure 5). The same pattern continued during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not show a significant effect during the intervention or return-to-baseline (see Table 2.5).

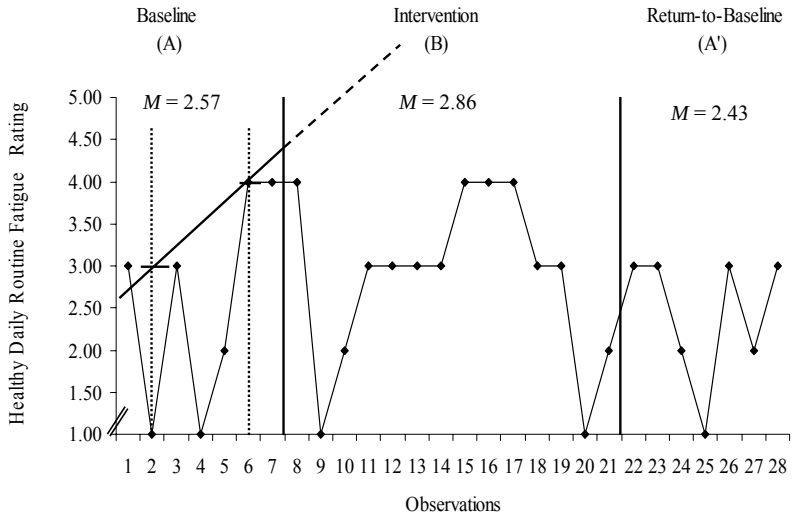

Figure 5: HDR Fatigue Celeration Line for Participant 1

PARTICIPANT 2

In Phase A, Participant 2 reported consistent levels of fatigue, resulting in a linear trend line (see Figure 6). Celeration line inspection of Phase B compared with Phase A indicated that Participant 2 did not perceive significant changes in fatigue (see Figure 6). This pattern remained in Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention or return-to-baseline (see Table 2.5).

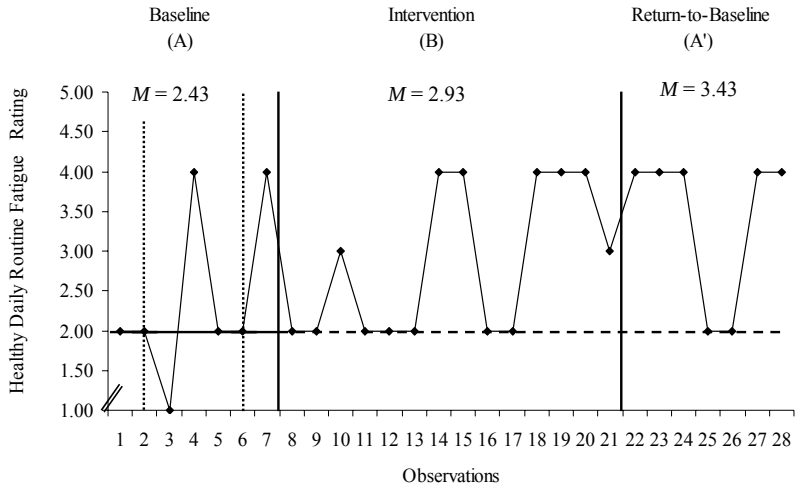

Figure 6: HDR Fatigue Celeration Line for Participant 2

PARTICIPANT 3

During Phase A, Participant 3 reported unchanging levels of fatigue, resulting in a linear trend line (see Figure 7). Celeration line analysis of Phase B compared with Phase A indicated that Participant 3 did not perceive significant changes in fatigue (see Figure 7). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of

significance did not indicate a significant effect during the intervention or return-to-baseline (see Table 2.5).

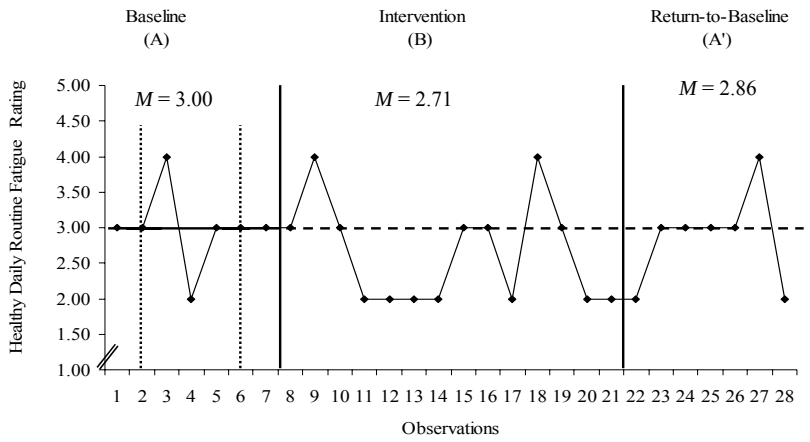

Figure 7: HDR Fatigue Celeration Line for Participant 3

PARTICIPANT 4

Throughout Phase A, Participant 4 reported increasing levels of fatigue, resulting in a decelerating trend line (see Figure 8). Celeration line examination of Phase B compared to Phase A indicated that Participant 4 experienced significantly less fatigue (see Figure 8). This pattern remained during Phase A'. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention or return-to-baseline (see Table 2.5).

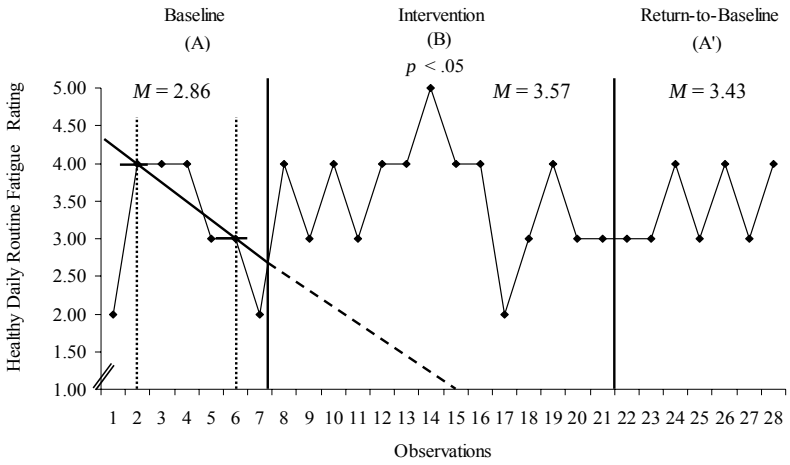

Figure 8: HDR Fatigue Celeration Line for Participant 4

PARTICIPANT 5

Participant 5 reported a consistent level of fatigue, resulting in a linear trend line (see Figure 9). Celeration line analysis comparing Phase B with Phase A indicated that Participant 5 did not perceive significant changes in fatigue (see Figure 9). This same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention or return-to-baseline (see Table 2.5).

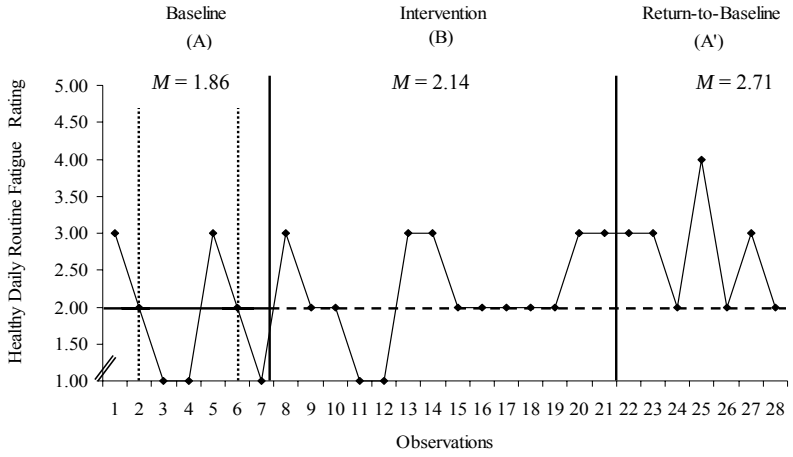

Figure 9: HDR Fatigue Celeration Line for Participant 5

See Table 2.5 for the summary of results of HDR fatigue for the low FIQ subgroup.

Table 2.5: Summary of Results of HDR Fatigue Ratings for Low FIQ Subgroup

Group/ Target behavior	Comparison 1	Celeration line	*C*-Statistic		Comparison 2	*C*-Statistic	
Low FIQ Subgroup		SIG*	*Z* Score	SIG*		*Z* Score	SIG*
HDR Fatigue							
Participant 1:	A → B	*ns*	1.19	*ns*	A → A'	0.08	*ns*
Participant 2:	A → B	*ns*	0.41	*ns*	A → A'	0.71	*ns*
Participant 3:	A → B	*ns*	0.38	*ns*	A → A'	-2.41	*SIG*
Participant 4:	A → B	SIG	0.54	*ns*	A → A'	0.22	*ns*
Participant 5:	A → B	*ns*	0.43	*ns*	A → A'	-0.27	*ns*

Note. HDR = Healthy Daily Routine. **Z* Scores ≥ ± 1.64 required for alpha of $p < .05$; if significance (SIG) is italicized significance is not in the hypothesized direction.

2.3.1.2. High FIQ Subgroup

Participants 6, 7, 8, 9 and 10 constituted the members of the high FIQ subgroup.

PARTICIPANT 6

Participant 6 reported consistent levels of fatigue through Phase A, resulting in a linear trend line (see Figure 10). Celeration line analysis of Phase B compared with Phase A indicated that Participant 6 experienced significantly less fatigue (see Figure 10). The same pattern did not remain during Phase A′. The more rigorous *C*-statistic -tailed test of significance also showed a significant intervention effect however; during Phase A′, return-to-baseline, the *C*-statistic did not indicate a significant effect from the baseline phase (see Table 2.6).

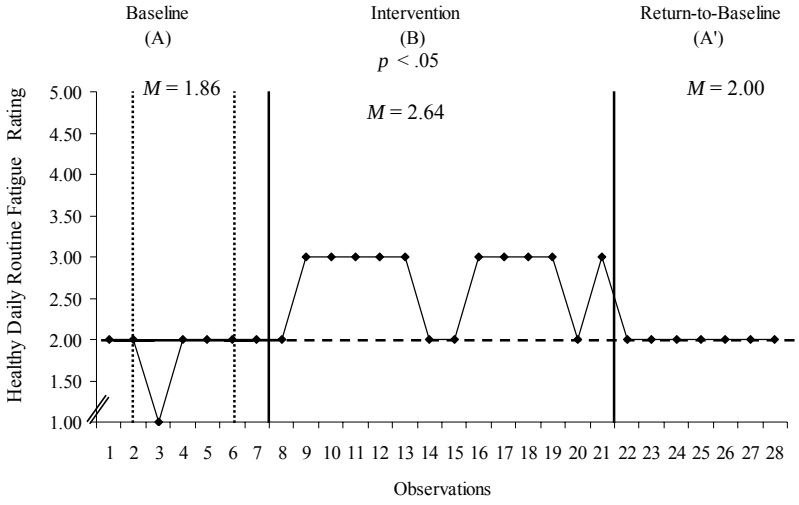

Figure 10: HDR Fatigue Celeration Line for Participant 6

PARTICIPANT 7

During Phase A, Participant 7 reported unchanging levels of fatigue, resulting in a linear trend line (see Figure 11). Celeration line inspection of Phase B compared with Phase A indicated that Participant 7 did not perceive significant changes in fatigue (see Figure 11). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention or return-to-baseline (see Table 2.6).

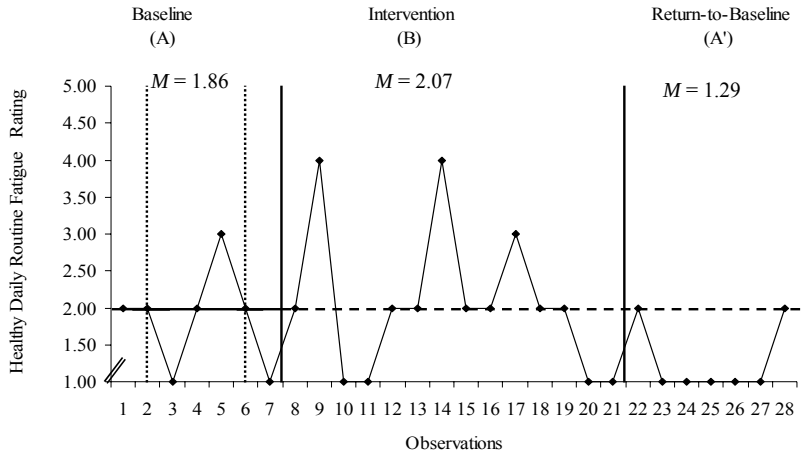

Figure 11: HDR Fatigue Celeration Line for Participant 7

PARTICIPANT 8

In Phase A, Participant 8 reported consistent levels of fatigue, resulting in a linear trend line (see Figure 12). Celeration line inspection of Phase B compared with Phase A indicated that Participant 8 did not perceive significant changes in fatigue (see Figure 12). This pattern remained in Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention or return-to-baseline (see Table 2.6).

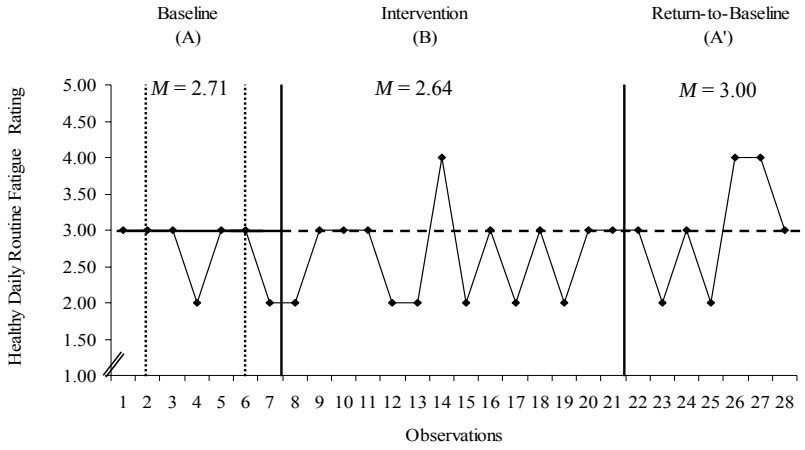

Figure 12: HDR Fatigue Celeration Line for Participant 8

PARTICIPANT 9

Through Phase A, Participant 9 reported increasing levels of fatigue, resulting in a decelerating trend line (see Figure 13). Celeration line analysis of Phase B compared with Phase A indicated that Participant 9 experienced significantly less fatigue (see Figure 13). The same trajectory remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention when compared to baseline; however, during Phase A′, return-to-baseline, the *C*-statistic 1-tailed test of significance did indicate a significant effect from the baseline phase (see Table 2.6).

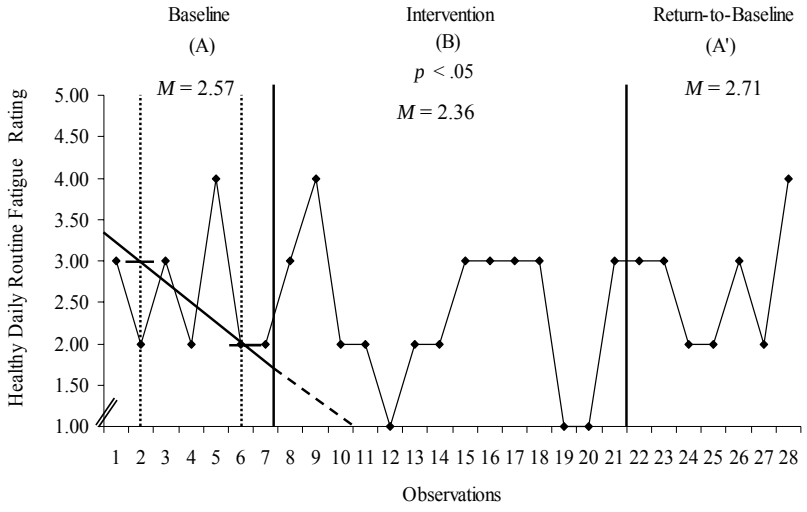

Figure 13: HDR Fatigue Celeration Line for Participant 9

PARTICIPANT 10

During Phase A, Participant 10 reported increasing levels of fatigue, resulting in a decelerating trend line (see Figure 14). Celeration line analysis of Phase B compared with Phase A indicated that Participant 9 experienced significantly less fatigue (see Figure 14). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not reveal a significant effect during the intervention or return-to-baseline (see Table 2.6). See Table 2.6 for the summary of results of HDR fatigue for the high FIQ subgroup.

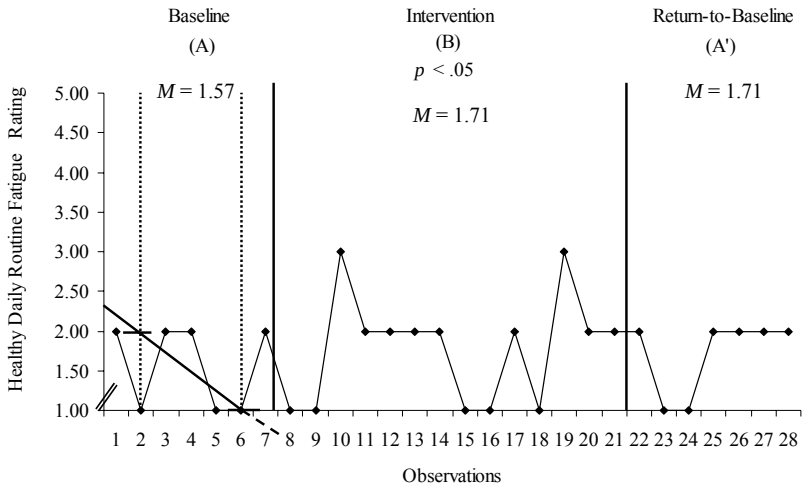

Figure 14: HDR Fatigue Celeration Line for Participant 10

Celeration line graphical analysis indicated that only one participant in the low FIQ subgroup reported significantly reduced fatigue symptoms during the Phase B intervention, compared to three participants in the high FIQ subgroup. The more rigorous C-Statistic analyses showed that none of the participants in the low FIQ subgroup reduced fatigue symptoms significantly during the intervention phase, compared to one participant in the high FIQ subgroup. After the intervention was withdrawn (Phase A′), C-statistic analyses indicated that none of the participants in the low FIQ subgroup reported significantly less fatigue than during Phase A, compared to one participant in the high FIQ subgroup.

The mean coefficients of variation (CVs) for the HDR fatigue for the low FIQ subgroup during Phases A, B, and A′ were 0.40, 0.34, and 0.28 respectively. The CVs for the high FIQ subgroup during Phases A, B, and A′ were 0.34, 0.37, and 0.39 respectively. Mann-Whitney *U* Test results indicate that the two FIQ subgroups did not differ during Phase A for fatigue levels;

however, for Phases B and A′ the low FIQ subgroup experienced significantly lower levels of fatigue than the high FIQ subgroup (see Table 2.7).

Table 2.6: Summary of Results of HDR Fatigue for High FIQ Subgroup

Group/ Target behavior	Comparison 1	Celeration line	*C*-Statistic		Comparison 2	*C*-Statistic	
High FIQ Subgroup		SIG*	*Z* Score	SIG*		*Z* Score	SIG*
HDR Fatigue							
Participant 6:	A → B	SIG	2.34	SIG	A → A'	-0.33	*ns*
Participant 7:	A → B	*ns*	-0.16	*ns*	A → A'	0.96	*ns*
Participant 8:	A → B	*ns*	-1.79	*SIG*	A → A'	-0.22	*ns*
Participant 9:	A → B	SIG	0.27	*ns*	A → A'	-3.10	SIG
Participant 10:	A → B	SIG	-0.45	*ns*	A → A'	0.13	*ns*

Note. HDR = Healthy Daily Routine. **Z* Scores ≥ ± 1.64 required for alpha of $p < .05$; if significance (SIG) is italicized significance is not in the hypothesized direction.

Table 2.7: Mann-Whitney *U* Test Results for Between Clinical Subgroup Comparisons of HDR Fatigue, by Phase

	Low FIQ Subgroup		High FIQ Subgroup		
	M	*SD*	*M*	*SD*	*U*
Target Behavior/ Phase					
HDR Fatigue					
Phase A	2.54	1.01	2.11	0.72	459.50
Phase B	2.84	0.96	2.29	0.84	1681.00**
Phase A'	2.97	0.82	2.14	0.85	303.00**

Note. Healthy Daily Routine (HDR) ratings 1 = very poor; 5 = very good. ** $p < .001$

2.3.2. Healthy Daily Routine Pain Rating

Healthy Daily Routine pain ratings range from 1 = strongly agree to 5 = strongly disagree.

2.3.2.1. Low FIQ Subgroup

Participants 1, 2, 3, 4, and 5 constituted the members of the low FIQ subgroup.

PARTICIPANT 1

Participant 1 reported increasing levels of pain in Phase A, resulting in a decelerating trend line (see Figure 15). Celeration line analysis of Phase B compared with Phase A indicated that Participant 1 experienced significantly less pain (see Figure 15). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention or return-to-baseline (see Table 2.8).

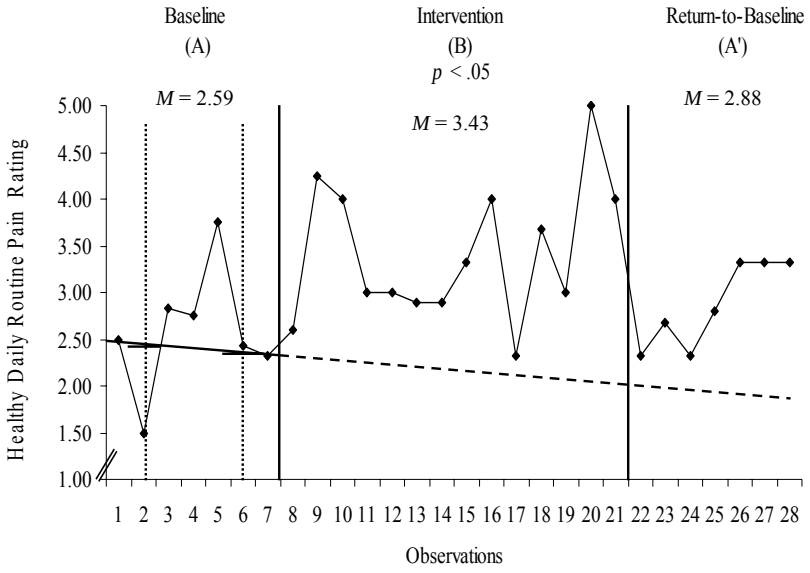

Figure 15: HDR Pain Celeration Line for Participant 1

PARTICIPANT 2

In Phase A, Participant 2 reported increasing levels of pain, resulting in a decelerating trend line (see Figure 16). Celeration line examination of Phase B compared with Phase A indicated that Participant 2 experienced significantly less pain (see Figure 16). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not show a significant effect during the intervention or return-to-baseline (see Table 2.8).

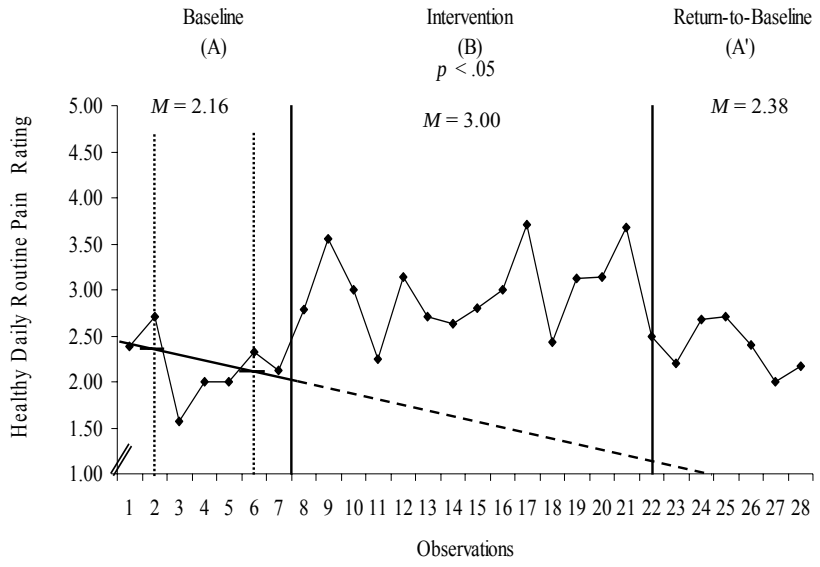

Figure 16: HDR Pain Celeration Line for Participant 2

PARTICIPANT 3

During Phase A, Participant 3 reported decreasing levels of pain, resulting in an accelerating trend line (see Figure 17). Celeration line inspection of Phase B compared with Phase A indicated that Participant 3 did not perceive significant changes in pain (see Figure 17). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of

significance registered a significant intervention effect; however, during Phase A′, return-to-baseline, the *C*-statistic did not indicate a significant effect from the baseline phase (see Table 2.8).

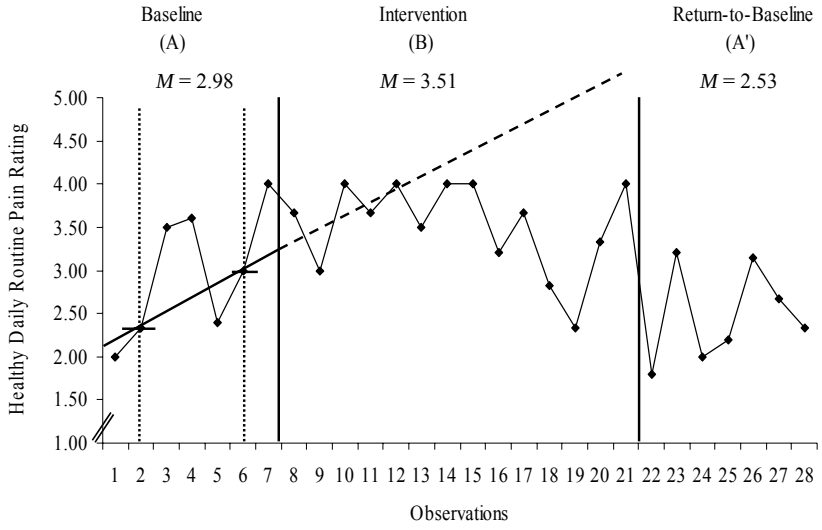

Figure 17: HDR Pain Celeration Line for Participant 3

PARTICIPANT 4

Participant 4 reported increasing levels of pain through Phase A, resulting in a decelerating trend line (see Figure 18). Celeration line evaluation of Phase B compared with Phase A revealed that Participant 4 experienced significantly less pain (see Figure 18). The same trajectory remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention in the hypothesized direction or during return-to-baseline (see Table 2.8).

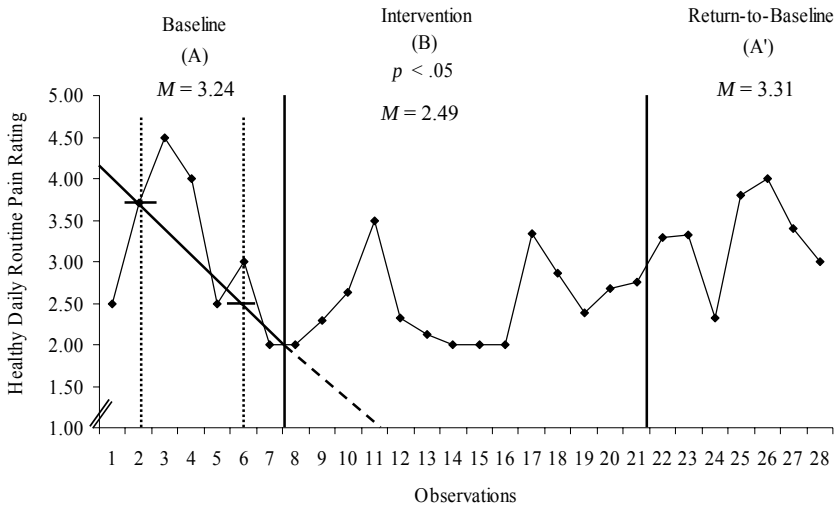

Figure 18: HDR Pain Celeration Line for Participant 4

PARTICIPANT 5

Throughout Phase A, Participant 5 described a continual level of pain, resulting in a linear trend line (see Figure 19). Celeration line analysis of Phase B compared to Phase A indicated that Participant 5 did not perceive significant changes in pain (see Figure 19). This pattern did not remain during Phase A'. The more rigorous *C*-statistic 1-tailed test of significance did not reveal a significant effect during the intervention or return-to-baseline (see Table 2.8).

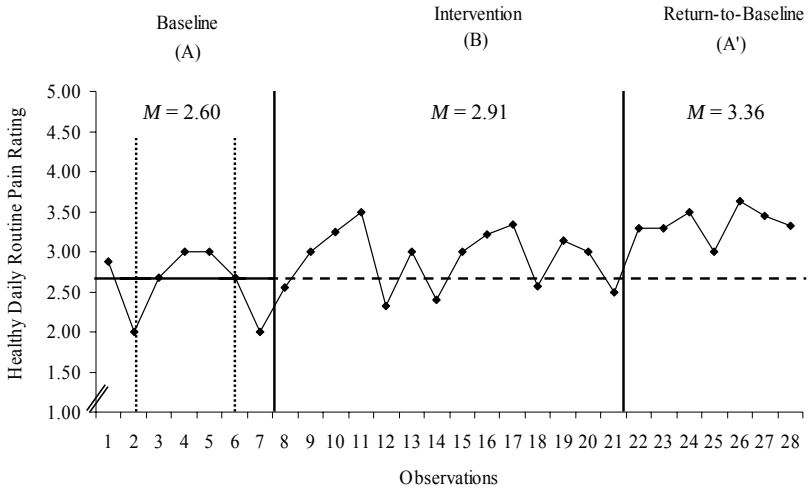

Figure 19: HDR Pain Celeration Line for Participant 5

See Table 2.8 for the summary of results of HDR pain for the low FIQ subgroup.

Table 2.8: Summary of Results of HDR Pain for Low FIQ Subgroup

Group/ Target behavior	Comparison 1	Celeration line	*C*-Statistic		Comparison 2	*C*-Statistic	
Low FIQ Subgroup		SIG*	*Z* Score	SIG*		*Z* Score	SIG*
HDR Pain							
Participant 1:	A → B	SIG	0.95	*ns*	A → A'	0.81	*ns*
Participant 2:	A → B	SIG	1.57	*ns*	A → A'	0.38	*ns*
Participant 3:	A → B	*ns*	1.80	SIG	A → A'	-0.67	*ns*
Participant 4:	A → B	SIG	2.36	*SIG*	A → A'	0.72	*ns*
Participant 5:	A → B	*ns*	0.25	*ns*	A → A'	1.34	*ns*

Note. HDR = Healthy Daily Routine. **Z* Scores ≥ ± 1.64 required for alpha of $p < .05$; if significance (SIG) is italicized significance is not in the hypothesized direction.

2.3.2.2. High FIQ Subgroup

Participants 6, 7, 8, 9 and 10 constituted the members of the high FIQ subgroup.

PARTICIPANT 6

Participant 6 reported decreasing levels of pain during Phase A, resulting in an accelerating trend line (see Figure 20). Celeration line findings of Phase B compared with Phase A indicated that Participant 6 experienced significantly less pain (see Figure 20). The same pattern did not remain during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance also substantiated a significant intervention effect; however, during Phase A′, return-to-baseline, the *C*-statistic did not indicate a significant effect from the baseline phase (see Table 2.9).

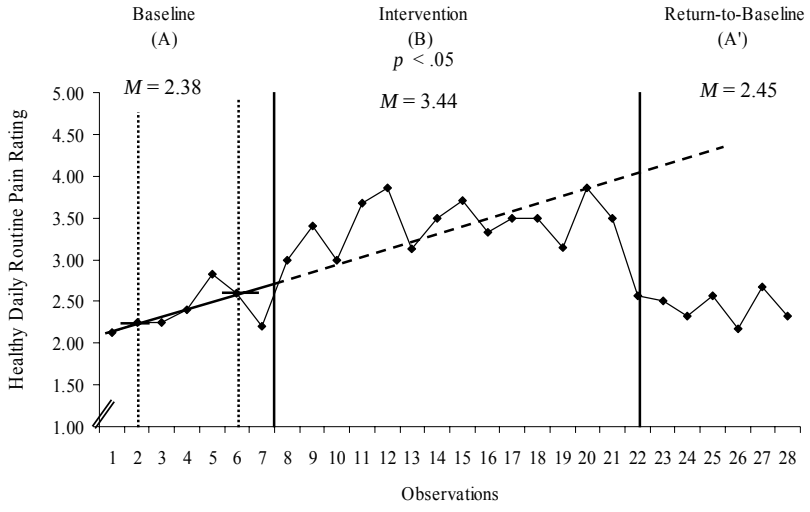

Figure 20: HDR Pain Celeration Line for Participant 6

PARTICIPANT 7

Through Phase A, Participant 7 reported intensifying levels of pain, resulting in a decelerating trend line (see Figure 21). Celeration line examination of Phase B compared with Phase A indicated that Participant 7 did not perceive significant changes in pain (see Figure 21). This same pattern remained in Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not detect a significant effect during the intervention in the hypothesized direction, or during return-to-baseline (see Table 2.9).

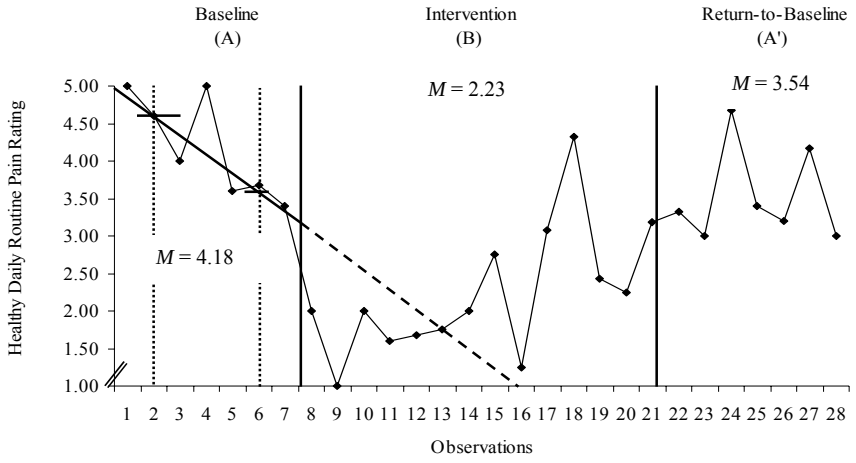

Figure 21: HDR Pain Celeration Line for Participant 7

PARTICIPANT 8

During Phase A, Participant 8 reported elevated levels of pain, resulting in a decelerating trend line (see Figure 22). Celeration line analysis of Phase B compared with Phase A indicated that Participant 8 experienced significantly less pain (see Figure 22). This pattern remained in Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention or return-to-baseline (see Table 2.9).

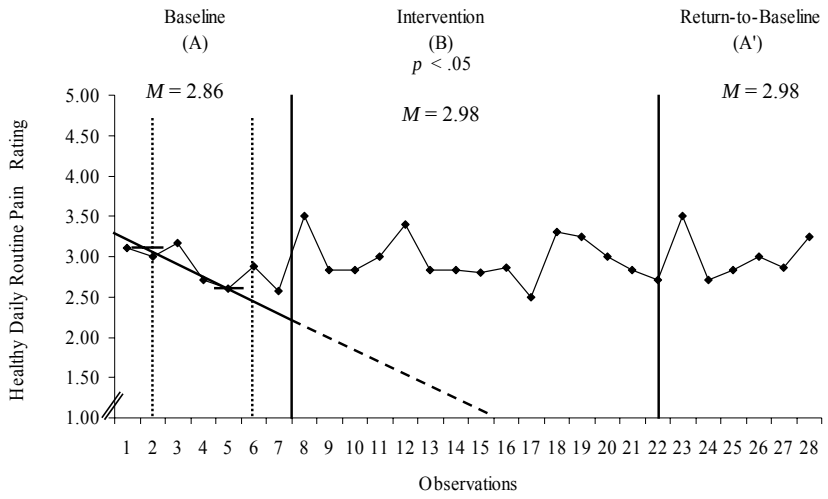

Figure 22: HDR Pain Celeration Line for Participant 8

PARTICIPANT 9

In Phase A, Participant 9 reported increasing levels of pain, resulting in a decelerating trend line (see Figure 23). Celeration line examination of Phase B compared with Phase A revealed that Participant 9 experienced significantly less pain (see Figure 23). This same trend remained in Phase A′. The more rigorous *C*-statistic 1-tailed test of significance detected a significant intervention effect in the hypothesized direction when compared to baseline; conversely, during Phase A′, return-to-baseline, the *C*-statistic did not detect a significant effect when compared to baseline (see Table 2.9).

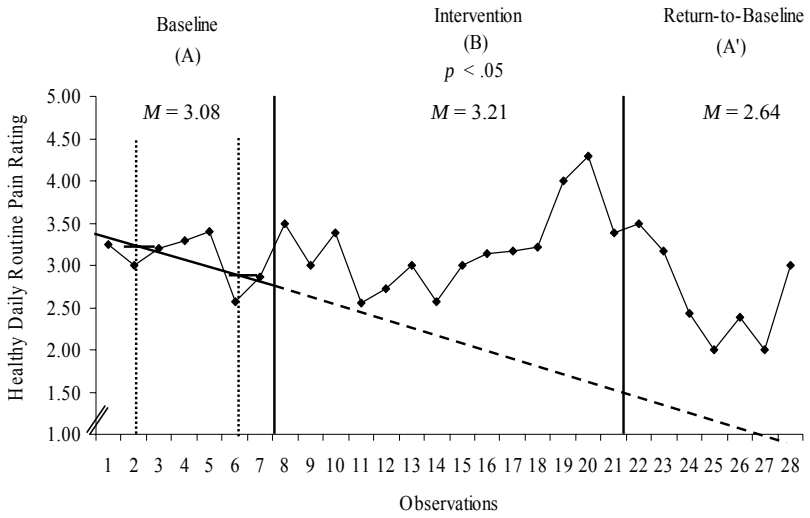

Figure 23: HDR Pain Celeration Line for Participant 9

PARTICIPANT 10

Throughout Phase A, Participant 10 reported heightening levels of pain, resulting in a decelerating trend line (see Figure 24). Celeration line examination of Phase B compared with Phase A indicated that Participant 10 experienced significantly less pain (see Figure 24). This same trend remained in Phase A′. The more rigorous *C*-statistic 1-tailed test of significance detected a significant intervention effect however, during Phase A′, return-to-baseline; the *C*-statistic did not detect a significant effect from the baseline phase (see Table 2.9). See Table 2.9 for the summary of results of HDR fatigue for the high FIQ subgroup.

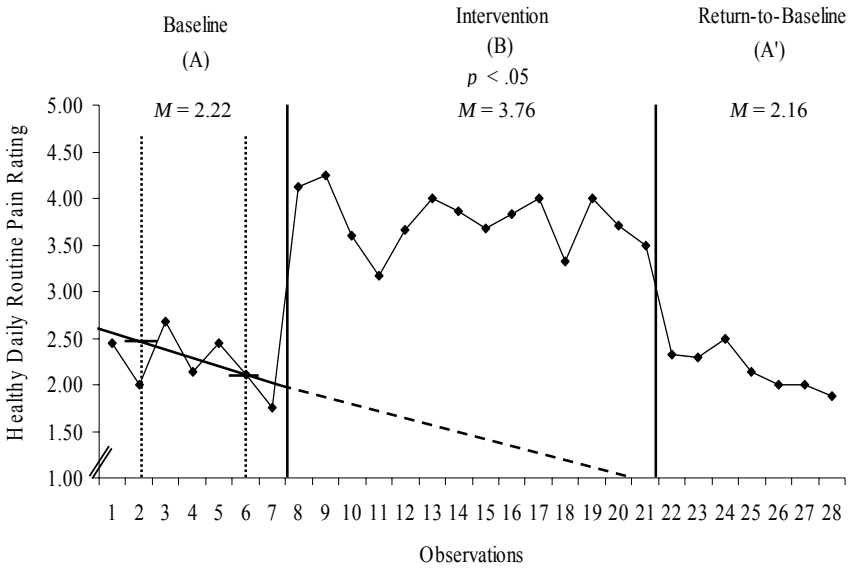

Figure 24: HDR Pain Celeration Line for Participant 10

Celeration line graphical analysis indicated that three participants in the low FIQ subgroup reported significantly reduced pain symptoms during the Phase B intervention, compared to four participants in the high FIQ subgroup. The more rigorous C-Statistic analyses showed that one participant in the low FIQ subgroup reduced pain symptoms significantly during the intervention phase, compared to three participants in the high FIQ subgroup. After the intervention was withdrawn (Phase A′), C-statistic analyses indicated that none of the participants in either clinical subgroup reported significantly less pain than during Phase A.

The mean coefficients of variation (CVs) for the HDR pain for the low FIQ subgroup during Phases A, B, and A′ were 0.26, 0.21, and 0.20 respectively. The CVs for the high FIQ subgroup during Phases A, B, and A′ were 0.27, 0.23, and 0.23 respectively. Mann-Whitney *U* Test results indicate that the two FIQ subgroups did not differ significantly for reported pain levels across Phases A, B, and A' (see Table 2.10).

Table 2.9: Summary of Results of HDR Pain for High FIQ Subgroup

Group/ Target behavior	Comparison 1	Celeration line	*C*-Statistic		Comparison 2	*C*-Statistic	
High FIQ Subgroup		SIG*	*Z* Score	SIG*		*Z* Score	SIG*
HDR Pain							
Participant 6:	A → B	SIG	3.51	SIG	A → A'	-0.13	*ns*
Participant 7:	A → B	*ns*	3.21	*SIG*	A → A'	0.47	*ns*
Participant 8:	A → B	SIG	-0.50	*ns*	A → A'	-0.70	*ns*
Participant 9:	A → B	SIG	1.94	SIG	A → A'	1.90	*SIG*
Participant 10:	A → B	SIG	3.12	SIG	A → A'	-0.54	*ns*

Note. HDR = Healthy Daily Routine. **Z* Scores ≥ ± 1.64 required for alpha of $p < .05$; if significance (SIG) is italicized significance is not in the hypothesized direction.

Table 2.10: Mann-Whitney *U* Test Results for Between Clinical Subgroup Comparisons of HDR Pain, by Phase

	Low FIQ Subgroup		High FIQ Subgroup		
	M	*SD*	*M*	*SD*	*U*
Target Behavior/ Phase					
HDR Pain					
Phase A	2.71	0.71	2.95	0.79	505.50
Phase B	3.07	0.64	3.13	0.71	2179.00
Phase A'	2.89	0.58	2.75	0.63	509.50

Note. Healthy Daily Routine (HDR) ratings 1 = strongly agree to 5 = strongly disagree.

2.3.3. Armband Sleep

SenseWear® Pro_2 Armband sleep data were recorded in minutes.

2.3.3.1. Low FIQ Subgroup

Participants 1, 2, 3, 4, and 5 constituted the members of the low FIQ subgroup.

PARTICIPANT 1

Participant 1 exhibited increasing durations of nighttime sleep in Phase A, resulting in an accelerating trend line (see Figure 25). Celeration line analysis of Phase B compared with Phase A indicated that Participant 1 did not exhibit significant changes in nighttime sleep duration (see Figure 25). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance also indicated a significant effect during the intervention but not during return-to-baseline (see Table 2.11).

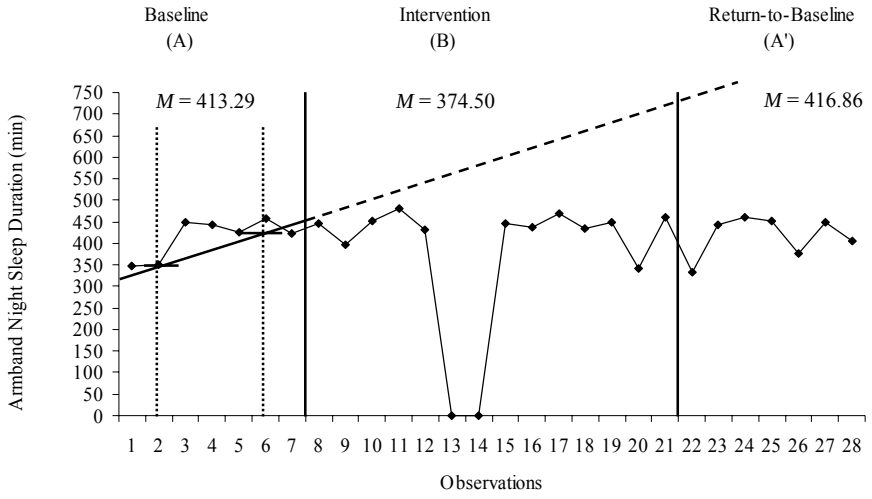

Figure 25: Armband Sleep Celeration Line for Participant 1

PARTICIPANT 2

In Phase A, Participant 2 exhibited decreasing durations of nighttime sleep, resulting in a decelerating trend line (see Figure 26). Celeration line examination of Phase B compared with Phase A indicated that Participant 2 experienced significantly more nighttime sleep (see Figure 26). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not show a significant effect during the intervention or return-to-baseline (see Table 2.11).

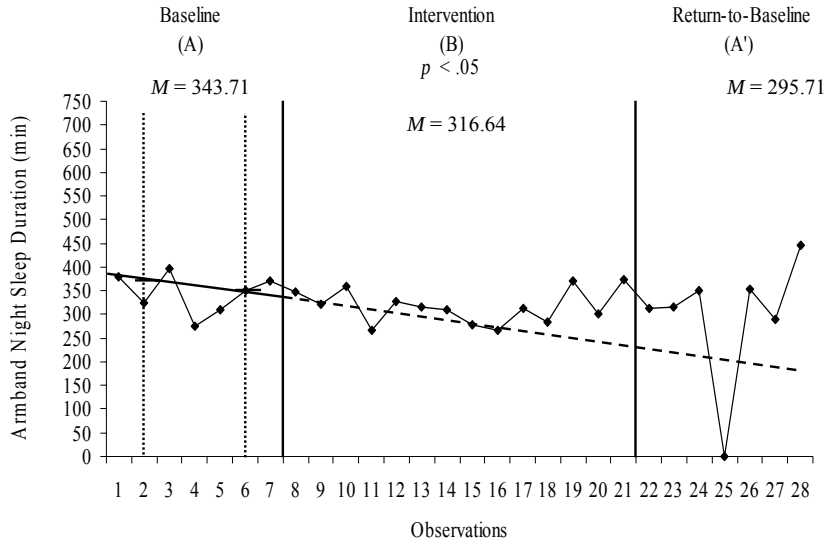

Figure 26: Armband Sleep Celeration Line for Participant 2

PARTICIPANT 3

During Phase A, Participant 3 exhibited consistent durations of nighttime sleep, resulting in a linear trend line (see Figure 27). Celeration line inspection of Phase B compared with Phase A

indicated that Participant 3 did not exhibit significant changes in nighttime sleep duration (see Figure 27). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not register a significant effect during the intervention or in the hypothesized direction during return-to-baseline (see Table 2.11).

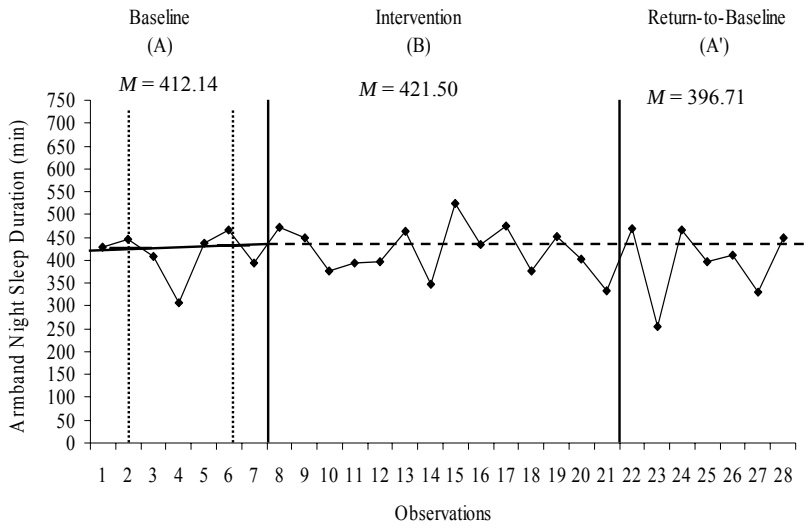

Figure 27: Armband Sleep Celeration Line for Participant 3

PARTICIPANT 4

Participant 4 exhibited decreasing durations of nighttime sleep through Phase A, resulting in a decelerating trend line (see Figure 28). Celeration line evaluation of Phase B compared with Phase A revealed that Participant 4 experienced significantly more nighttime sleep (see Figure 28). The same trajectory remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention or return-to-baseline (see Table 2.11).

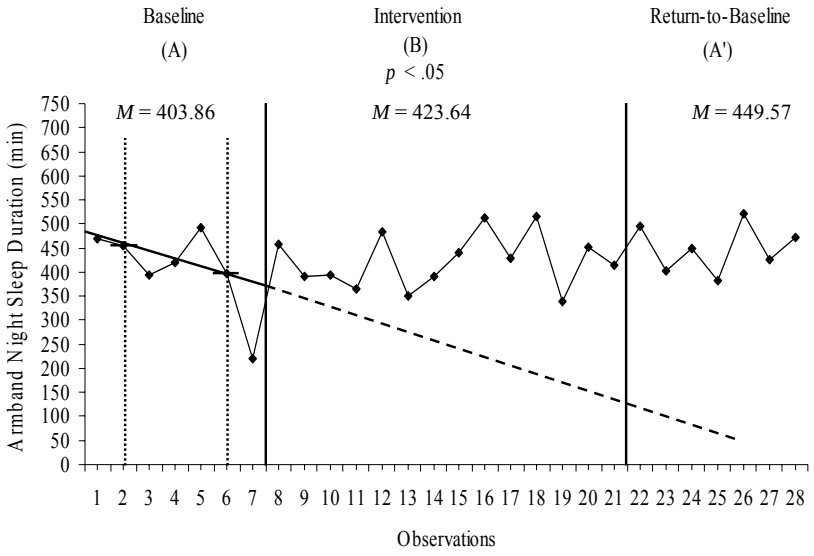

Figure 28: Armband Sleep Celeration Line for Participant 4

PARTICIPANT 5

Throughout Phase A, Participant 5 exhibited increasing durations of nighttime sleep, resulting in an accelerating trend line (see Figure 29). Celeration line analysis of Phase B compared to Phase A indicated that Participant 5 did not exhibit significant changes in nighttime sleep duration (see Figure 29). This pattern remained during Phase A'. The more rigorous *C*-statistic 1-tailed test of significance did not reveal a significant effect during the intervention or return-to-baseline (see Table 2.11).

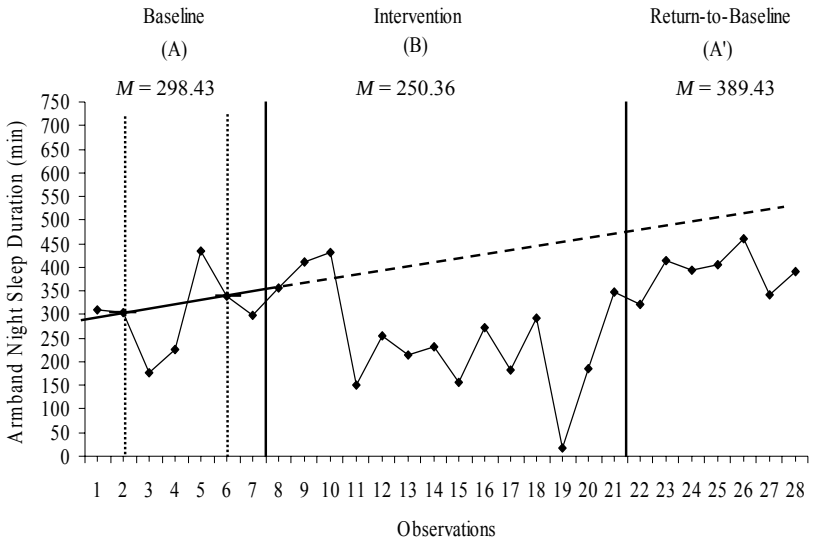

Figure 29: Armband Sleep Celeration Line for Participant 5

See Table 2.11 for the summary of results of armband sleep for the low FIQ.

Table 2.11: Summary of Results of Armband Sleep for Low FIQ Subgroup

Group/ Target behavior	Comparison 1	Celeration line	*C*-Statistic		Comparison 2	*C*-Statistic	
Low FIQ Subgroup		SIG*	*Z* Score	SIG*		*Z* Score	SIG*
Armband Sleep							
Participant 1:	A → B	*ns*	1.88	SIG	A → A'	0.54	*ns*
Participant 2:	A → B	SIG	-1.16	*ns*	A → A'	-1.19	*ns*
Participant 3:	A → B	*ns*	-1.62	*ns*	A → A'	-1.97	*SIG*
Participant 4:	A → B	SIG	-0.43	*ns*	A → A'	-1.00	*ns*
Participant 5:	A → B	*ns*	0.90	*ns*	A → A'	1.45	*ns*

Note. **Z* Scores ≥ ± 1.64 required for alpha of $p < .05$; if significance (SIG) is italicized significance is not in the hypothesized direction.

2.3.3.2. High FIQ Subgroup

Participants 6, 7, 8, 9 and 10 constituted the members of the high FIQ subgroup.

PARTICIPANT 6

Participant 6 exhibited decreasing durations of nighttime sleep during Phase A, resulting in an decelerating trend line (see Figure 30). Celeration line findings of Phase B compared with Phase A indicated that Participant 6 experienced significantly more nighttime sleep (see Figure 30). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not show a significant effect during the intervention or return-to-baseline (see Table 2.12).

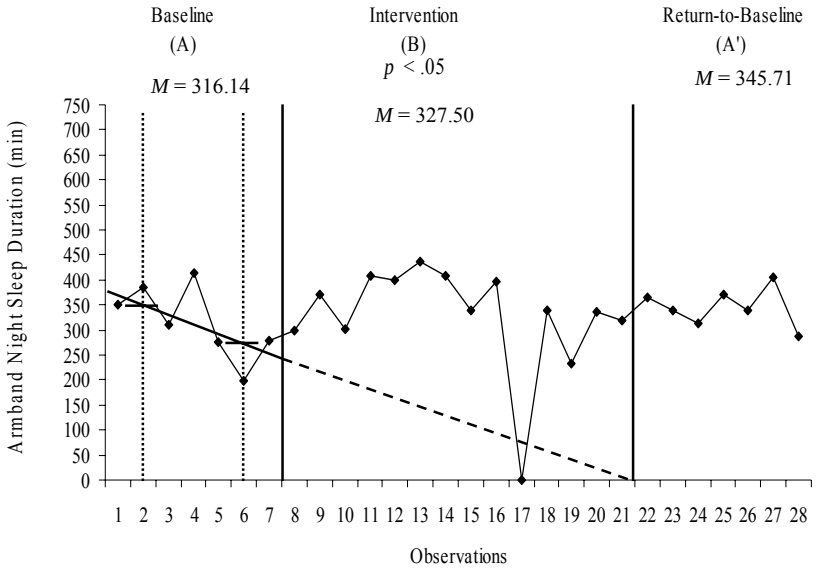

Figure 30: Armband Sleep Celeration Line for Participant 6

PARTICIPANT 7

Through Phase A, Participant 7 exhibited decreased durations of nighttime sleep, resulting in a decelerating trend line (see Figure 31). Celeration line examination of Phase B compared with Phase A revealed that Participant 7 experienced significantly more nighttime sleep (see Figure 31). This same pattern remained in Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not detect a significant effect during the intervention or return-to-baseline (see Table 2.12).

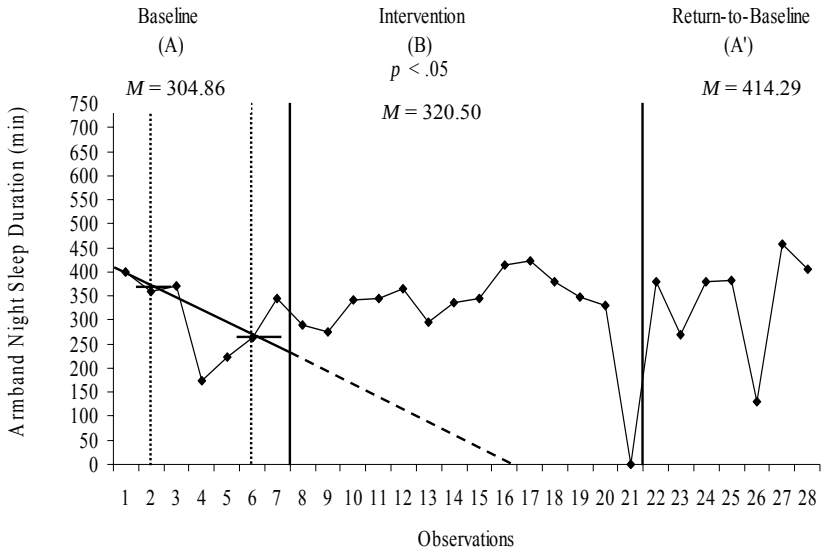

Figure 31: Armband Sleep Celeration Line for Participant 7

PARTICIPANT 8

During Phase A, Participant 8 exhibited reduced durations of nighttime sleep, resulting in a decelerating trend line (see Figure 32). Celeration line analysis of Phase B compared with Phase A indicated that Participant 8 experienced significantly more nighttime sleep (see Figure 32).

This pattern remained in Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention or return-to-baseline (see Table 2.12).

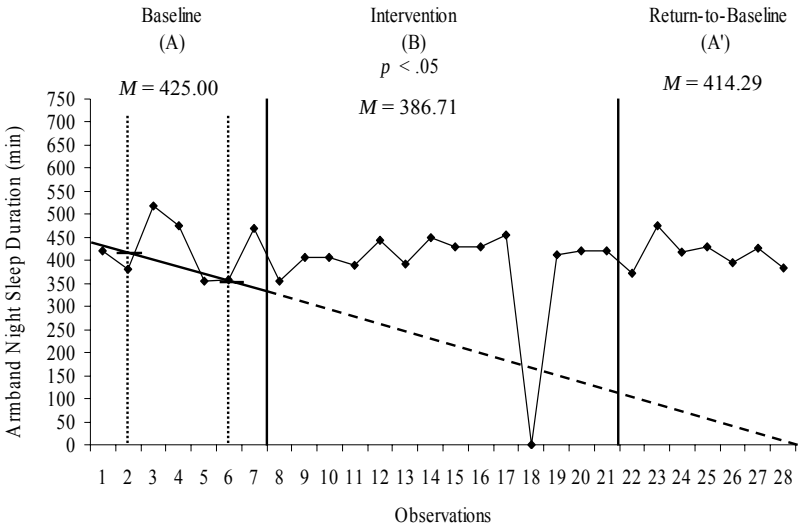

Figure 32: Armband Sleep Celeration Line for Participant 8

PARTICIPANT 9

In Phase A, Participant 9 exhibited decreasing durations of nighttime sleep, resulting in a decelerating trend line (see Figure 33). Celeration line examination of Phase B compared with Phase A revealed that Participant 9 experienced significantly more nighttime sleep (see Figure 33). This same trend remained in Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention or return-to-baseline (see Table 2.12).

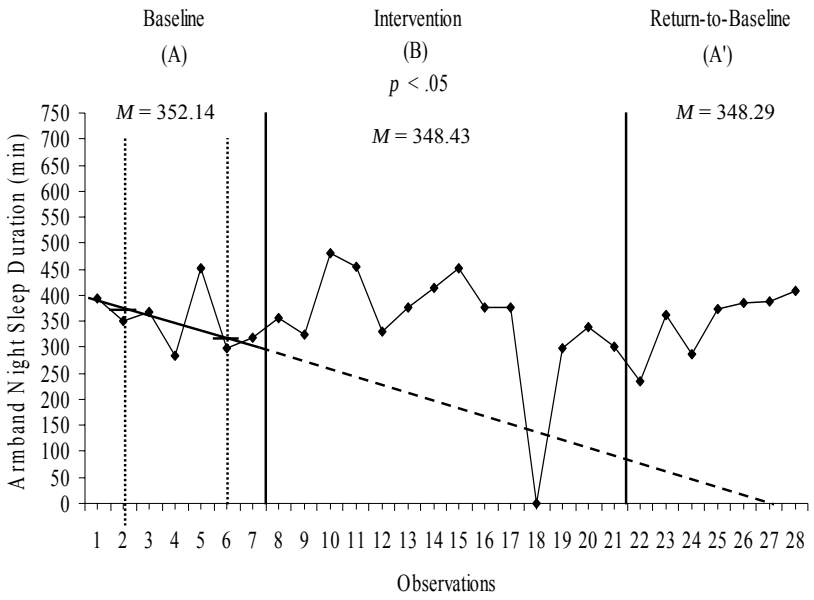

Figure 33: Armband Sleep Celeration Line for Participant 9

PARTICIPANT 10

Throughout Phase A, Participant 10 exhibited reduced durations of nighttime sleep, resulting in a decelerating trend line (see Figure 34). Celeration line examination of Phase B compared with Phase A indicated that Participant 9 did not exhibit significant changes in nighttime sleep duration (see Figure 34). This same trend remained in Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not detect a significant effect in the hypothesized direction during the intervention or return-to-baseline (see Table 2.12). See Table 2.12 for the summary of results of armband sleep for the high FIQ subgroup.

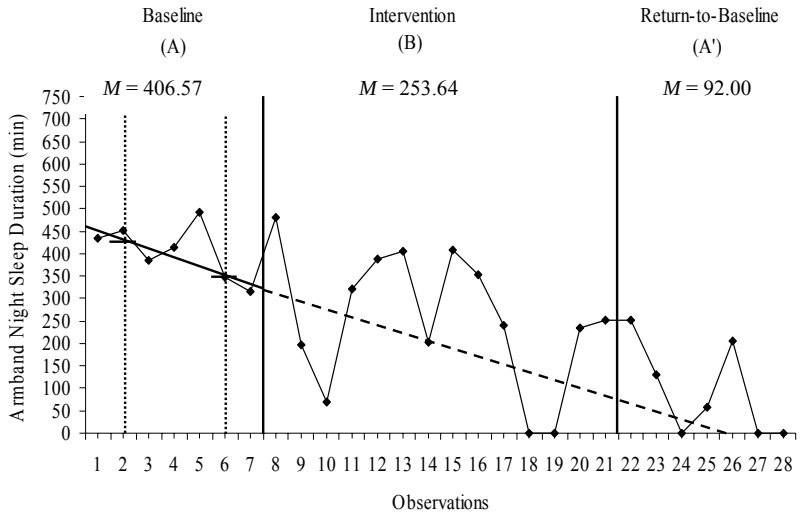

Figure 34: Armband Sleep Celeration Line for Participant 10

Celeration line graphical analysis indicated that two participants in the low FIQ subgroup exhibited significantly increased nighttime sleep duration during the Phase B intervention, compared to four participants in the high FIQ subgroup. The more rigorous C-Statistic analyses indicated that one participant in the low FIQ subgroup increased nighttime sleep duration significantly during the intervention phase, compared to none of the participants in high FIQ subgroup. After the intervention was withdrawn (Phase A′), C-statistic analyses indicated that none of the participants in either clinical subgroup increased nighttime sleep duration significantly more than during Phase A.

The mean coefficients of variation (CVs) for the armband sleep for the low FIQ subgroup during Phases A, B, and A′ were 0.21, 0.32, and 0.24 respectively. The CVs for the high FIQ subgroup during Phases A, B, and A′ were 0.22, 0.38, and 0.44 respectively. Mann-Whitney *U* Test results indicate that for the two FIQ subgroups sleep quantity did not differ during Phases A

and B; however, for Phase A′ the low FIQ subgroup experienced significantly longer durations of sleep (see Table 2.13).

Table 2.12: Summary of Results of Armband Sleep for High FIQ Subgroup

Group/ Target behavior	Comparison 1	Celeration line	*C*-Statistic		Comparison 2	*C*-Statistic	
High FIQ Subgroup		SIG*	*Z* Score	SIG*		*Z* Score	SIG*
Armband Sleep							
Participant 6:	A → B	SIG	0.01	*ns*	A → A'	0.16	*ns*
Participant 7:	A → B	SIG	1.49	*ns*	A → A'	-0.40	*ns*
Participant 8:	A → B	SIG	-0.62	*ns*	A → A'	-1.01	*ns*
Participant 9:	A → B	SIG	0.44	*ns*	A → A'	-0.77	*ns*
Participant 10:	A → B	*ns*	2.35	*SIG*	A → A'	3.29	*SIG*

Note. *Z Scores $\geq \pm 1.64$ required for alpha of $p < .05$; if significance (SIG) is italicized significance is not in the hypothesized direction.

Table 2.13: Mann-Whitney *U* Test Results for Between Clinical Subgroup Comparisons of Armband Sleep, by Phase

	Low FIQ Subgroup		High FIQ Subgroup		
	M	*SD*	*M*	*SD*	*U*
Target Behavior/ Phase					
Armband Sleep					
Phase A	374.29	78.50	360.94	80.98	543.00
Phase B	357.33	114.83	327.36	124.18	2061.00
Phase A'	389.66	92.01	308.77	134.38	359.00†

Note. Armband data recorded in minutes. † $p < .003$.

2.3.4. Armband Physical Activity

SenseWear® Pro_2 Armband physical activity data were recorded in minutes.

2.3.4.1. Low FIQ Subgroup

Participants 1, 2, 3, 4, and 5 constituted the members of the low FIQ subgroup.

PARTICIPANT 1

Participant 1 exhibited decreasing amounts of time engaged in physical activity in Phase A, resulting in a decelerating trend line (see Figure 35). Celeration line analysis of Phase B compared with Phase A indicated that Participant 1 engaged in significantly more physical activity (see Figure 35). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect in the hypothesized direction during the intervention or return-to-baseline (see Table 2.14).

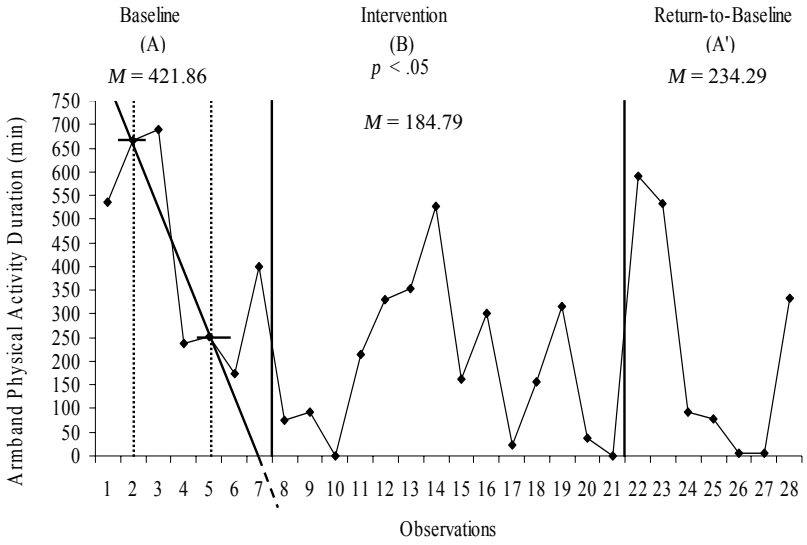

Figure 35: Armband Physical Activity Celeration Line for Participant 1

PARTICIPANT 2

In Phase A, Participant 2 exhibited decreasing amounts of time engaged in physical activity, resulting in a decelerating trend line (see Figure 36). Celeration line examination of Phase B compared with Phase A indicated that Participant 2 engaged in significantly more physical activity (see Figure 36). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not show a significant effect during the intervention or return-to-baseline (see Table 2.14).

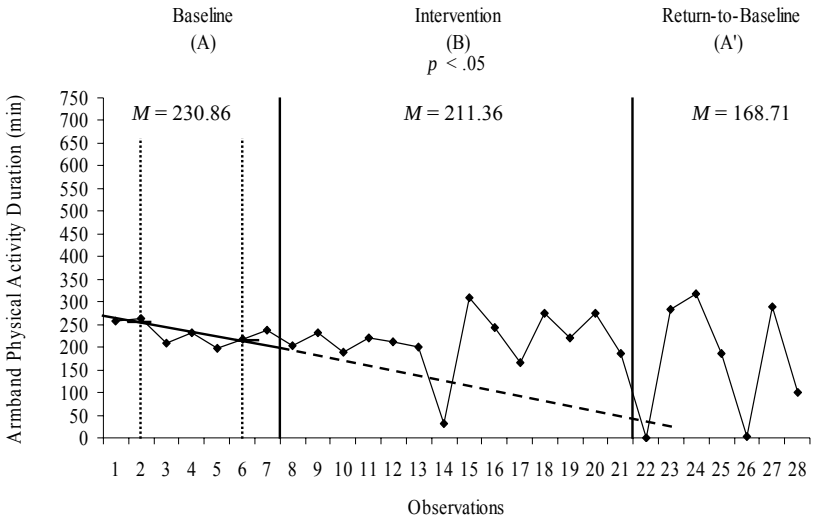

Figure 36: Armband Physical Activity Celeration Line for Participant 2

PARTICIPANT 3

During Phase A, Participant 3 exhibited decreasing of amounts of time engaged in physical activity, resulting in a decelerating trend line (see Figure 37). Celeration line inspection of Phase B compared with Phase A indicated that Participant 3 engaged in significantly more physical

activity (see Figure 37). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not register a significant effect during the intervention or return-to-baseline (see Table 2.14).

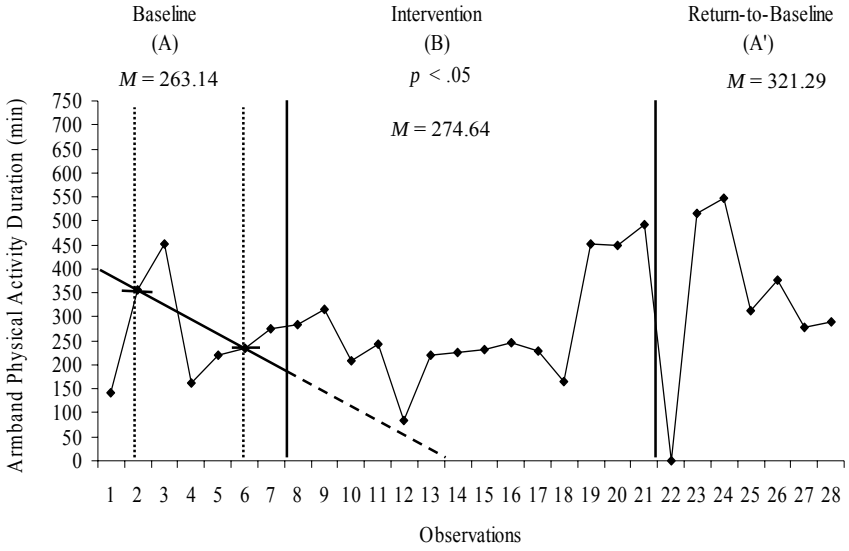

Figure 37: Armband Physical Activity Celeration Line for Participant 3

PARTICIPANT 4

Participant 4 exhibited increasing of amounts of time engaged in physical activity through Phase A, resulting in an accelerating trend line (see Figure 38). Celeration line evaluation of Phase B compared with Phase A revealed that Participant 4 did not experience significant changes in physical activity duration (see Figure 38). The same trajectory remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention or return-to-baseline (see Table 2.14).

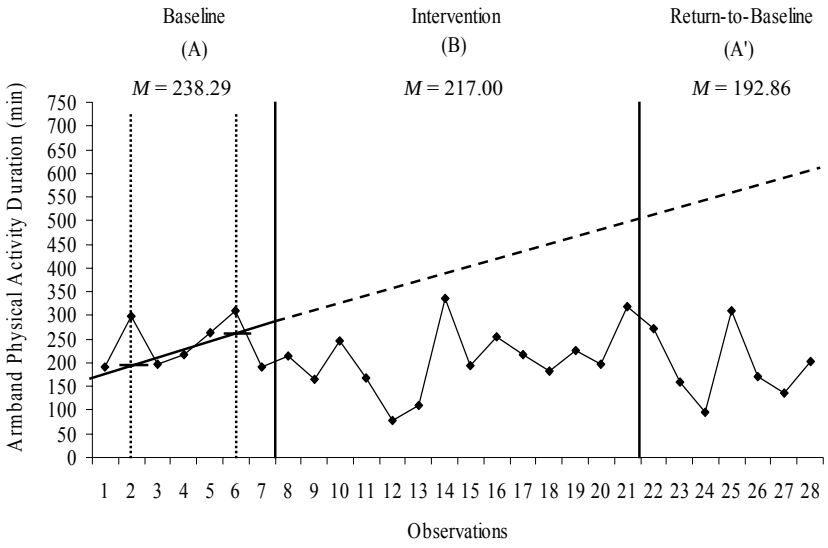

Figure 38: Armband Physical Activity Celeration Line for Participant 4

PARTICIPANT 5

Throughout Phase A, Participant 5 exhibited decreasing amounts of time engaged in physical activity, resulting in a decelerating trend line (see Figure 39). Celeration line analysis of Phase B compared to Phase A indicated that Participant 5 engaged in significantly more physical activity (see Figure 39). This pattern remained during Phase A'. The more rigorous *C*-statistic 1-tailed test of significance did not reveal a significant effect during the intervention or return-to-baseline (see Table 2.14). *C*-statistic results did not support the 1-tailed test of significance.

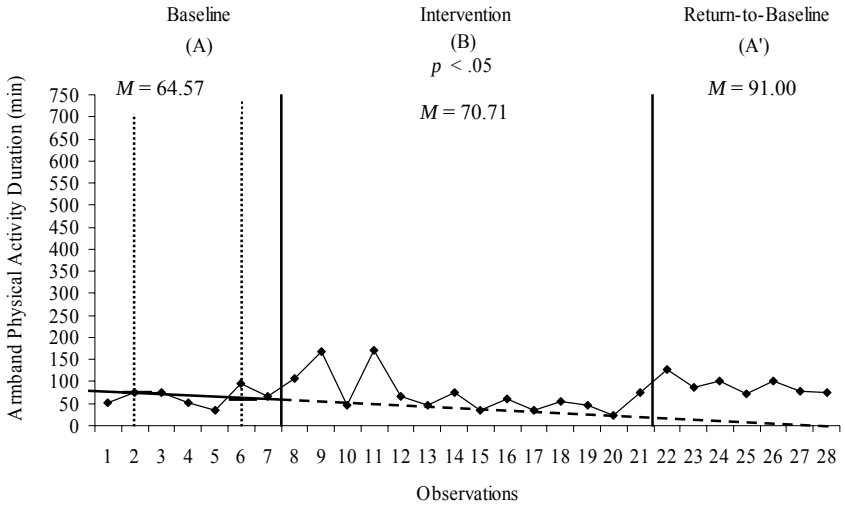

Figure 39: Armband Physical Activity Celeration Line for Participant 5

See Table 2.14 for the summary of results of armband physical activity for the low FIQ subgroup.

Table 2.14: Summary of Results of Armband Physical Activity for Low FIQ Subgroup

Group/ Target behavior	Comparison 1	Celeration line	*C*-Statistic		Comparison 2	*C*-Statistic	
Low FIQ Subgroup		SIG*	*Z* Score	SIG*		*Z* Score	SIG*
Armband Physical Activity							
Participant 1:	A → B	SIG	2.30	*SIG*	A → A'	2.39	*SIG*
Participant 2:	A → B	SIG	-1.37	*ns*	A → A'	-1.30	*ns*
Participant 3:	A → B	SIG	1.28	*ns*	A → A'	0.11	*ns*
Participant 4:	A → B	ns	-0.79	*ns*	A → A'	-0.70	*ns*
Participant 5:	A → B	SIG	0.11	*ns*	A → A'	0.26	*ns*

Note. **Z* Scores ≥ ± 1.64 required for alpha of $p < .05$; if significance (SIG) is italicized significance is not in the hypothesized direction.

2.3.4.2. High FIQ Subgroup

Participants 6, 7, 8, 9 and 10 constituted the members of the high FIQ subgroup.

PARTICIPANT 6

Participant 6 exhibited decreasing amounts of time engaged in physical activity during Phase A, resulting in an decelerating trend line (see Figure 40). Celeration line findings of Phase B compared with Phase A indicated that Participant 6 did not experience significant changes in physical activity duration (see Figure 40). The same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not reveal a significant effect in the hypothesized direction during the intervention, or during return-to-baseline (see Table 2.15).

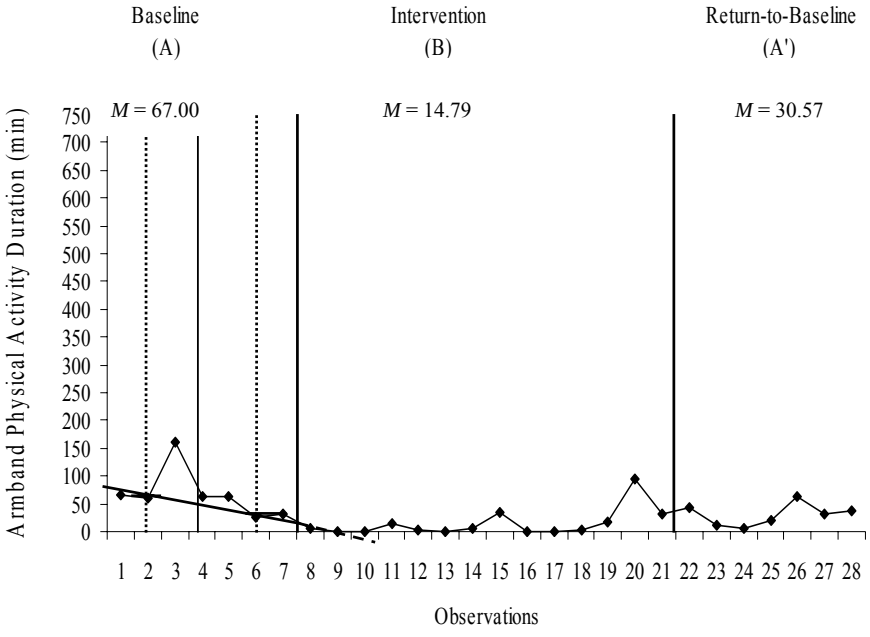

Figure 40: Armband Physical Activity Celeration Line for Participant 6

PARTICIPANT 7

Through Phase A, Participant 7 exhibited decreasing amounts of time engaged in physical activity, resulting in a decelerating trend line (see Figure 41). Celeration line examination of Phase B compared with Phase A revealed that Participant 7 engaged in significantly more physical activity (see Figure 41). This same pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance indicated a significant effect during the intervention when compared to baseline; however, during Phase A′, return-to-baseline, the *C*-statistic did not indicate a significant effect from the baseline phase (see Table 2. 15).

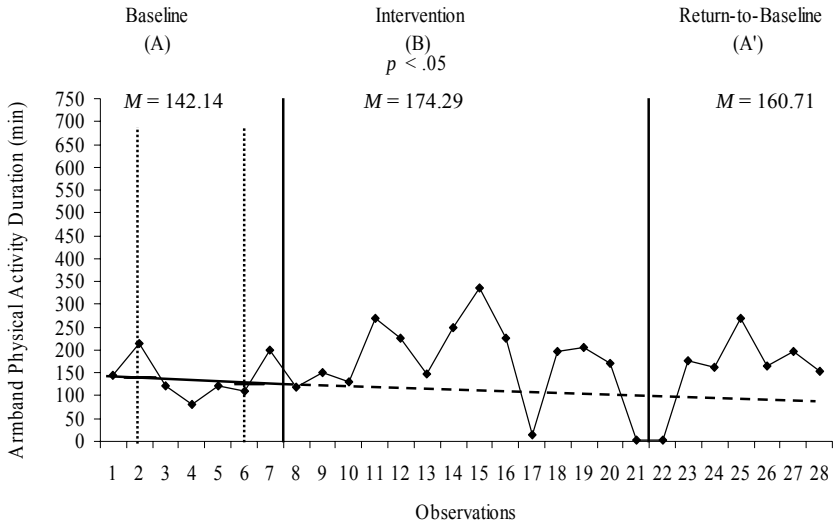

Figure 41: Armband Physical Activity Celeration Line for Participant 7

PARTICIPANT 8

During Phase A, Participant 8 exhibited increasing amounts of time engaged in physical activity, resulting in an accelerating trend line (see Figure 42). Celeration line analysis of Phase B compared with Phase A indicated that Participant 8 did not experience significant changes in

physical activity duration (see Figure 42). This pattern remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention when compared to baseline; however, during Phase A′, return-to-baseline, the *C*-statistic did indicate a significant increase in physical activity over the baseline phase (see Table 2. 15).

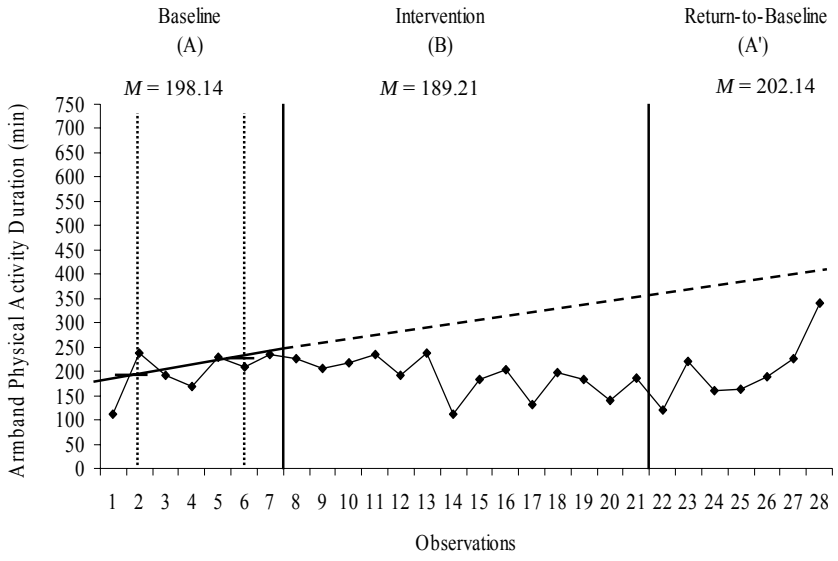

Figure 42: Armband Physical Activity Celeration Line for Participant 8

PARTICIPANT 9

In Phase A, Participant 9 exhibited increasing amounts of time engaged in physical activity, resulting in an accelerating trend line (see Figure 43). Celeration line examination of Phase B compared with Phase A revealed that Participant 9 did not experience significant changes in physical activity duration (see Figure 43). This same trend remained in Phase A′. The more

rigorous *C*-statistic 1-tailed test of significance did not indicate a significant effect during the intervention or return-to-baseline (see Table 2. 15).

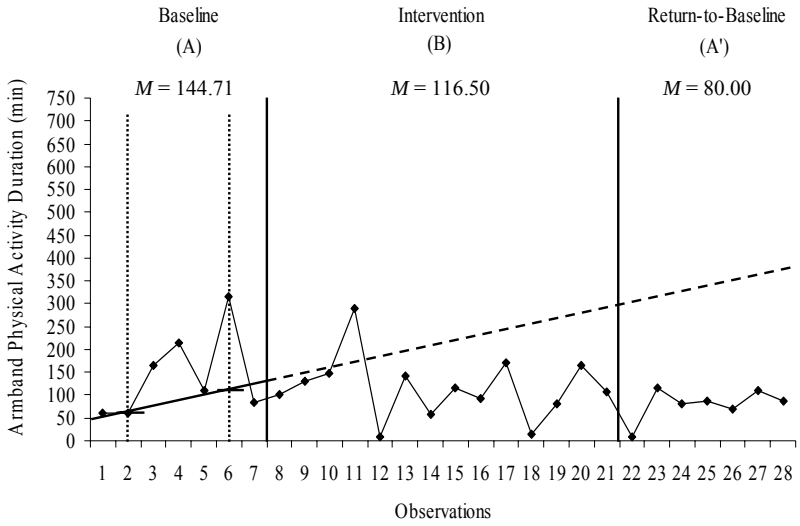

Figure 43: Armband Physical Activity Celeration Line for Participant 9

PARTICIPANT 10

Throughout Phase A, Participant 10 exhibited consistent time engaged in physical activity, resulting in a linear trend line (see Figure 44). Celeration line examination of Phase B compared with Phase A indicated that Participant 10 did not experience significant changes in physical activity duration (see Figure 44). This same trend remained during Phase A′. The more rigorous *C*-statistic 1-tailed test of significance did not detect a significant effect during the intervention or return-to-baseline (see Table 2. 15). See Table 2.15 for the summary of results of armband physical activity for the high FIQ subgroup.

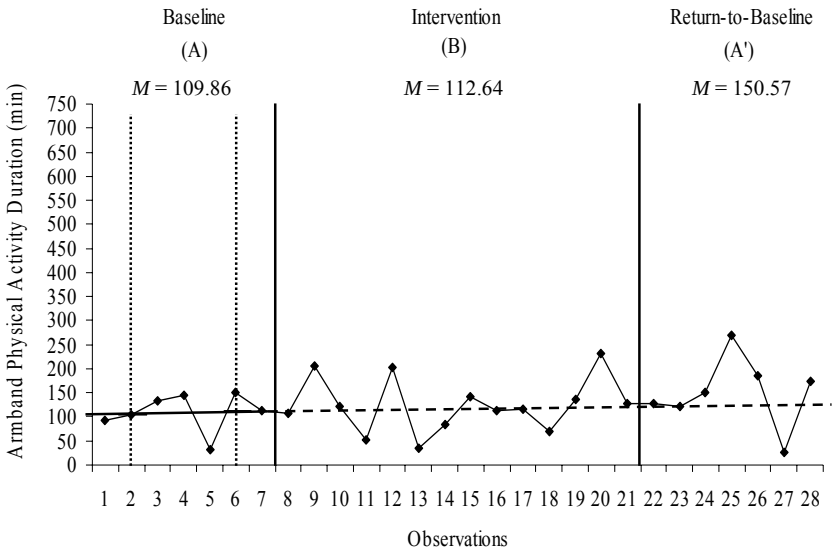

Figure 44: Armband Physical Activity Celeration Line for Participant 10

Celeration line graphical analysis indicated that four participants in the low FIQ subgroup exhibited significantly increased physical activity duration during the Phase B intervention, compared to one participant in the high FIQ subgroup. The more rigorous C-Statistic analyses showed that none of the participants in the low FIQ subgroup increased physical activity duration significantly across during the intervention phase, compared to one participant in the high FIQ subgroup. After the intervention was withdrawn (Phase A′), C-statistic analyses indicated that none of the participants in low FIQ subgroup increased physical activity duration significantly, compared to one participant in the high FIQ subgroup.

The mean coefficients of variation (CVs) for the armband physical activity for the low FIQ subgroup during Phases A, B, and A′ were 0.63, 0.61, and 0.68 respectively. The CVs for the high FIQ subgroup during Phases A, B, and A′ were 0.53, 0.70, and 0.82 respectively. Mann-Whitney *U* Test results indicate that the low FIQ subgroup demonstrated significantly

greater physical activity levels during Phases A and B; however, the data for Phase A' indicated that no difference in physical activity between subgroups (see Table 2.16).

Table 2.15: Summary of Results of Armband Physical Activity for High FIQ Clinical Subgroup

Group/ Target behavior	Comparison 1	Celeration line	*C*-Statistic		Comparison 2	*C*-Statistic	
High FIQ Subgroup		SIG*	*Z* Score	SIG*		*Z* Score	SIG*
Armband Physical Activity							
Participant 6:	A → B	*ns*	2.29	*SIG*	A → A'	1.29	*ns*
Participant 7:	A → B	SIG	1.91	SIG	A → A'	-0.50	*ns*
Participant 8:	A → B	*ns*	0.01	*ns*	A → A'	-1.70	SIG
Participant 9:	A → B	*ns*	-1.02	*ns*	A → A'	0.23	*ns*
Participant 10:	A → B	*ns*	-1.21	*ns*	A → A'	-0.24	*ns*

Note. *Z Scores ≥ ± 1.64 required for alpha of $p < .05$; if significance (SIG) is italicized significance is not in the hypothesized direction.

Table 2.16: Mann-Whitney *U* Test Results for Between Clinical Subgroup Comparisons of Armband Physical Activity, by Phase

	Low FIQ Subgroup		High FIQ Subgroup		
	M	*SD*	*M*	*SD*	*U*
Target Behavior/ Phase					
Armband Physical Activity					
Phase A	243.74	154.68	132.37	70.12	301.50*
Phase B	191.70	117.54	121.49	85.49	1559.00**
Phase A'	203.63	166.19	124.80	84.47	473.00

Note. Armband data recorded in minutes. ** $p < .001$.

2.4. DISCUSSION

The purpose of this study was to examine the effectiveness of a self-monitored, cognitive-behavioral, and interactive technology-based intervention to improve the clinical outcomes for two subgroups of women with fibromyalgia: those with low FIQ scores and those with high FIQ scores. We examined four target behaviors (HDR fatigue, HDR pain, armband sleep, armband physical activity) in the two subgroups over 8-weeks. Study results indicated that the 10 women with fibromyalgia responded differently to the health promotion intervention. The ABA′ withdrawal, multiple baseline single-subject design allowed for an examination of within- and between-subjects comparisons for these women with fibromyalgia before, during, and after the experimental arm of the FIBRO-RCT for the 4 target behaviors. The premise of this health promotion intervention was that with access to printed and electronic educational materials, Internet resources on self-management of behaviors and symptoms, objective personalized daily feedback on lifestyle behaviors from the data collected by the SenseWear® Pro_2 Armband, and cognitive-behavioral strategies, participants would exhibit improvement in the target behaviors.

Although we expected both subgroups to be responsive to the intervention, because the high FIQ subgroup reported greater fibromyalgia impact, we hypothesized that they would demonstrate less change than those in the low FIQ subgroup. Based on the method of analysis (individual versus group), as well as the target behavior of interest, our hypotheses were not always supported.

2.4.1. Individual Within Subgroups Intervention Effects

At the individual level, the intervention had a comparable impact for participants of both the low and high FIQ subgroups. Celeration line analyses indicated that the intervention enabled all 5 participants in the low FIQ group to make significant changes in one or more of the target behaviors. During the intervention phase, 1 low FIQ participant reported a significant reduction in fatigue, 3 reported a significant reduction in pain, 2 demonstrated significant increases in nighttime sleep duration, and 4 demonstrated significant increases in minutes of physical activity. Likewise, celeration line analyses indicated that the intervention enabled all 5 participants in the high FIQ subgroup to make significant changes in one or more of the target behaviors. During the intervention phase, 3 high FIQ participants reported a significant reduction in fatigue, 4 reported a significant reduction in pain, 4 demonstrated significant increases in nighttime sleep duration, and 1 demonstrated significant increases in minutes of physical activity. However, the more rigorous *C*-statistic indicated significant changes for participants during the intervention phase 2 times for the low FIQ subgroup (pain reduction, increased nighttime sleep) and 5 times for the high FIQ subgroup (reduced fatigue, reduced pain [n=3], increased physical activity). Similarly, the low FIQ subgroup had no significant changes from baseline to the withdrawal phase, whereas 2 participants in the high FIQ subgroup showed significant changes. An examination of individuals in each subgroup indicated that 3 of the 5 participants in each subgroup changed 3 target behaviors significantly (either celeration line or *C*-statistic), and 1 participant in the low FIQ subgroup and 2 in the high FIQ subgroup achieved significant changes in 2 target behaviors. In the low FIQ subgroup, 1 participant made significant changes in only 1 target behavior (increased physical activity).

Our hypothesis that participants in both the low FIQ and high FIQ subgroups would make significant changes following the intervention was supported. However, the individual trajectories of the low FIQ subgroup participants presented differently than expected, because the high FIQ subgroup participants made more significant changes in the target behaviors, based on individual analyses. Therefore, our hypothesis that the low FIQ subgroup would make more significant changes than the high FIQ subgroup was not supported at the level of the individual participant. This may be due to the lower impact of fibromyalgia on the low FIQ subgroup at baseline, and thus, the modest changes that occurred in the target behaviors of these participants did not reach significance. For the baseline to withdrawal phase comparisons, neither hypothesis was supported. Participants in the low FIQ subgroup made no significant changes over baseline, whereas only 2 participants did so in the high FIQ subgroup.

2.4.2. Between Subgroup Intervention Effects

When we examined the impact of the intervention between the low FIQ and high FIQ subgroups, we found that the low FIQ subgroup differed significantly from the high FIQ subgroup across all phases, for at least 1 of the target behaviors. During the baseline phase, the low FIQ subgroup engaged in significantly more physical activity than did members of the high FIQ subgroup. Likewise, during the intervention phase, the SenseWear® Pro_2 Armband again detected more time engaged in physical activity for the low FIQ subgroup, and they reported significantly lower fatigue levels. Similarly, during the withdrawal phase, the low FIQ subgroup again reported significantly lower fatigue levels and longer nighttime sleep duration. In contrast to the

individual participant analyses, the between group analyses partially supported our hypothesis that the low FIQ subgroup would make greater changes than the high FIQ subgroup.

Measuring relevant clinical change is a complex issue, especially in a chronic condition in which symptom variability is a hallmark (Fortin, Stucki, & Katz, 1995; O'Keeffe, Lye, Donnellan, & Carmichael, 1998; Turk et al., 1998). Therefore, we also explored the degree of data variability for each of the target behaviors, by phase and by subgroup, using the coefficient of variation. Ottenbacher (1986) defines variability as the amount of fluctuation or spread of data points in a series. For fatigue, the low FIQ subgroup demonstrated moderate (40%) variability during the 7 days of baseline, and consistently decreased across study phases to 28% during the 7 days of withdrawal. In contrast, the high FIQ subgroup exhibited less variability in fatigue over the baseline phase (34%), but continued to increase variability across study phases to 39% during withdrawal. Therefore, although the Internet-based intervention yielded less fatigue in both subgroups, and significantly less fatigue in the low FIQ subgroup, variability differed. These findings are consistent with previous research that found modest fluctuations over time characterize the symptoms of fibromyalgia (Kennedy & Felson, 1996; White & Nielson, 1995).

The target behavior pain showed the least variability among the target behaviors for both subgroups. Both the low and high FIQ subgroups decreased variability across phases. As a cardinal symptom of fibromyalgia, the within subject changes in pain ratings are important clinically even though in this study no statistical between group changes occurred. Nevertheless, as did the study by Lorig et al. (2002), the current study suggests that the Internet-based intervention not only reduced reported pain in participants with low and high FIQ, it also reduced the variability of the pain, especially for those in the low FIQ subgroup.

SenseWear® Pro_2 Armband sleep data indicated that variability for the nighttime sleep duration fluctuated moderately for both subgroups across study phases. Although participants slept less during the intervention phase than during baseline, and variability increased for both subgroups during the intervention phase, the low FIQ subgroup significantly increased nighttime sleep duration over the high FIQ subgroup during with withdrawal phase, and decreased variability. Thus, overall, the Internet-based intervention had a mixed effect on nighttime sleep duration. In the low FIQ subgroup, there was a quadratic effect for both duration (374.29, 357.33, 389.66) and variability (21%, 32%, 24%), ultimately resulting in more nighttime sleep, but for the high FIQ subgroup nighttime sleep duration decreased over the phases, and variability increased. In general, participants of the current study slept less than individuals with fibromyalgia and chronic fatigue syndromes whose nighttime sleep data were collected with similar real-time body monitoring devices (Kop et al., 2005, Landis et al., 2003). However, they slept more during nights 1 and 2 of the baseline compared to individuals with insomnia associated with chronic musculoskeletal pain (Wilson, Watson, & Currie, 1998). Unfortunately, comparison of findings from this study and similar research by Korszun and colleagues (2002) that monitored sleep and activity levels were not possible due to differences in the data presentation.

SenseWear® Pro_2 Armband data indicated that physical activity duration decreased in both FIQ subgroups during the intervention phase, however, this trajectory did not continue for either subgroup after the intervention was withdrawn. The overall degree of variability was greatest for the target behavior of physical activity duration for both subgroups. Although participants in the low FIQ subgroup demonstrated significantly more physical activity duration than the high FIQ subgroup during both the baseline and intervention phases, both subgroups

decreased physical activity from baseline to intervention, and variability remained high in all phases (low = 63%, 61%, 68% respectively; high = 53%, 70%, 82% respectively). The high variability in physical activity among our participants was not unexpected. The cycle of pain experienced by individuals with fibromyalgia has been shown to diminish physical performance, cause fear-avoidance behaviors, and limit activities of daily living (Keel, 1999). However, the current participants' physical activity duration data were greater than or equal to individuals with fibromyalgia and depression collected with a similar real-time body-monitoring sensor (Korszun et al., 2002).

2.4.3. Limitations and Recommendations

Our study had several limitations, as is the case with single subject design, because results offer limited generalizability for other populations and settings. Of note was the subgroups' small sample size. Secondly, our sample was drawn from one academic clinical rheumatology practice and all had the same ethnic background. Fibromyalgia is not a syndrome exclusive to a particular ethnic group (Macfarlane, 1999; White & Harth, 2001). Thus, individuals from other health care settings or ethnic backgrounds were not well represented. In addition, although the FIQ is the most commonly used disease-specific tool to measure the functional status of persons with fibromyalgia, it has not been used to define subgroups until the current study. Moreover, the paper version of the HDR is in use, but it's expanded Internet-based HDR version has unknown reliability and validity.

Further studies should replicate these methods, particularly the examination of clinical subgroups of individuals with fibromyalgia based on the impact of fibromyalgia as measured by

the FIQ. Also, examination of the Internet-base HDR is needed to establish reliability and validity. Future research to investigate the long-term effectiveness of this Internet-based health promotion intervention may consider the addition of a follow-up component to broaden the impact of this intervention for replication with comparable participants to facilitate a consensus in the management of fibromyalgia.

2.4.4. Summary

Evidence-based clinical practice, driven by research that evaluates the functional relationships between the applied interventions and outcomes, may translate into "doing the right things" (Gray, 1997, p. 17). Single-subject designs offer practical appeal and a means of documenting evidence-based practice outcomes at the individual level for rehabilitation practitioners and researchers (Backman, Harris, Chisholm, & Monette, 1997; Cadenhead, McEwen, & Thompson, 2002; Casby & Holm, 1994; Holm, Santangelo, Fromuth, Brown, & Walter, 2000; Horner et al., 2005; Zhan & Ottenbacher, 2001). The integration of traditional graphic presentation and visual analysis of data with more rigorous statistical analysis of single-subject designs enhances the ability to evaluate the utility of interventions (Ottenbacher, 1986, 1990).

The present Internet-based health promotion intervention focused on individual within- and between- subgroups effects of women with fibromyalgia. These methods of analyses revealed mixed results at the individual and subgroup levels. The extent of change for the study participants may have clinical significance considering that rehabilitation professions typically offer 1-on-1 services. With celeration line analysis, the variability seen in the target behaviors revealed day-by-day variability of individual participants by study phase and by fibromyalgia

impact. Several participants reported reduced pain and fatigue symptomotology, increased their nighttime sleep durations, and increased their levels of physical activity performance, regardless of fibromyalgia impact. Hence, the change detected with single-subject designs can provide pivotal information unavailable in grouped data for the development and modification of interventions (Kazdin, 2003). The single-subject research design method of the current study facilitated the measurement of relevant clinical changes with an intervention focused on physical activity, education, and cognitive-behavioral strategies. As with previous research (Rossy et al., 1999; Sim & Adams, 2002), when combined, these components facilitated favorable therapeutic results in the management of fibromyalgia.

When we used between subgroup analyses, the low FIQ subgroup differed significantly from the high FIQ group in fatigue ratings and physical activity duration in partial support of our hypothesis that the low FIQ subgroup would make greater changes than the high FIQ subgroup. Although variability in the four target behaviors was readily observable in the celeration line analyses, subgroup analyses using the coefficient of variation enabled us to identify the average percentage of variability for each subgroup, by phase. Thus, the extreme variability in physical activity among participants in both subgroups, compared to variability in pain, fatigue, and sleep was readily evident. However, the current subgroup findings demonstrate limited generalization due to the small sample sizes. Even though the samples were small, the changes in the four target behaviors detected during the intervention and withdrawal phases of the single-subject design study for individual participants, as well as for the two subgroups, may lend support to the connection between well-being and physical activity participation for individuals with fibromyalgia (Culos-Reed & Brawley, 2000).

In conclusion, our findings indicate that this Internet-based health promotion intervention had mixed results regarding the effectiveness a self-monitored, cognitive-behavioral, and interactive technology-based intervention to improve the clinical outcomes for two subgroups of women with fibromyalgia: those with low FIQ scores and those with high FIQ scores. We found that the clinical response to the intervention depended on the method of analysis (individual versus group) and the target behavior of interest.

3. FIBROMYALGIA CLINICAL SUBGROUPS: CHARACTERISTICS OF PATIENTS WITH FAVORABLE AND UNFAVORABLE OUTCOMES

3.1. INTRODUCTION

Fibromyalgia (FM) is an elusive chronic pain syndrome that affects 2% of the United States (US) population (Lawrence et al., 1998) and surpasses $20 billion each year in health care costs (*Fibromyalgia syndrome: Hearing before the Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies*, House of Representative, (1998) [testimony of Ronald C. Kramis]). Because of the chronic and multidimensional symptoms that characterize the syndrome, fibromyalgia continues to challenge clinicians and researchers. These challenges reinforce the need to gain additional understanding of how fibromyalgia influences the functional status of persons with FM.

To promote efficacious and effective management of persons with fibromyalgia and other chronic conditions, the Institute of Medicine (IOM, 1999, 2001) outlined clear guidelines for clinicians and researchers that recommend the use of empirical data to guide clinical priorities. The priorities identified were safe, effective, patient centered, timely, efficient, and equitable health care services (IOM, 1999, 2001). The use of empirical data to develop clinical guides for populations with chronic conditions has also been promoted by numerous clinical and research teams (Fuhrer, 2003, Goldenberg, Burckhardt, & Crofford, 2004; Gordon et al., 2006; Oliver, Cronan, & Walen, 2001; Ragnarsson, Wuermser, Cardenas, & Marino, 2005; Rossy et al., 1999; Sim & Adams, 2002; Smith, 2004). Because of the heterogeneity of many conditions and the

resultant multidimensional clinical presentations, clinicans and researchers working with conditions such as cardiovascular disease, chronic pain, traumatic brain injury, and spinal cord injury began to classify or subgroup patients to more effectively target interventions and assess functional outcomes (Epker & Gatchel, 2000; Gordon et al., 2006; Johansson, & Lindberg, 2000; Ragnarsson et al, 2005; Rosenberg & Popelka, 2000; Smith, 2004).

Similarly, researchers theorize that FM is a heterogeneous, rather than a homogeneous syndrome based on the variability of its manifestation (Gatchel et al., 2002; Turk, Okifuji, Sinclair, & Starz, 1996; Turk, Okifuji, Sinclair, & Starz, 1998; Turk & Rudy, 1988; Walen, Cronan, Serber, Groessl, & Oliver, 2002). For persons with chronic pain, researchers were able to classify them into three distinct subgroups: psychosocial and behaviorally dysfunctional (DYS), interpersonally distressed, (ID) and adaptive copers (AC); based on the similar impact of FM on physical, psychological, social, and behavioral functions persons with FM have been classified into these subgroups (Turk et al., 1996; Turk & Rudy, 1988). Moreover, responses to FM, low back pain, and temporomandibular disorder interventions have been shown to differ based on subgroup membership (Epker & Gatchel, 2000; Johansson, & Lindberg, 2000; Turk et al., 1996; Turk et al., 1998).

Consequently, research into the classification of subgroups of persons with fibromyalgia has increased, however, the clinical relevance of developing and implementing appropriately tailored evidence-based intervention and management protocols based on these classifications remains unclear (Giesecke et al., 2003; Masi & Yunus, 1990; Turk et al., 1996; Turk et al., 1998). Techniques used demonstrated the ability to identify relevant clinical subgroup differences (Cassisi, Sypert, Lagana, Friedman, & Robinson, 1993; Giesecke et al., 2003; Hurtig, Raak, Kendall, Gerdle, & Wahren, 2001; Raak, Hurtig, & Wahren, 2003; Turk et al., 1996) or

document post-intervention changes in FM subgroups (Walen et al., 2002; Turk et al., 1998) include pain thresholds, coping strategies, physical performance, psychological function, self-reported pain disability, and social support.

Functional status research of persons with FM, related syndromes, and other chronic conditions has typically included functional outcome data such as performance-based measures derived from functional tasks (Burckhardt, Mannerkorpi, Hendenberg, & Bjelle, 1994; Gowans et al., 2001), exercise (Bailey, Starr, Alderson, & Moreland, 1999; Ramsay, et al., 2000; Wigers, Stiles, & Vogel, 1996), psychological function (Buckelew et al., 1998; Gowans, deHueck, & Abbey, 2002; Nicassio et al., 1997), daily activities (Cedraschi et al., 2004; Culos-Reed & Brawley, 2000; Henriksson & Burckhardt, 1996), and perceived pain (Cedraschi et al., 2004; Jentoft, Kvalvik, & Mengshoel, 2001). However, these studies did not use functional status to develop FM subgroups.

The clinical relevance of FM subgroups may be better understood with an examination of function-related factors and objective and subjective functional status data. Functional status refers to the ability of a person to engage in daily activities and participate in personal and societal roles (National Committee on Vital and Health Statistics [NCVHS], 2002). Fibromyalgia researchers and health care professionals have recently begun to take advantage of technological advances to integrate objective real-time data (Kop et al., 2005; Korszun et al., 2002; Landis et al., 2003) with the more traditional subjective self-report data (Bierman, 2001; Ruggieri, 2003) for measuring the functional status of persons with FM. Body-monitoring devices (e.g., SenseWear® Pro_2 Armband, BodyMedia®, 2003) are among the technologies that detect and record objective real-time data, and they enhance the ability to diagnose, manage, and prevent health conditions (Dittmar, Axisa, Delhomme, & Gehin, 2004; Kop et al., 2005; Korszun

et al., 2002; Landis et al., 2003; Lilja & Nordic, 2005; Sung, Marci, & Pentland, 2005; Tractenberg, Singer, Cummings, & Thal, 2003). Objective functional status data serves as a surrogate measure of participation in daily activities. Moreover, the objective lifestyle (i.e., participation time in physical activities and sleep quantity) and physiological (i.e., galvanic skin response and body temperature) functional status data collected by the body-monitoring devices can be used to complement and corroborate self-report data offered by the wearer. These technologies have a novel appeal and hold promise for gathering accessible and reliable health information as well as empowering health care consumers (Balas et al., 1997; Robinson, Patrick, Eng, & Gustafson (For the Science Panel on Interactive Communication and Health), 1998; Sung et al., 2005).

Because functional status data can be both subjective and objective, there may be differences in data collected and their interpretation (Bierman, 2001). Their interpretation can lead to different estimations of the functional status of persons and populations, which in turn can impact the ability of clinicians and researchers to more effectively target interventions and assess functional outcomes. The current study examined the associations among symptoms of FM and objective and subjective functional status measures, and then used the functional status data to classify FM clinical subgroups.

3.2. METHODS

3.2.1. Study Design

Data collected as a part of a prospective intervention study, The Efficacy of Computer and SenseWear® Technologies for Promoting Health in Adults with Fibromyalgia: A Randomized Clinical Trial (FIBRO-RCT) were used for data analysis. The present study was a cross-sectional analysis of baseline data examining the associations among symptoms of fibromyalgia and functional status, which were then used to develop fibromyalgia clinical subgroup profiles.

3.2.2. Participants

Individuals were recruited from clinical rheumatology practices at the University of Pittsburgh Medical Center (UPMC) - Arthritis and Internal Medicine Associates and from other physician practices that see a high percentage of fibromyalgia patients. Inclusion criteria for the study were: (a) female gender (b) age 18 or older; (c) diagnosis of FM consistent with the 1990 American College of Rheumatology criteria (Wolfe et al., 1990); (d) diagnosis of FM for a minimum of 1-year; (e) vision sufficient to read newsprint for computer use; (f) English speaking; and (g) working telephone line in the home. Exclusion criteria were: (a) disability due to a medical diagnosis other than FM (e.g., stroke, Parkinson disease) and (b) residence further than 40-miles from the Oakland campus of the University of Pittsburgh.

3.2.3. Instrumentation

Data for this study were collected with six outcome measures and were classified as objective (armband data) or subjective (self-reported, non-armband data) (see Figures 45 and Figures 46). Outcome measures were data from the SenseWear® Pro_2 Armband (BodyMedia®, 2003), Fibromyalgia Impact Questionnaire (FIQ) (Burckhardt, Clark, & Bennett, 1991), the Multidimensional Pain Inventory (MPI) (Kerns, Turk, & Rudy, 1985), the Manual Tender Point Survey (MTPS) (Okifuji, Turk, Sinclair, Starz, & Marcus, 1997), the paper version of the Healthy Daily Routine (HDR), and the Fibromyalgia Health Behavioral Self-Assessment (FHBSA).

3.2.3.1. Objective Measure

The SenseWear® Pro_2 Armband was used to objectively measure physical activity, energy expenditure, active energy expenditure, sleep, and steps.

SENSEWEAR® PRO_2 ARMBAND

The SenseWear® Pro_2 Armband, worn on the upper right arm over the triceps muscle 24-hours a day (except while bathing), records real-time lifestyle and physiological data over time in the home, community, and/or work environment (BodyMedia®, 2003). The Armband uses BodyMedia® proprietary algorithms to calibrate data with demographic characteristics (e.g., age, gender, height, weight). Lifestyle data are timestamps, total energy expenditure, active energy expenditure, number of steps, lying down, sleep duration, and physical activity duration.

Physiological data are longitudinal and transverse accelerometers, galvanic skin response (GSR), heat flux, near-body temperature, and skin temperature.

Calibration of the armband data with demographic characteristics (e.g., age, gender, height, weight) were based on Body Media® proprietary algorithms. Data collection channels include three longitudinal and three transverse accelerometer channels which use 2-axis accelerometers with a micro-electro-mechanical sensors (MEMS)) that detect (a) static and dynamic motion, (b) galvanic skin response (GSR) or skin conductivity affected by the sweat from physical activity and emotional stimuli, and (c) heat flux, or heat exchange between a participant's arm and the environment. Additional data collection channels are near-body temperature (i.e., the temperature of the metal cover exposed to air on one side of the armband), skin temperature (i.e., the temperature of the skin under the armband), and step counter (i.e., pedometer reading of number of steps taken). Moreover, the SenseWear® Pro_2 Armband has a timestamp button to record the number of times pressed, which for the FIBRO-RCT study to record pain medication usage. Total energy expenditure (EE) calculates the number of calories burned and includes an off-body estimate of resting energy expenditure when not worn. Active energy expenditure (AEE) calculates the calories burned during physical activity. Lying down time calculates the cumulative amount of time lying down and being sedentary. Sleep time calculates the cumulative amount of time spent sleeping (i.e., lying down and not moving). Physical activity data are the cumulative time spent engaged in physical activity, such as walking, housework, and gardening as well as activities that are more vigorous. Physical activity data were derived from a combination of heat flux, skin temperature, GSR, and longitudinal and transverse accelerometer (e.g., 2-axis accelerometer with MEMS).

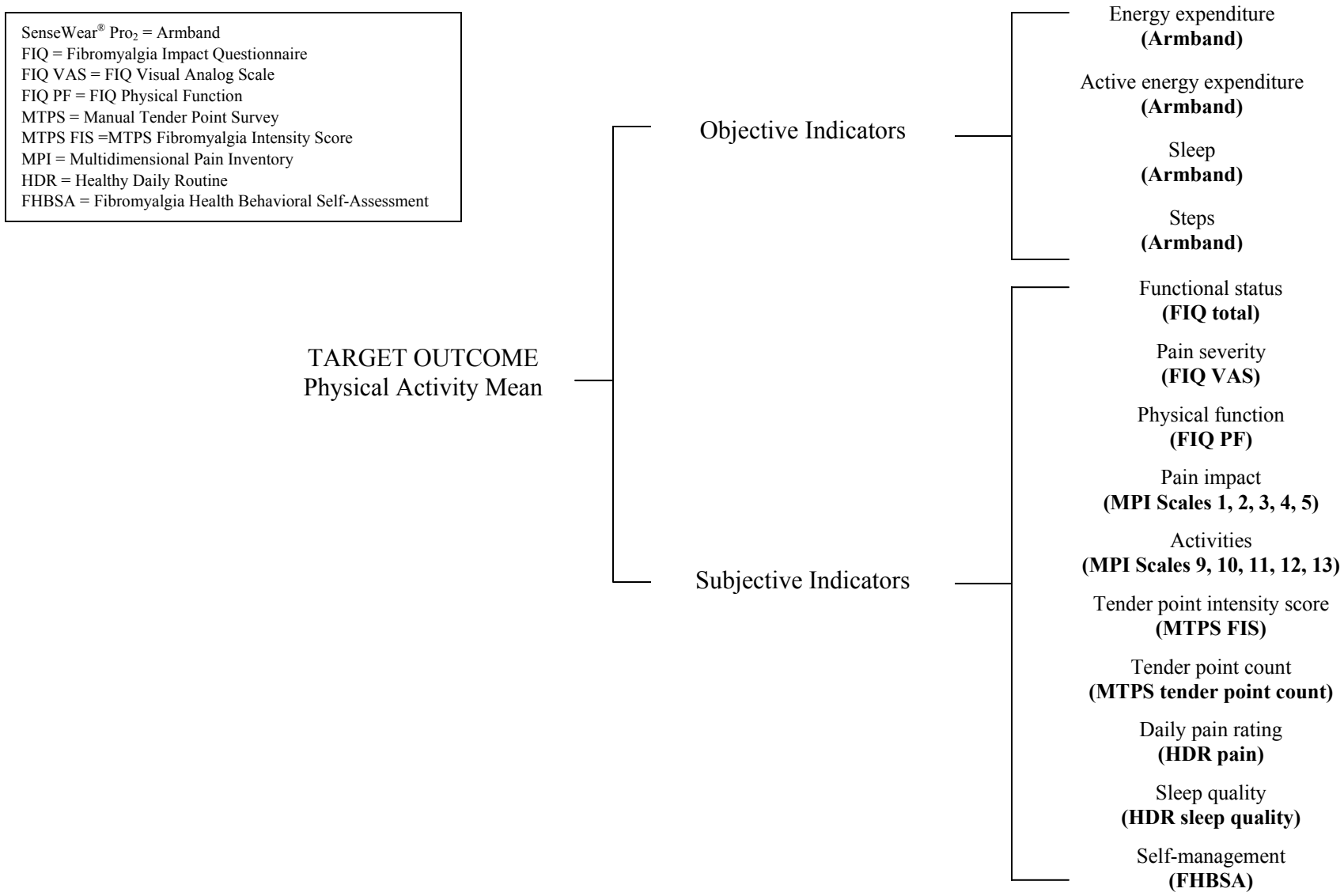

Figure 45: Target Outcome: Physical Activity and Functional Indicators Analyzed

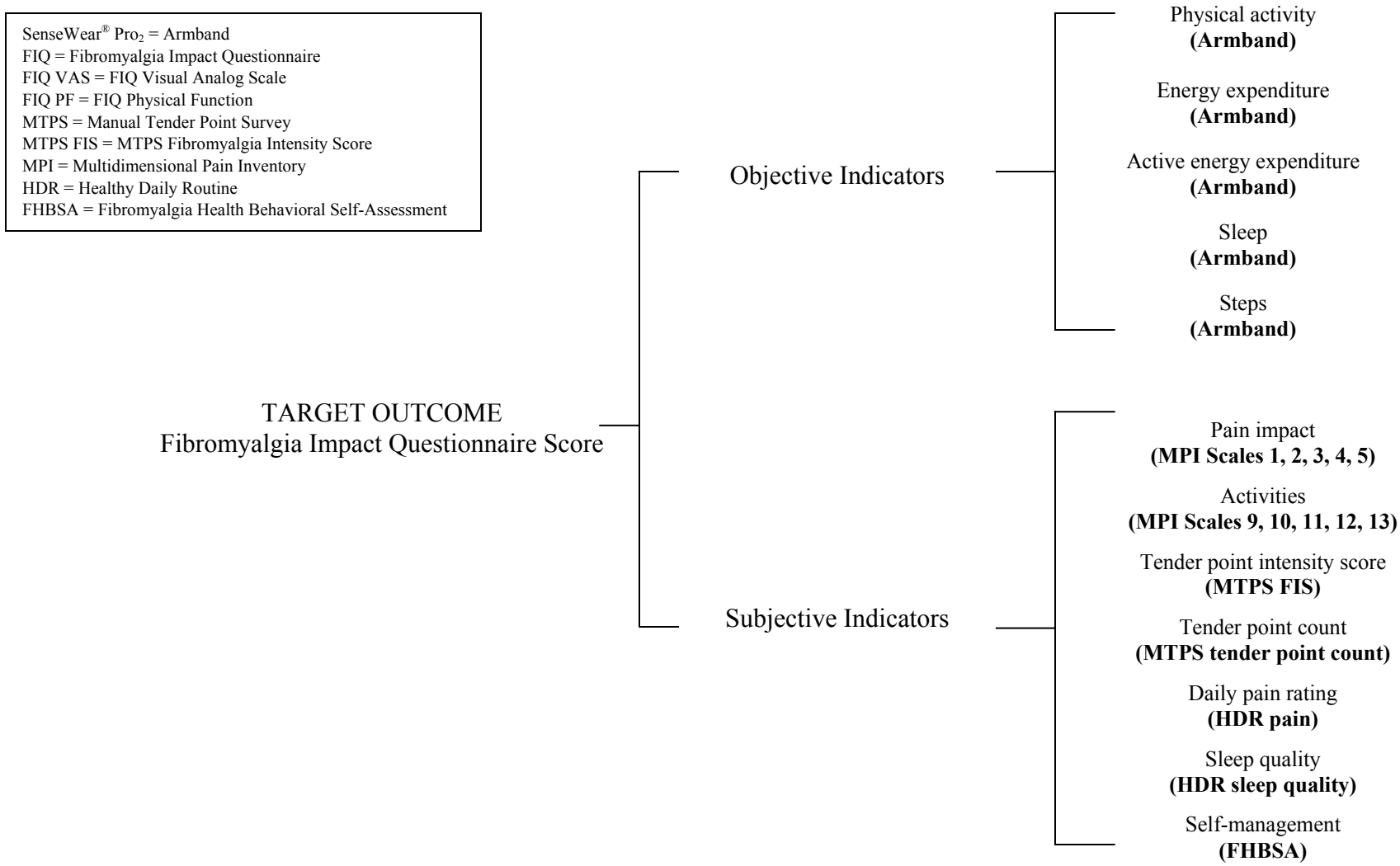

Figure 46: Target Outcome: Fibromyalgia Impact Questionnaire and Functional Indicators Analyzed

3.2.3.2. Subjective Measures

The five subjective measures were the Fibromyalgia Impact Questionnaire (FIQ), the Multidimensional Pain Inventory (MPI), the Manual Tender Point Survey (MTPS), the paper version of the Healthy Daily Routine (HDR), and the Fibromyalgia Health Behavioral Self-Assessment (FHBSA).

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FIBROMYALGIA IMPACT QUESTIONNAIRE

The Fibromyalgia Impact Questionnaire (FIQ) is a reliable and valid 10-item self-report questionnaire (Burckhardt et al., 1991). It is the most commonly used disease-specific tool developed to measure the functional status of persons with fibromyalgia. No established norms are available for the FIQ; however, data from several studies describe persons with FM, including the developmental sample (Burckhardt et al., 1991), two cross-sectional studies (Fitzcharles & Esdaile, 1997; Goldenberg, Mossey, & Schmit, 1995), and three randomized controlled trials (Burckhardt et al., 1994; Dunkl, Taylor, McConnell, Alfano, & Conaway, 2000; Redondo et. al., 2004).

The first item assesses physical functioning for 10 activities on a 4-point ordinal scale, by asking, "over the past week were you able to?" The responses and scores range from 0 to 3 (0 represents always and 3 represents never). An average of the 10 activities produces a physical functioning score. Item 2 assesses the number of days the participant was "feeling good" with scores ranging from 0 to 7 (i.e., inverse scoring is used, meaning 0 represents 7 days of severe impairment and 7 represents 0 days of impairment). Items 3 and 4 assess work status. Item 3 assesses days of "work missed" with raw scores ranging from 0 to 7. The remaining seven items

of the FIQ (including item 4 "work difficulty") assess fibromyalgia symptoms (i.e., pain, fatigue, rested, stiffness, anxiety, and depression scales) on an anchored, 10 cm horizontal visual analog scale (VAS). The VAS is standardized and is recorded and reported in cm scores that range from 0 cm to 10 cm; 0 cm corresponds to the no symptoms and 10 cm corresponds to very severe symptoms. For the purposes of this study, the total score of the FIQ reflects the sum of the physical function, days feeling good, pain, fatigue, rested, stiffness, anxiety, and depression scales with a maximum score of 80, excluding the work status items as recommended by the authors. Higher scores suggest a greater extent of fibromyalgia impact. For Chi-square Automatic Interaction Detector (CHAID) analysis, FIQ data are numeric on a continuous measurement level.

MULTIDIMENSIONAL PAIN INVENTORY

The Multidimensional Pain Inventory (MPI) is a reliable and valid 60-item self-report measure that examines the physical, behavioral, and psychological impact of chronic pain (Bernstein, Jaremko, & Hinkley, 1995; Kerns et al., 1985; Turk & Rudy, 1988). The MPI demonstrates the ability to identify three distinct subgroups of individuals with chronic pain: dysfunctional, interpersonally distressed, or adaptive copers (Gatchel et al., 2002; Turk et al., 1996; Turk et al., 1998; Turk & Rudy, 1988). MPI Scales 1 - 5 (24 of the 60-items) measure pain impact, namely pain severity, interference, life control, affective distress, and support. MPI Scales 9 - 12 (18 of the 60-items) measure activity performance relative to the impact of pain during household chores, outdoors work, activities away from home, and social activities, respectively. Furthermore, MPI Scale 13 indicates general activity level as a mean composite score based on the average of MPI Scales 9 - 12. The 12 MPI Scales are rated with ordinal ratings on a 7-point

scale from 0 to 6; 0 indicates no impact and 6 indicates high impact. For CHAID analysis, these data are numeric on a continuous measurement level.

MANUAL TENDER POINT SURVEY

The Manual Tender Point Survey (MTPS) is a standardized tender point examination and diagnostic measure of fibromyalgia (Okifuji et al., 1997). Twenty-one tender point sites are palpated with standard pressure (i.e., 4 kg), 18 of which were originally identified in a multicenter study of tender point assessment (Wolfe et al., 1990) and 3 control points were added to the MTPS as a baseline indication of patients' pain threshold (Okifuji et al., 1997). Patients rate each tender point's pain severity using an 11-point rating scale after each palpation, where 0 indicates no pain and 10 indicates the worst pain ever experienced. This diagnostic examination provides a tender point count and a Fibromyalgia Intensity Score (FIS). Tender point ratings are positive with a rating of ≥ 2; hence generating a positive tender point count. The sum of the 18 original tender point sites ratings divided by 18 produces the FIS score. Because patients' responses to standard pressure on the MTPS are subjective, it is categorized as a subjective measure. For CHAID analysis, MTPS data are numeric on a continuous measurement level.

HEALTHY DAILY ROUTINE

The Healthy Daily Routine (HDR) is a study-specific tool created to assess subjective experiences of well-being (i.e., step 1 of 3), the nutritional value of meals (i.e., step 2 of 3), and the daily impact of fibromyalgia (e.g., pain, fatigue) on activity performance (i.e., step 3 of 3; IRB # 020771). The five aspects of the HDR well-being rating scales are physical, fatigue, sleep quality, emotional/psychological, and spiritual. The four meals rated on the HDR nutrition

scales are breakfast, lunch, dinner, and snack, plus serving of fruits/vegetables and water. Participants rate their well-being and the nutritional value of meals daily according to a 5-point rating scale, where 1 represents very poor and 5 represents very good. Finally, the HDR activity performance items are rating scales for the participants' assessment of the impact of fibromyalgia on activity performance (e.g., participation, difficulty, satisfaction with performance, fatigue, and pain) for each of 11 required and optional activities on the "How did you spend your day?" portion of the questionnaire. Participants rated activity performance items using a 5-point rating scale, where 1 represented strongly agree and 5 represented strongly disagree. HDR sleep quality and HDR daily pain ratings were included in the current study for data analyses. For CHAID analysis, these data are numeric on a continuous measurement level.

FIBROMYALGIA HEALTH BEHAVIORAL SELF-ASSESSMENT

The Fibromyalgia Health Behavioral Self-Assessment (FHBSA) is a 20-item self-efficacy instrument developed by Cedars-Sinai Medical Center. The nominal scale ranges from 0 to 100%; 0 equals no certainty of controlling fibromyalgia health and 100% equals complete certainty of controlling fibromyalgia health. For CHAID analysis, FHBSA data are numeric on a continuous measurement level.

3.2.4. Procedures and Data Collection

Informed consent approved by the University of Pittsburgh's Institutional Review Board for the Protection of Human Subjects and was obtained from individuals who met the inclusion and exclusion criteria and agreed to participate in the study. Socio-demographic and functional status data (e.g., age, ethnic background, weight, education, marital status, living status,

household income, employment status, and income) were collected during the FIBRO-RCT for descriptive purposes. Participants completed all measures at baseline prior to randomization in the FIBRO-RCT. A licensed occupational therapist who was also a member of the FIBRO-RCT research team collected all data.

3.2.5. Data Analyses

For the purpose of this study, we examined functional predictors of two target outcomes, physical activity, and FIQ score, in an effort to identify profiles of homogenous clinical subgroups. The outcomes of this study were analyzed using multiple methods of data analyses: descriptive statistics were computed to describe the sample, Pearson correlation coefficients (*r*) were calculated to establish the relationships between the functional predictor outcomes; and Exhaustive Chi-square Automatic Interaction Detector (Exhaustive CHAID) was used to develop the clinical subgroup profiles. Exhaustive CHAID is a multivariate decision method of data analysis that examines the associations between a target outcome variable and predictor variables (Biggs, DeVille, & Suen, 1991; Kass, 1980). Data were managed and analyzed with SPSS 13.0.1 for Windows database (SPSS Inc., 2004) and exploratory data analyses were completed using AnswerTree 3.1 (SPSS Inc., 2002).

Exhaustive CHAID differs from regression methods in that models are data-driven through an iterative process. Detection of associations are based on the data in the analyses rather than with data that are "forced" using predetermined conceptual models. Exhaustive CHAID is ideal for small samples and analyses of clinical data (i.e., nominal, ordinal, continuous) because it has the capacity to automatically select parametric or non-parametric data as appropriate (Biggs et al., 1991; Kass, 1980; SPSS Inc., 2002). Regression and Exhaustive

CHAID data analyses use nominal, ordinal, or continuous data as predictors (independent variables) but Exhaustive CHAID may use nominal, ordinal, or continuous data as the target outcome (dependent variables) rather than a binary target outcome like logistic regression analysis (Portney & Watkins, 2000; SPSS Inc., 2002). Exhaustive CHAID executes parametric or non-parametric statistical analyses based on the data measurement level to identify interactions, without violation of statistical assumption for normal distribution (SPSS Inc., 2002). In this case, for continuous data, Analyses of Variance *F* tests of all functional indicators initiated tree growth and the likelihood ratio chi-square tests interactions between functional indicator scores (Goodman, 1978; SPSS Inc., 2002). To reduce the chances of a Type I error (i.e., better control for false-positives) due to multiple comparisons, Bonferroni adjustments with the significance level set at $p = .05$ were performed (Biggs et al., 1991; Portney & Watkins, 2000; SPSS Inc., 2002). The Exhaustive CHAID tree growth method splits data through a $k - 1$ procedure with k representing the best number of splits; this procedure allows for multiple splits (Biggs et al., 1991). For this study, rules for stopping of tree growth included subgroups refined by statistical significance or subgroups of no less than 10 subjects.

Validation of tree-based analyses models establishes predictive validity by evaluating the accuracy of the model, particularly with small samples. Exhaustive CHAID validates tree-based models by cross-validation, based on the *n*-fold technique (SPSS Inc., 2002). The *n*-fold technique splits the sample into sub-samples, in this case 10, for cross-validation tests. Validation analyses produced an averaged estimation of misclassification risk of the *n*-fold samples, referred to as cross-validation risk estimate. Risk estimate calculations for continuous target outcomes represent the pooled within-node variance relative to the mean (SPSS Inc., 2002). The pooled within-node variance corresponds to the extent of uncertainty with the target

outcome at the end of tree growth compared to the target outcome's variance for the entire sample prior to tree analysis (SPSS Inc., 2002). Therefore, comparisons of the target outcome variance, the misclassification risk estimate, and the cross-validation risk estimate data relate to the predictive validity of Exhaustive CHAID models. Cross-validation was employed for each Exhaustive CHAID model.

In this study, Exhaustive CHAID generated two models from two separate tree-based analyses after an examination of the interactions between the distinct functional indicators (SPSS Inc., 2002). Each of the models identified (a) distinct functional indicators most strongly associated with the target outcome (segmentation), and (b) categorical split scores that separated the sample into homogenous clinical subgroups along the continuum of favorable and unfavorable categories (stratification) (SPSS Inc., 2002).

Model I examined 22 objective and subjective functional indicators of physical activity. Physical activity (PA) was measured with the SenseWear® Pro_2 Armband (BodyMedia®, 2003). PA data were the average amount of time spent engaged in physical activity, such as walking, housework, and gardening as well as activities that are more vigorous. Data were collected 24-hours a day during the 7-day baseline, and were recorded in minutes. PA data were derived from a combination of heat flux, skin temperature, GSR, and longitudinal and transverse accelerometers. SenseWear® Pro_2 Armband data are derived based on BodyMedia® proprietary algorithms.

Model II examined 20 objective and subjective functional indicators of functional status. Functional status was measured with the Fibromyalgia Impact Questionnaire (FIQ; Burckhardt et al., 1991). The self-report of functional status was based on the baseline FIQ total score.

3.3. RESULTS

Seventy-two participants were analyzed in the present study; see Table 3.1 for characteristics of study participants. The average participant was a Caucasian married female with a mean age 48.96 years (*SD* = 10.07), college-educated with a household income of $30,000 - $79,999. Fibromyalgia impact ranged from mild to severe (9.3 – 75.7; *M* = 45.93, *SD* = 15.80) on the FIQ and the Manual Tender Point Fibromyalgia Intensity Score ranged from 3.56 – 9.06 (*M* = 6.55, *SD* = 1.60).

Pearson correlations (*r*) were used to examine the relationships among the 23 outcomes, (see Table 3.2). Objective measure-to-objective measure correlations ranged from *r* = .90 to *r* = .19. The strongest significant objective-to-objective relationship emerged between physical activity and active energy expenditure (*r* = .90, *p* = .01) and the weakest significant relationship emerged between sleep and number of steps (*r* = .25, *p* = .05). Subjective measure-to-subjective measure correlations ranged from *r* = .82 to *r* = .00. The strongest significant subjective-to-subjective relationship emerged between pain interference and the ability to participate in social activities (*r* = .82, *p* = .01) and the weakest significant relationship emerged between daily pain ratings and the ability to perform household chores (*r* = -.23, *p* = .05). Objective measure-to-subjective measure correlations ranged from *r* = -.42 to *r* = .00. The strongest significant objective-to-subjective relationship emerged between pain interference (*r* = -.42, *p* = .01) and

sleep duration and the weakest significant relationship emerged between daily pain ratings and sleep duration ($r = .23$, $p = .05$).

Table 3.1: Characteristics of Participants with Fibromyalgia (N = 72)

Variable (score range)	*M*	*SD*
Age, years	48.96	10.07
Ethnic Background, %		
White	97	
Black	3	
Education, %		
GED/high school graduate	37	
College graduate (technical, associates, bachelors)	42	
Graduate/professional training	21	
Marital Status, %		
Single	22	
Married	57	
Other (Widowed, Separated, Divorced)	21	
Employment Status		
Work full-time (≥ 35 hours/week)	36	
Work part-time (≤ 35 hours/week)	18	
Disabled	24	
Other (retired, laid-off, homemaker, student)	22	
Household Income, %		
Under $10,000 - $19,999	14	
$30,000 - $79,999	56	
$80,000 or more	19	
Unknown or refused	11	
Fibromyalgia Impact Questionnaire (0 – 80†)	45.93	15.80
Manual Tender Point Fibromyalgia Intensity Score (0-10‡)	6.55	1.60

Note. *M* = Mean and *SD* = Standard deviation for age, Fibromyalgia Impact Questionnaire, and Manual Tender Point Fibromyalgia Intensity Score. Other variable data are reported in percents (%). † Higher score indicates greater impact. ‡ Higher score indicates greater pain intensity.

Table 3.2: Correlation Matrix for All Outcome Measures

Outcome	*M*	*SD*	Correlation																					
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
1 FIQ VAS pain	6.68	2.29	1.00	.65†	.06	.72†	.25*	-.27*	.31†	.21	.42†	.05	.29*	.43†	.37†	-.18	.31*	.14	-.45†	-.13	.16	.12	-.15	.07	.15
2 FIQ total	51.73	13.62		1.00	.13	.59†	.52†	-.54†	.56†	.07	.22	.05	.41†	.56†	.40†	-.40†	.46†	.42†	-.43†	-.26*	-.14	-.10	-.26*	-.12	-.11
3 FIQ PF	4.73	2.41			1.00	-.06	-.02	-.06	.21	.15	.11	-.18	-.01	-.08	-.05	.13	-.06	-.08	-.11	.00	-.01	.02	-.09	.04	.05
4 MPI Scale 1	3.69	1.04				1.00	.41†	-.24*	.31†	.19	.43†	.26*	.42†	.66†	.56†	-.37†	.35†	.11	-.49†	-.28*	.07	.13	-.10	.09	.11
5 MPI Scale 2	3.89	1.24					1.00	-.33†	.33†	-.05	.14	.67†	.68†	.82†	.81†	-.56†	.20	.19	-.40†	-.34†	-.27*	-.15	-.42†	-.13	-.20
6 MPI Scale 3	3	1.02						1.00	-.62†	.10	.06	.17	-.21	-.36†	-.12	.23*	-.33*	-.45†	.28*	.27*	.06	-.06	.07	.03	.03
7 MPI Scale 4	3.26	1.16							1.00	.18	.23	-.12	.30†	.35†	.18	-.27*	.38†	.31*	-.41†	-.23	.06	.10	-.02	.08	.09
8 MPI Scale 5	3.97	1.39								1.00	.67†	-.09	.01	-.06	.14	.02	.08	.02	-.08	-.11	.08	.12	-.10	.10	.14
9 MPI Scale 9	3.5	0.87									1.00	.03	.22	.13	.34†	.00	.23	.09	-.23*	-.07	.01	.04	-.05	.01	.11
10 MPI Scale 10	3.57	0.8										1.00	.50†	.53†	.70†	-.51†	.12	.06	-.27*	-.15	-.17	-.09	-.34†	.02	-.10
11 MPI Scale 11	3.79	1.07											1.00	.60†	.76†	-.39†	.39†	.21	-.60†	-.22	-.08	-.04	-.27*	-.02	-.07
12 MPI Scale 12	3.9	1.04												1.00	.78†	-.49†	.20	.10	-.43†	-.32†	-.07	.04	-.36†	-.01	-.01
13 MPI Scale 13	3.69	0.66													1.00	-.45†	.26	.11	-.45†	-.27*	-.11	-.04	-.34†	-.02	-.06
14 FHBSA	36.85	18.38														1.00	-.28*	-.29*	.34†	.31†	.16	.00	.27*	.02	.10
15 MTPS FIS	6.34	1.53															1.00	.66†	-.37†	-.13	-.06	.06	-.04	.02	.01
16 MTPS tender point count	16.64	2.02																1.00	-.16	-.13	-.04	.07	-.17	-.10	.00
17 HDR pain	3.05	0.7																	1.00	.29*	.02	-.06	.23*	-.13	.00
18 HDR sleep quality	2.68	0.7																		1.00	.00	.00	.27*	-.23	-.03
19 Armband steps	5573.76	2837.81																			1.00	.82†	.25*	.56†	.85†
20 Armband physical activity	151.3	91.83																				1.00	.23	.65†	.90†
21 Armband sleep	361.02	68.45																					1.00	.19	.22
22 Armband EE	1939.48	397.42																						1.00	.76†
23 Armband AEE	550.37	321.55																							1.00

Note: *M* = Mean. *SD* = Standard deviation. FIQ = Fibromyalgia Impact Questionnaire; VAS = Visual Analog Scale; PF = Physical function; MPI = Multidimensional Pain Inventory; FHBSA = Fibromyalgia Health Behavioral Self-Assessment; MTPS = Manual Tender Point Survey; FIS = Fibromyalgia Intensity Score; HDR = Healthy Daily Routine; EE = Energy expenditure; AEE = Active energy expenditure. * $p = .05$. † $p = .01$.

3.3.1.1. Model I: Objective Indicators of Physical Activity

Model I associated 22 objective and subjective functional predictor indicators with the objective target outcome physical activity. Steps was the functional indicator most strongly associated with physical activity (F (3, 68) = 51.83, p = .001) (see Figure 47). Four clinical subgroups (Nodes 1 - 4) were identified based on the association between physical activity and steps. Members of the first clinical subgroup (Node 1) had the least favorable physical activity outcomes; engaged in approximately 48 minutes of physical activity over 7 days, and took no more than 3,171 steps. The second clinical subgroup (Node 2) had moderate physical activity outcomes; engaged in approximately 123 minutes of physical activity over 7 days, and took no more than 3,171 – 5,776 steps. The third clinical subgroup (Node 3) had good physical activity outcomes; engaged in approximately 204 minutes of physical activity over 7 days, and took between 5,776 – 10,935 steps. Members of the fourth clinical subgroup (Node 4) had the most favorable physical activity outcomes; engaged in approximately 312 minutes of physical activity over 7 days, and took more than 10,935 steps.

Two of the clinical subgroups were further differentiated (Nodes 1 and 2), resulting in 2 branches. For the first branch, steps under Node 1 further stratified members of the first clinical subgroup who had the least favorable physical activity outcomes into two distinct clinical subgroups (Nodes 5 and 6) (F (1, 12) = 7.28, p = .019). Segmentation of steps outcomes for these participants were differentiated as either low (< 2,270 steps) or high (> 2,270 steps). For the second branch, active energy expenditure (AEE) below Node 2 further stratified the members of the second clinical subgroup into three separate clinical subgroups (Nodes 7, 8, 9) (F (2, 26) = 38.18, p = .001). Segmentation of AEE for these participants were characterized as those who

burned the least calories during 95 minutes of PA (AEE ≤ 408) compared to those who burned a moderate number of calories during 124 minutes of PA (AEE 408 ~ 566), and finally compared those who burned the most calories during 189 minutes of PA (AEE > 566).

3.3.1.2. Cross Validation: Model I

The variance of physical activity over 7 days for the entire sample was 8432.75. The misclassification risk estimate for Model I was 1975.19. The averaged cross-validation risk estimate was 1082.04. The tree analysis reduced the uncertainty of physical activity variance over 7 days for this sample from 8432.75 to 1082.04, a substantial amount.

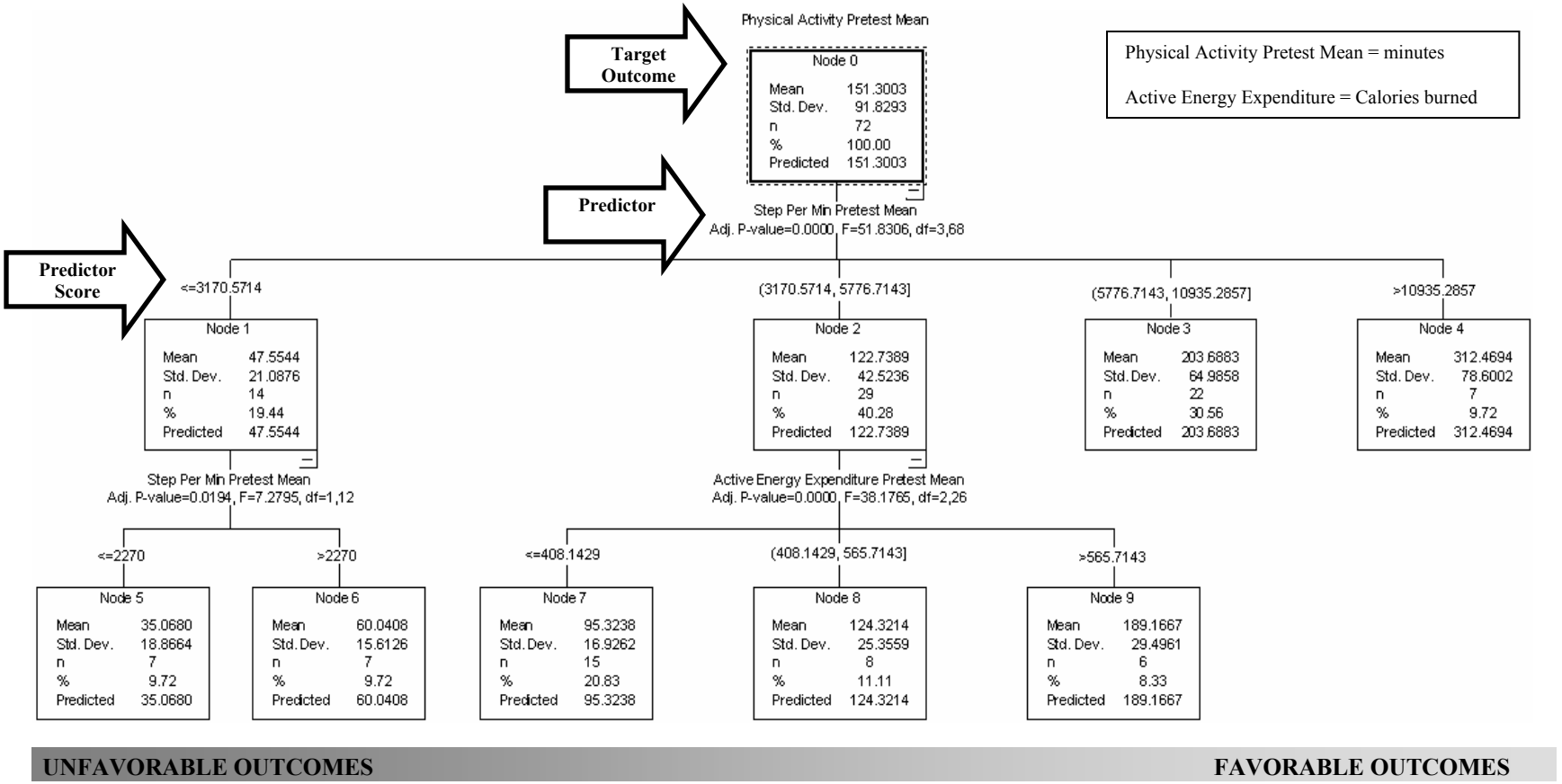


Figure 47: Model I - Predictors of Physical Activity Outcome (all measures combined)

3.3.2. Model II: Subjective Indicators of Functional Status

Of the 20 objective and subjective functional predictor indicators analyzed in Model II, affective distress due to pain impact was the functional indicator most strongly associated with the subjective outcome FIQ total (F (3, 69) = 20.54, p = .001) (see Figure 48). Three clinical subgroups (Nodes 1 - 3) emerged based on the association between the FIQ and affective distress. Members of the first clinical subgroup (Node 1) reported severe FM impact (FIQ = 70.98) over 7 days, and reported severe affective distress due to pain impact (MPI > 4). Participants in the second clinical subgroup (Node 2) reported moderate FM impact (FIQ = 49.66) over 7 days, and reported fair affective distress due to pain impact (MPI = 4 - 1). Members in the third clinical subgroup (Node 3) reported mild FM impact (FIQ = 39.99) over 7 days, and reported minimum affective distress due to pain impact (MPI = ≤ 1).

Tree growth continued to a second level resulting in one branch, under Node 2. For this branch, pain severity stratified the members of the second clinical subgroup into two distinct clinical subgroups (Nodes 4 and 5) (F (1, 54) = 14.86, p = .003). Segmentation of pain severity for these clinical subgroups were differentiated as either high (MPI > 3, extreme pain severity) or low (MPI ≤ 3, mild pain severity).

3.3.2.1. Cross Validation: Model II

The variance of FIQ total over 7 days was 185.50. The misclassification risk estimate for Model II was 92.29. The averaged cross-validation risk estimate was 62.72. The tree analysis reduced

the uncertainty of FIQ total variance over 7 days for this sample from 185.50 to 62.72, a substantial amount.

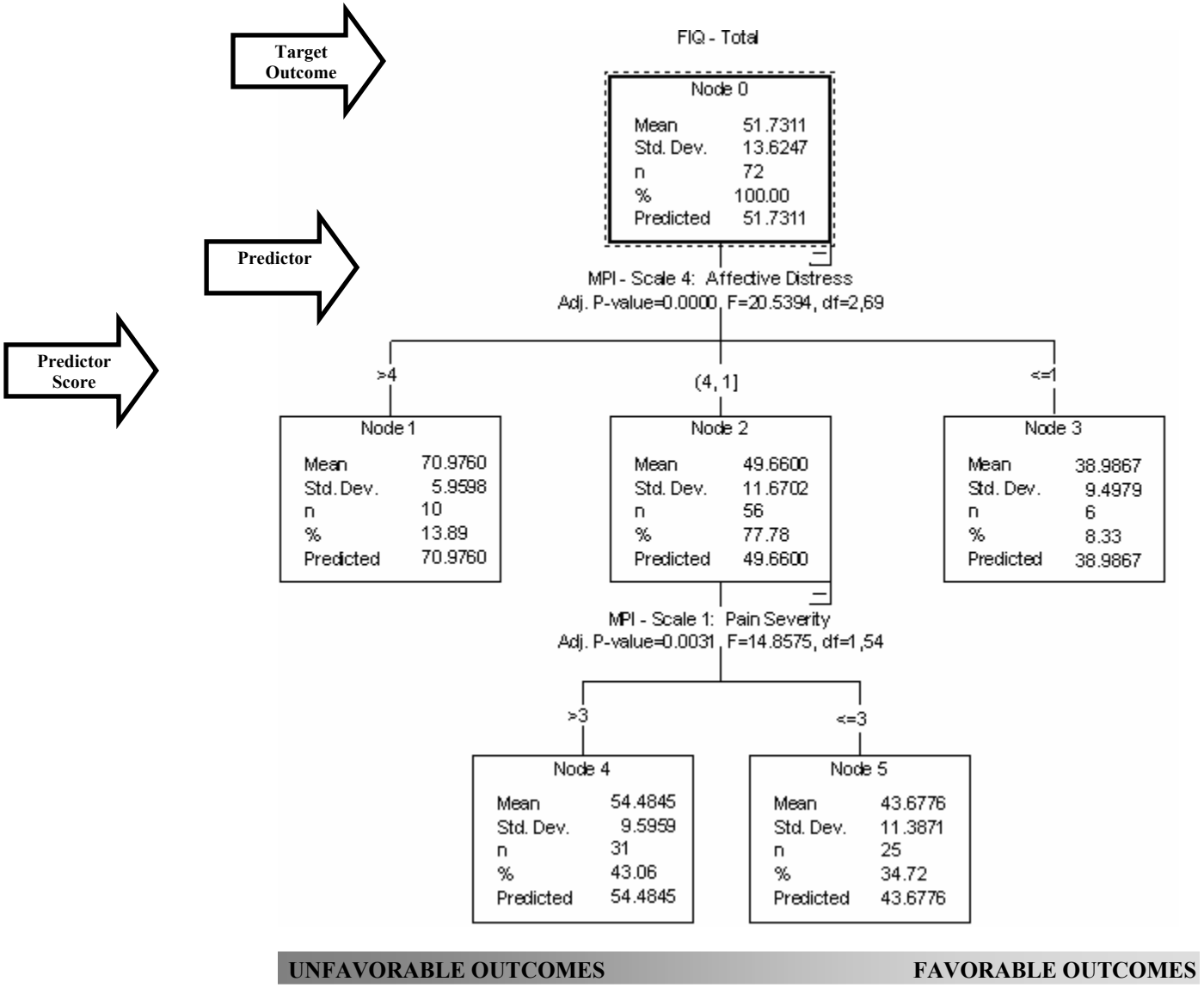


Figure 48: Model II - Predictors of Fibromyalgia Impact Questionnaire outcome (all measures combined)

3.4. DISCUSSION

The purpose of this study was to develop profiles of fibromyalgia clinical subgroups by examining the associations among symptoms of fibromyalgia, physical activity, and functional status. Using Exhaustive CHAID, we developed two models from the objective and subjective baseline data of the FIBRO-RCT. Profiles of fibromyalgia clinical subgroups emerged from each model. Although basically the same objective and subjective functional indicators were entered as predictors in each model, the significant predictors did not overlap between the two models. Moreover, only objective indicators surfaced as significant predictors in Model I, with physical activity as the target outcome, and only subjective indicators surfaced as significant predictors in Model II, with functional status as the target outcome.

Predictor indicators consisted of functional status, pain, physical activity, tender point count and intensity, sleep duration and quality, and activity performance variables. All the constructs represented by the predictor indicators have been described in fibromyalgia literature as responsive to changes following fibromyalgia interventions (Dunkl et al., 2000; Hewett et al., 1995; Simms, Felson, & Goldenberg, 1991).

Model I, with the target outcome of physical activity, yielded 9 distinct clinical subgroups, whose members had characteristics that were significantly associated with very unfavorable physical activity outcomes to very favorable physical activity outcomes. For all clinical subgroups, steps were the strongest predictor of physical activity outcomes, differentiating participants into four distinct clinical subgroups. The clinical subgroup that had the most unfavorable physical activity outcome took the fewest number of steps, and this subgroup was further differentiated into two additional clinical subgroups, based again on

number of steps taken over 7 days. Similarly, the clinical subgroup that participated in a moderate level of physical activity, took a moderate number of steps over the 7 days. This subgroup yielded three more clinical subgroups, which were differentiated by their levels of active energy expenditure. The two clinical subgroups with higher levels of physical activity participation and favorable physical activity outcomes took the most steps and presented as homogenous subgroups without other differentiating characteristics.

The development of a fully objective data-driven model was not a surprise given the strong correlations between objective measures in the present study and similar findings in previous FM research (Kop et al., 2005; Korszun et al., 2002; Landis, 2003). Measuring physical activity by self-report or accelerometer-based and pedometer-based sensors has both advantages and disadvantages (Bouten, Westerterp, Verduin, & Janssen, 1994; Freedson, & Miller, 2000; Patterson et al., 1993; Sallis, & Saelens, 2000; Tudor-Locke & Myers, 2001). The accepted benefits of self-report measures of physical activity are the easy of administration for large samples at low cost (Sallis & Saelens, 2000) and the recognized limitations are inaccurate recall or inaccurate perception of activity levels (Freedson & Miller, 2000; Sallis & Saelens, 2000). Accelerometer-based and pedometer-based sensors also have disadvantages such as cost, the reliability of the algorithms used in these devices, and the inconsistent units of measurement for physical activity (e.g., duration versus counts), however the advantages are the objective quantification of various levels of physical activity in real-time without impeding on daily routines as well as the ability to utilize that data to facilitate health promotion and therapeutic interventions (Bouten et al., 1994; Freedson & Miller, 2000; Patterson et al., 1993; Sallis & Saelens, 2000; Tudor-Locke & Myers, 2001). Therefore, the current study may be indicative of the benefits of objectively measuring physical activity to develop profiles of fibromyalgia

clinical subgroups; as our results demonstrated that steps taken and active energy expenditure were both strongly associated predictors of physical activity for women with FM.

Validation of this Exhaustive CHAID model may offer adequate exploratory results to consider its utility to generalize the findings of the current study. The target outcome of physical activity demonstrated extremely large variability over 7 days. The data-driven model generated clinical subgroups, which engaged in various levels of physical activity, and offers insight into physical activity patterns based on a continuum of unfavorable to favorable outcomes. Moreover, the reduction of the data variability by the examination and comparison of the variance, the misclassification risk estimates, and the cross validation estimates facilitated the validation of Model I. The tree analysis reduced the uncertainty of physical activity variance over 7 days for this sample with the misclassification risk estimate; however, the cross-validation risk estimate reduced the misclassifications even more resulting in a substantial reduction of variance in the Model. Thus, these data demonstrate the predictive validity of Model I to develop clinical subgroups of individuals with fibromyalgia through the use of objective surrogate indicators of overall physical activity, namely steps and calories burned.

Model II, with the target outcome of the FIQ total score, yielded 5 distinct clinical subgroups whose members had characteristics that were significantly associated with very unfavorable functional status outcomes to very favorable functional status outcomes. For all clinical subgroups, affective distress attributable to pain emerged as the strongest predictor of functional status. Three clinical subgroups emerged from the stratification of the functional outcomes predictor scores. The first clinical subgroup was composed of participants who reported unfavorable functional status outcomes (i.e., high FM impact) and severe affective distress due to pain. The second clinical subgroup included those who reported moderate

functional status outcomes (i.e., moderate FM impact) and severe to fair affective distress due to pain. The third clinical subgroup consisted of those participants who reported favorable functional status outcomes (i.e., low FM impact) and minimum affective distress due to pain. The fourth and fifth clinical subgroups consisted of members of the moderate functional status subgroup who were further differentiated into two clinical subgroups based on pain severity.

Only subjective indicators were significant predictors of functional status in Model II. Similar findings have been reported related to classification profiles of persons with chronic pain, which were also developed based on subjective, self-report data (Gatchel et al., 2002; Turk et al., 1996; Turk et al., 1998; Turk & Rudy, 1988). The FIQ total score demonstrated the ability to detect clinically relevant changes in functional status between patients who reported improved clinical status and those who did not (Dunkl et al., 2000). The current results differ from the chronic pain models, however, because the results were derived from data-driven analysis rather than regression-based analysis that fit the data to a pre-existing or theoretic model. Kop et al. (2005) also found that objective activity levels were not predictive of subjective FM symptom ratings. The validity of Model II was also based on examination and comparison of the variance, the misclassification risk estimates, and the cross validation estimates. The target outcome FIQ total score demonstrated less variability over 7 days compared to physical activity. The total variance for the FIQ total score was based on the entire sample; however, the Exhaustive CHAID data-driven analysis reduced the uncertainty of FIQ total variance over 7 days with the misclassification risk estimate. The cross-validation risk estimate reduced the misclassifications further resulting in a substantial reduction of FIQ total variance. Thus, these data demonstrate the predictive validity of Model II to develop clinical subgroups of individuals with fibromyalgia through the examination of subjective predictors of functional status. Tree-based analysis and

cross validation methods improved the outcomes for misclassification, with Model II demonstrating stronger predictive validity than Model I.

3.4.1. Limitations and Recommendations

Although the FIQ is the most commonly used disease-specific tool to measure the functional status of persons with fibromyalgia, it has not been used to define subgroups until the current study, and this study should be replicated. Our sample was drawn from one clinical rheumatology practice and Caucasians are the majority ethnic group that represents this region. Fibromyalgia, however, is not a syndrome exclusive to a particular ethnic group (Macfarlane, 1999; White & Harth, 2001). Thus, individuals from other health care settings or ethnic backgrounds were not well represented. Of note are the considerable data ranges for the target outcomes of physical activity and FIQ total used in both Models I and II, reiterating the need for developing profiles of clinical subgroups for individuals with fibromyalgia.

While acknowledging how these limitations may have affected the outcomes, Exhaustive CHAID offers a unique method for the identification of clinically relevant subgroups of individuals with fibromyalgia. The use of Exhaustive CHAID's predecessor CHAID has been documented for medical and rehabilitation research with other populations including persons with asthma, intracranial hemorrhages, and traumatic injuries (Barton, McKenzie, Walters, Abramson, & The Victorian Asthma Mortality Study, 2005; Dubinsky & Penello, 2002; Hill, Delaney, & Roncal, 1997; Levi et al., 1998). Data-driven decision tree analysis eliminates the need for researchers to determine arbitrary data cut-off scores, yielding empirical rather than arbitrary clinical subgroups. For example, persons who experienced moderate affective distress

reported high pain ratings and were associated with moderate fibromyalgia impact. Future research should examine the validity and generalizability of Exhaustive CHAID methods with a larger, yet comparable, sample to confirm and facilitate identification of FM clinical subgroups. Identification of such clinical subgroups can only enhance the management of fibromyalgia.

3.4.2. Summary

Because of the multidimensional symptoms that characterize this enigmatic syndrome, fibromyalgia continues to challenge clinicians and researchers, and no consensus on interventions exists. This may lead one to ask where we go from here. The classification of subgroups of persons with fibromyalgia holds promise for developing and implementing appropriate evidence-based intervention and management protocols (Cassisi et al., 1993; Giesecke et al., 2003; Hurtig et al., 2001; Raak et al., 2003; Turk et al., 1996; Turk et al., 1998). The present study was the first to investigate the clinical utility of Exhaustive CHAID methods to examine the interactions between relevant objective and subjective functional indicators of physical activity and functional status for homogenous clinical subgroups for persons with fibromyalgia.

The tree-based analyses generated two models that did not overlap. These findings may prove to be an opportunity to improve interventions and management protocols tailored for clinical subgroups for persons with fibromyalgia. As with previous research (Gatchel et al., 2002, Kop et al., 2005; Korszyn et al., 2002; Landis, 2003; Turk et al., 1996; Turk et al., 1998), objective and subjective data are associated with or predictive of objective and subjective outcomes respectively. However, given that Exhaustive CHAID models are data-driven the clinical subgroups for persons with fibromyalgia identified using this method demonstrate

several advantages over traditional regression-based analysis. Specifically, Exhaustive CHAID methods identified the objective and subjective functional indicators most strongly associated with physical activity and functional status target outcomes (segmentation) respectively, and identified predictor scores that separated the sample into homogenous clinical subgroups along the continuum of favorable to unfavorable outcomes (stratification) rather fitting data based on pre-existing or theoretical models. For Model I, with the target outcome of physical activity, steps were the most significant predictor of favorable and unfavorable physical activity outcomes. For Model II, with the target outcome of the FIQ total score, the MPI affective distress subscale was the strongest predictor, followed by the MPI pain severity subscale, for favorable and unfavorable functional status outcomes.

In conclusion, our findings offer a foundation for incorporating Exhaustive CHAID as an exploratory and complementary method for evidence based practice interventions by examining the interactions between relevant functional indicators of physical activity and functional status for homogenous clinical subgroups for persons with fibromyalgia.

4. TRIGGERS OF FIBROMYALGIA FLARES AND FUNCTIONAL STATUS IN SUBBROUPS OF WOMEN WITH FIBROMYALGIA: A MIXED METHODS STUDY

4.1. INTRODUCTION

The etiology of fibromyalgia is unknown; however, 15-20% of all new rheumatology referrals met the 1990 American College of Rheumatology (ACR) diagnosis criteria for fibromyalgia (Doron, R. Peleg, A. Peleg, Neumann, & Buskila, 2004; Wolfe et al., 1990). Fibromyalgia increasingly commands attention and clinical consideration because of its significant health service costs and the life altering affect it has on those living with it. Based on self-report data, in 1996 the average health services costs totaled $2,274 per patient with fibromyalgia. However, in a more recent study Wassem and Hendrix (2003) suggest that the economic burden for society and persons living with fibromyalgia has almost doubled since 1996. According to questionnaire data from 102 fibromyalgia study participants, Wassem and Hendrix found that the mean direct costs for health services of the study participants totaled $3,814 while indirect costs averaged $720. Therefore, persons living with fibromyalgia spent a yearly average $4,534 to manage the syndrome (Wassem & Hendrix, 2003).

In addition to significant health service costs, fibromyalgia alters lives by interfering with everyday lifestyles and routines (i.e., household and leisure activities, social relationships, and work related activities). Thus, persons with the syndrome are required to plan and adjust participation levels due to pain and fatigue (Gaston-Johansson, Gustafsson, Felldin, & Sanne,

1990; Henriksson, 1994; Henriksson, Gundmark, Bengtsson, & Ek, 1992). Cognitive functions such as short-term memory and concentration are also altered (Grace, Nielson, Hopkins, & Berg, 1999) and Gaston-Johansson et al. (1990) found that persons with fibromyalgia reported more negative personal feelings (e.g., unsure of self) and felt others viewed them with more mistrust compared to the study participants with rheumatoid arthritis.

In addition to managing their physical and cognitive symptoms, those with fibromyalgia are required to develop and implement new strategies for coping with the stigma associated with an elusive diagnosis (Åsbring & Närvänen, 2002). Furthermore, fibromyalgia alters lives by influencing the need for illness acknowledgement and reassurance from physicians and loved ones that the symptoms they experience can be attributed to a genuine syndrome (Hellström, Bullington, Karlsson, Lindqvist, & Mattsson, 1999). Because of the chronic and multidimensional symptoms that characterize the syndrome and the variability of its manifestation, fibromyalgia continues to challenge clinicians and researchers.

The largest portion of fibromyalgia research to date consists of quantitative studies that encompass a broad scope of inquiry. Fibromyalgia research has ranged from etiology - pathogenetic mechanisms (e.g., peripheral and central sensory sensitization) (Geenen & Jacobs, 2001; Henriksson, 2003; Staud & Domingo, 2001; Staud & Smitherman, 2002) to psychosocial reactions to the syndrome (e.g., abuse and stress) (Hassett, Cone, Patell, & Sigal, 2000; Henriksson, 2003; Staud & Domingo, 2001), to appropriate diagnosis versus misdiagnosis of fibromyalgia (Fitzcharles & Boulos, 2003; Katz, Wolfe, & Michaud, 2006; Wolfe et al., 1990). There is no consensus on interventions for fibromyalgia, although the research literature has focused on two primary types of interventions: pharmacological and nonpharmacological (Burckhardt, 2002; Forseth & Gran, 2002; Goldenberg, Burckhardt, & Crofford, 2004; Hadhazy,

Ezzo, Berman, Creamer, & Bausell, 2002; Karjalainen et al., 2004; Keel, 1999; Okifuji & Ashburn, 2001; Oliver, Cronan, & Walen, 2001; Rossy et al., 1999; Sim & Adams, 2002; White & Harth, 1996). The results of intervention studies have yielded inconsistent results, even though they used reliable and valid quantitative measures to explore, predict, or define the effects on fibromyalgia, based on the interventions applied (Adams & Sim, 2005; Crofford & Appleton, 2000; Dunkl et al., 2000; Hewett et al., 1995; Okifuji & Ashburn, 2001; Oliver, Cronan, & Walen, 2001; Rossy et al., 1999; Sim & Adams, 2002; Turk, Okifuji, Sinclair, & Starz, 1998; Wolfe et al., 2000). Therefore because the quantitative measures did not seem to capture the total picture of how fibromyalgia impacted those with the syndrome, some researchers began to explore the use of qualitative methods to gain new insights.

Qualitative methods such as narratives, diaries, video interpretation, and interviews that probe personal histories and experiences of persons with fibromyalgia have been employed to query the experiences, meaning, and consequences of life with fibromyalgia (Cudney, Bulter, Weinert, & Sullivan, 2002; Henriksson et al., 1992; Schaefer, 2005; Söderberg, Lundman, & Norberg, 1999). Schaefer (1995) used qualitative methods, grounded theory, and feminist viewpoints to understand how persons with fibromyalgia live with the syndrome. The participants characterized life with fibromyalgia as a battle to manage a balanced life and recounted how they moved on with life, relegating fibromyalgia to the background, after discovering ways of tolerating the pain. Additionally, researchers have used qualitative methods to elucidate pain behaviors related to fibromyalgia (Schwartz, Slater, & Birchler, 1994), pain influences (Gustafsson, Ekholm, & Ohman, 2004; Hellström et al., 1999; Horwitz, Theorell, & Anderber, 2003), psychological functioning (Wentz, Lindber, & Hallberg, 2004), functional status (Liedberg & Henriksson, 2002), work related issues (Liedberg & Henriksson, 2002;

Löfgren, Ekholm, & Öhman, 2006) quality of life related issues (Bernard, Prince, & Edsall, 2000; Hallberg & Carlsson, 1998), and recovery from fibromyalgia (Mengshoel & Heggen, 2004). The common findings in these qualitative studies were a greater understanding of the specific impact of fibromyalgia on everyday life. However, the studies did not provide insight into what triggers began the cycle of a fibromyalgia flare, which in turn led to the specific impact of fibromyalgia on their daily lives.

Several researchers have combined quantitative and qualitative methods to gain insight into how persons with fibromyalgia cope with chronic pain, and the effects of social and health care support related to quality of life (Kelley & Clifford, 1997; Schoofs, Bambini, Ronning, Bielak, & Woehl, 2004). The mixing of quantitative and qualitative methods is complementary. Mixed methods studies allow the data to frame and reframe the direction of the research, as well as confirm findings through data triangulation (Tashakkori & Teddle, 2003). In this study, the aim was to use mixed methods to identify clinically relevant triggers of fibromyalgia flares, experienced by three subgroups women with low, average, and high fibromyalgia impact, and explore the effect of triggers on their functional status.

4.2. METHODS

4.2.1. Study Design

This study used a prospective mixed methods design. The quantitative components were descriptive data from the Data Demographic Form (DDF), the Fibromyalgia Impact Questionnaire (FIQ), and the Current Symptoms Checklist (CSC). Semi-structured qualitative

interviews employing ethnographic techniques and grand tour questions were conducted with persons with fibromyalgia (FM) to enhance understanding of triggering signs and symptoms of fibromyalgia and to examine their impact on activity limitations and participation restrictions. Ethnographic research refers to the systematic description of a group and its culture. Ethnographic techniques include grand tour questions that are open-ended as well as probes that are designed to build knowledge and gain understanding of a phenomenon, which may in turn guide the investigation to a meaningful solution of an identified problem (Bailey, 1991; Tashakkori & Teddle, 2003).

4.2.2. Participants

The study was approved by the University of Pittsburgh Institutional Review Board for the Protection of Human Subjects. Eligible participants were those whose written consents were previously obtained by the research team for participation in "The Efficacy of Computer and SenseWear® Technologies for Promoting Health in Adults with Fibromyalgia: A Randomized Clinical Trial" (FIBRO-RCT), and who also agreed to be contacted for future studies, but were not currently active participants in the FIBRO-RCT. Participants met the following inclusion criteria: (a) were 18 years of age or older; (b) met the ACR criteria for a diagnosis of FM (Wolfe et al., 1990); (c) were diagnosed with FM at least 1 year before enrollment into the study; (d) had adequate vision (i.e., read newsprint) to use a computer; (e) spoke English; and (f) had a home telephone. Exclusion criteria were disability in daily activities due to a medical diagnosis other than FM (e.g., stroke, Parkinson disease) and living further than 40-miles from the Oakland campus of the University of Pittsburgh. Participants again provided informed consent that included permission to audio record the interview to facilitate accurate transcription. The

investigators estimated that 15 interviews would achieve data saturation based on experience with qualitative research and the fibromyalgia population.

4.2.2.1. Participant Selection

Participant selection for this study used stratified random and typical sampling strategies. Stratified random sampling is the identification of a relevant population characteristic that divides a population into homogeneous, non-overlapping subgroups (Portney & Watkins, 2000). Typical sampling indicates a case selection that represents the majority (Bailey, 1991).

The Fibromyalgia Impact Questionnaire (FIQ) without the work status items included (i.e., maximum score of 80) (Burckhardt, Clark, & Bennett, 1991) was used to stratify eligible participants into tertiles for selection into the study (i.e., low FM impact, average FM impact, high FM impact), based on the most recent total FIQ score available (i.e., pretest FIQ data from the FIBRO-RTC was used if a participant withdrew from FIBR-RTC; posttest FIQ data from the FIBRO-RTC was used if a participant completed FIBR-RTC). The FIQ score is referred to as the selection FIQ. The FIQ is the most commonly used disease-specific instrument for measuring the functional status of persons with fibromyalgia. The FIQ measures health status outcomes over the past week believed to affect: (1) physical functioning (e.g., home management, community involvement, mobility); (2) well-being (e.g., days they felt well); (3) work attendance; and (4) FM symptoms. Higher scores suggest a greater extent of fibromyalgia impact. Fifteen women, six from the low FIQ subgroup (low FM impact; FIQ $\leq$ 44.4), five from the average FIQ subgroup (average FM impact; FIQ 44.5 – 54.9), and four from the high FIQ subgroup (high FM impact; FIQ $\geq$ 55.0) were randomly selected using the online program, Research Randomizer (Urbaniak, 1997). In qualitative sampling, typical sampling focuses on

selecting participants who have representative characteristics of a specific diagnostic group. Thus, our sample was selected to be representative of the total range of FM impact.

4.2.3. Instrumentation

In addition to the Fibromyalgia Impact Questionnaire (FIQ), several study-specific data collection forms were used during data collection. The collection forms were the Demographic Data Form (DDF) (see Appendix E), the Current Symptoms Checklist (CSC) from the FIBRO-RCT, and the Symptom Identification Form (SIF). Other materials used during interviews were a qualitative interview field notes form (see Appendix E), a flip chart with individual semi-structured grand tour questions, audio tapes of the interviews, interview transcripts, and ten 5 x 8-note cards (SIF note cards) (see Appendix E). The FIQ score obtained at the time of the interview is referred to as the interview FIQ. The DDF was used to collect socio-demographic data (e.g., age, weight, living status, education, employment status, occupation, and salary) for each participant. The CSC was a compilation of symptoms common to fibromyalgia based on literature. On the CSC participants identified their current symptoms with a check mark, and on the SIF, participants identified and ranked the 10 most severe fibromyalgia symptoms (1 = most severe to 10 = least severe). The 10 most severe fibromyalgia symptoms from the SIF were recorded on the SIF note cards by the interviewer during the interview.

4.2.4. Procedures and Data Collection

Prior to the interviews, participants identified an interview site where they would feel most comfortable. All participants selected their home as the site of the interview. Interviews were audio taped to ensure data accuracy and followed a semi-structured ethnographic process. A flip chart with the 8-open-ended grand tour questions was used to enhance communication between the interviewer and participants. Written copies of each grand tour question were displayed for participants on the flip chart as the question was spoken to promote concentration on the specific question (see Table 4.1) and follow-up probes (see Table 4.2). The open-ended grand tour questions allowed the participants to respond based on their perceptions (Fetterman, 1998); and the semi-structured method elicited data specific to the present study. The selection of semi-structured interviews over structured interviews occurred because the latter have been criticized as being limiting rather than exploratory (Fetterman, 1998; Fontana & Frey, 2000). The interviewer conducted individual interviews. Participants were informed that the appointment would take 90 to 120 minutes. Interviews ranged from 45 to 150 minutes. Depicted in Figure 49 is a diagram of the mixed methods data collection procedures.

At the time of the interview, the interviewer collected socio-demographic data using the DDF and participants completed the FIQ and the CSC before the interview (see Appendix E). Each interview began with the interviewer saying, "Today is [date], it is [time], and this is the interview of subject [subject identification]." Subsequently, the interviewer posed grand tour questions 1 to 5 (see Table 4.1) one at a time for the participants to respond. Next participants completed the SIF, and then the interviewer printed the 10 most severe fibromyalgia symptoms identified and ranked on the SIF on side one of the SIF note cards as the participant read them

aloud. After that, the interviewer repeated the rank of the 10 most severe symptoms printed on the note cards aloud to verify the correct order as indicated by the participant. The interviewer posed grand tour question 6 (see Table 4.1) and the participants responded. Participants were then probed to describe what about the activity triggers the symptom. Participants recorded and ranked the activities most and least affected (1 = most affected to least affected) by each of their 10 most severe fibromyalgia symptoms, one symptom at a time on side one of the SIF note cards. Once the participants identified and ranked the activities most and least affected by a symptom then they proceeded to the next symptom. Next, the interviewer posed grand tour question 7 (see Table 4.1) and the participants responded. Participants were then probed to describe the strategies they used to control each symptom before its onset, and strategies to manage each symptom after its onset. Participants recorded the management strategies on side two of the SIF note cards, one symptom at a time. The interview was concluded with the interviewer posing grand tour question 8 (see Table 4.1) and the participants' response.

A professional transcriptionist transcribed all interviews, which were then sent to each participant for data checking. Participants reviewed their interview transcripts to check the accuracy of content and to clarify tentative information discussed during the interview. Data checks were conducted by telephone, mail, or in-person to foster accurate data collection. The interviewer verified the accuracy of each transcript by reviewing each tape and transcript before participant data checking and then reviewed any edits to the transcripts after participant data checking.

Table 4.1: Grand Tour Questions

1. How does fibromyalgia affect you?
2. What triggers your fibromyalgia flares?
3. Which activities trigger a fibromyalgia flare?
4. Which activities have you given up due to your fibromyalgia symptoms?
5. Which activities do you immediately engage in when you start feeling better after a flare?
6. Tell me about how your symptoms change throughout the day, and if there is a pattern.
7. How do you manage your fibromyalgia symptoms daily, compared to how you manage them during a flare?
8. If you had a friend who was diagnosed with fibromyalgia, what would you tell her/him is the best way to manage fibromyalgia symptoms?

Table 4.2: Sample Grand Tour Follow-up Probes

1. What do you mean when you say _____?
2. Was this what you expected?
3. Could you elaborate on this?
4. How do you feel about this?
5. You talked previously about _____; can you tell me more about that?

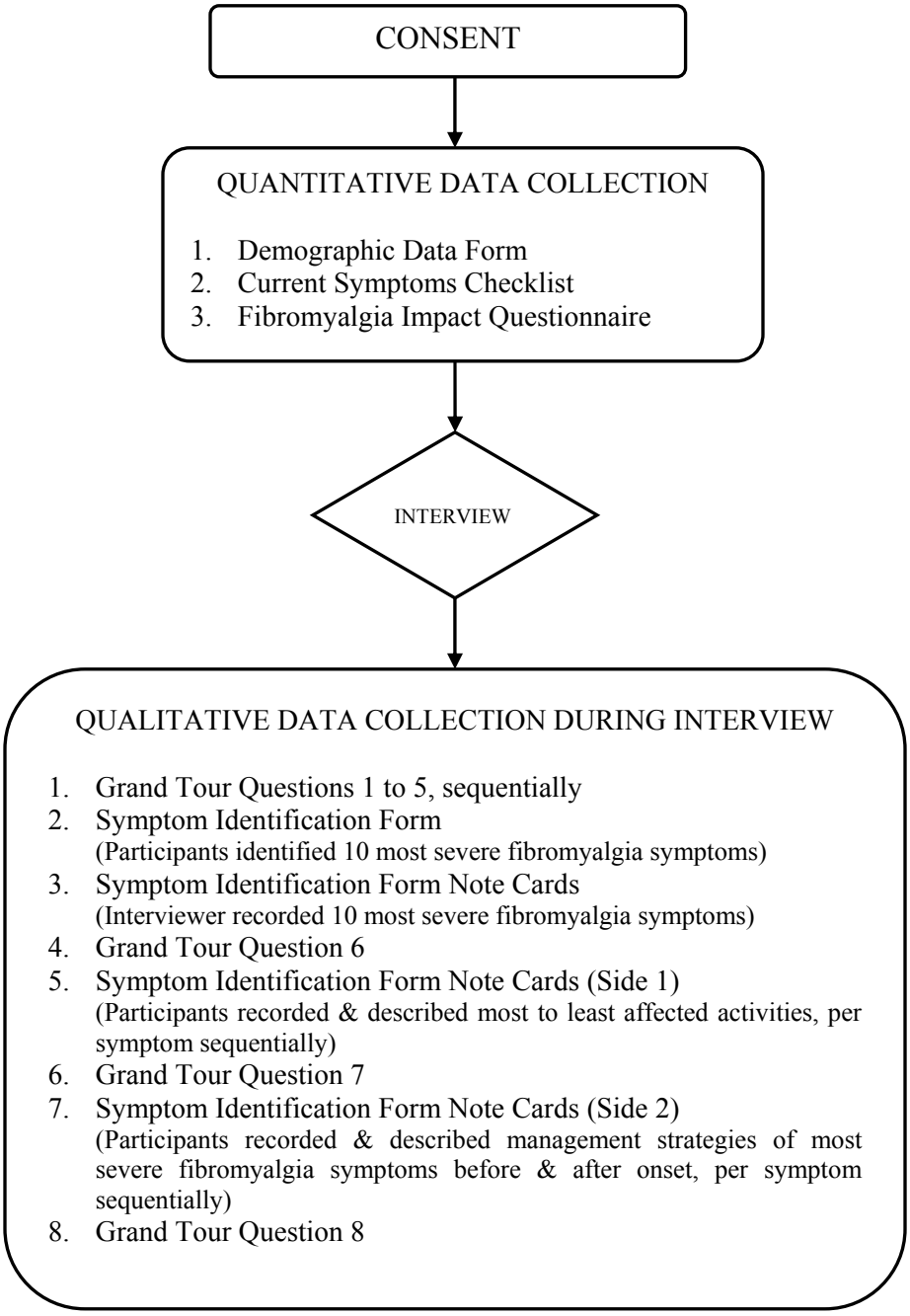


Figure 49: Mixed Methods Data Collection Procedures

4.2.4.1. Field Notes

Brief field notes regarding the participants' appearance, facial expressions, gestures, and body language were recorded during the interview. The interviewer immediately elaborated on the notes after each interview to recall the details not captured during the interviews.

4.2.5. Data Analysis

Transcripts were imported into Non-numerical Unstructured Data Indexing Searching and Theorizing or NUD*IST version 6.0 (N6), ("NUD*IST (N6) [Computer software]," 2002) a qualitative research program, and divided into text units. A posteriori, the themes extracted from the interview transcripts were organized using N6 (Bailey, 1991). Coding was completed within N6 using a "bottom-up" coding methodology based on the themes identified by the participants during the interviews (Bailey, 1991; Patton, 1990). Coding also consisted of analyzing each text unit and classifying it in the appropriate theme category (Bailey, 1991; N6, 2002; Patton, 1990; Richards, 2002). The text units were reviewed after coding each transcript to classify the themes. Categorizing text units allowed proper analysis of texts with similar meaning. Case-oriented analysis and data triangulation were also conducted; as these methods consider individual cases as well as multiple cases (Tashakkori & Teddle, 2003).

The research team discussed and reviewed tree displays of coding at meetings to confirm the accuracy of the coding. A priori, it was established that data saturation occurred once no new codes were added to the core classifications for two consecutive interviews.

The socio-demographic, SIF note cards, and quantitative data (e.g., FIQ, CSC, SIF) were managed using SPSS 13.0.1 for Windows (SPSS Inc., 2004). Descriptive statistics were computed to describe the participants. Participants identified the 10 most severe fibromyalgia symptoms on the SIF. The symptoms were ranked 1 = most severe to 10 = least severe. Then the 10 ranked symptoms were assigned a weighted rank order (WRO) value using a reverse ranking system (10 = highest priority to 1 = lowest priority) that combined ranking and the intensity of the ranking (Carroll & Lovejoy, 2005). Similarly, the WRO method was employed for the ranked activities most affected by each of the most severe fibromyalgia symptoms. Due to the diverse lifestyles of the study participants, yielding voluminous numbers of activities, only the top 5 activities affected by the 5 most severe symptoms were analyzed with the WRO method.

Data from the interviews were triangulated with the participants' responses on the FIQ and the CSC (Fetterman, 1998; Portney & Watkins, 2000; Tashakkori & Teddle, 2003), and represented in tabular format for interpretation. The triangulation of data was used to enhance the inference quality (e.g., quantitative internal validity and generalizability, qualitative transferability) and inference transferability (e.g., quantitative external validity, qualitative trustworthiness, and credibility) of the research findings through the convergence or corroboration of quantitative and qualitative methods (Tashakkori & Teddle, 2003).

4.3. RESULTS

Based on selection criteria all participants were female; 14 of 15 were white. Participants had a mean age ± standard deviation of 49.60 ± 8.69 years, 6 of 15 were married, and 10 of 15 were college-educated. Household income ranged from at least $10,000 > $90,000. Fibromyalgia impact of the total sample was average, with a mean of 50.66 on the FIQ and a mean Current Symptoms Checklist score of 17.60. See Table 4.3 for an overview of the participant characteristics, see Table 4.4 for individual participant characteristics, by FIQ subgroup, and see Table 4.5 for an overview of the characteristics specific to the three FIQ subgroups.

Table 4.3: Characteristics of Participants with Fibromyalgia (N = 15)

Variable (score range)	*M*	*SD*
Age, years	49.60	8.69
Ethnic Background, %		
White	93	
Black	7	
Education, %		
High School graduate	33	
College graduate	40	
Graduate/professional training	27	
Marital Status, %		
Single	33	
Married	40	
Separated	7	
Divorced	20	
Living Status, %		
Alone	33	
With spouse/significant other or family	67	
Employment Status		
Work full-time (≥ 35 hours/week)	20	
Work part-time (≤ 35 hours/week)	7	
Retired	27	
Disabled	20	
Other (student, medical leave, laid off)	26	
Household Income, %		
$10,000 - $29,999	33	
$30,000 - $ 59,999	33	
$60,000 - $89,999	13	
$90,000 or more	7	
Refused	14	
Fibromyalgia Impact Questionnaire (0 – 80†)	50.66	19.22
Current Symptoms Checklist (0 – 34‡)	17.60	7.12

Note. *M* = Mean and *SD* = Standard deviation for age, Fibromyalgia Impact Questionnaire, and Manual Tender Point Fibromyalgia Intensity Score. Other variable data are reported in percents (%). † Higher score indicates greater impact. ‡ Higher score indicates greater number of current symptoms.

Table 4.4: Characteristics of Individual Participants with Fibromyalgia, by Subgroup (N = 15)

Subgroup/Participant	Age	Race	Marital Status	Lives With:	Education	Employment Status	Household Income
Low FIQ Impact							
2	50	White	Married	Spouse	Graduate degree	Full-time	$90K to $150,000
6	47	White	Married	Spouse	High school	Part-time	Refused
7	62	White	Married	Spouse	High school	Retired	Refused
12	54	White	Divorced	Alone	High school	Retired	$30K to $59,999
13	56	White	Married	Spouse	High school	Retired	$30K to $59,999
14	50	White	Separated	Alone	Graduate degree	Laid-off, looking	$10K to $29,999
Average FIQ Impact							
4	62	White	Married	Spouse	High school	Retired	$60K to $89,999
5	50	White	Single	Family	Bachelor's degree	Disabled	$10K to $29,999
8	28	White	Single	Significant other	Graduate degree	Full-time	$30K to $59,999
10	48	White	Married	Spouse	Bachelor's degree	Disabled	$30K to $59,999
11	36	White	Single	Alone	Bachelor's degree	Laid-off, looking	$60K to $89,999
High FIQ Impact							
1	57	White	Single	Family	Bachelor's degree	Disabled	$10K to $29,999
3	49	Black	Divorced	Family	Bachelor's degree	Student	$10K to $29,999
9	58	White	Single	Alone	Graduate degree	Full-time	$30K to $59,999
15	37	White	Divorced	Alone	Bachelor's degree	Medical leave	$10K to $29,999

Table 4.5: Characteristics of Fibromyalgia Subgroups (N = 15)

Group	Age	Race	Marital Status	Lives With:	Education	Employment Status	Household Income
Low FIQ Impact (*n* = 6)	*M* (*SD*) 53.2 (5.4)	White (*n* = *6*)	Married (*n* = *4*)	Spouse or SO (*n* = *4*)	Graduate degree (*n* = *2*)	Full-time (*n* = 1)	$10K to $29,999 (*n* = 1)
			Separated (*n* = *1*)	Alone (*n* = *2*)	High school (*n* = *4*)	Part-time (*n* = 1)	$30K to $59,999 (*n* = 2)
			Divorced (*n* = *1*)			Retired (*n* = *3*)	$90K to $150,000 (*n* = 1)
						Laid-off (*n* = 1)	Refused (*n* = 2)
Average FIQ Impact (*n* = 5)	*M* (*SD*) 44.8 (13.1)	White (*n* = *5*)	Married (*n* = *2*)	Family (*n* = *1*)	Bachelor's degree (*n* = *3*)	Disabled (*n* = 2)	$10K to $29,999 (*n* = 1)
			Single (*n* = *3*)	Spouse or SO (*n* = *3*)	Graduate degree (*n* = *1*)	Full-time (*n* = 1)	$30K to $59,999 (*n* = 2)
				Alone (*n* = *1*)	High school (*n* = *1*)	Retired (*n* = 1)	$60K to $89,999 (*n* = 2)
						Laid-off (*n* = 1)	
High FIQ Impact (*n* = 4)	*M* (*SD*) 50.3 (9.7)	White (*n* = *3*)	Single (*n* = *2*)	Family (*n* = *2*)	Bachelor's degree (*n* = *3*)	Disabled (*n* = 1)	$10K to $29,999 (*n* = 3)
		Black (*n* = *1*)	Divorced (*n* = *2*)	Alone (*n* = *2*)	Graduate degree (*n* = *1*)	Full-time (*n* = 1)	$30K to $59,999 (*n* = 1)
						Other† (*n* = 2)	

Note. *M* = Mean and *SD* = Standard deviation for age. SO = significant other. † = student or medical leave.

4.3.1. Semi-structured Interviews

The semi-structured interviews included 8 grand tour (GT) questions and SIF note card responses to the 10 most severe fibromyalgia symptoms, the activities affected by those symptoms, and the management strategies before and after onset of those symptoms.

4.3.2. Coding for Semi-structured Interviews

The 8 grand tour questions were coded by the interviewer with 222 subcategories that described specific data from the grand tour questions. Data saturated with participant 14, meaning that interviews 14 - 15 were fully coded with existing nodes. Voluminous amounts of data were collected from participants during the interviews; however, the findings presented focus on the participants' responses to the grand tour questions (see Table 4.1) and note cards. Presented in Appendix F is an overview of the N6 coding structure for the grand tour questions.

4.3.3. Semi-structured Interviews Grand Tour Questions and Note Cards Responses

4.3.3.1. GT #1: "How does fibromyalgia affect you?"

Participants shared lived experiences of the affects of fibromyalgia on their lives to facilitate a deeper understanding of this chronic syndrome. Three broad categories emerged from participant responses that captured the essence of how fibromyalgia affects their lives. The categories are well-being, symptoms, and the consequences of this enigmatic syndrome.

4.3.3.2. Well-being

Participants identified that FM affected there overall well-being, and specifically their physical, emotional/psychological, and social well-being.

> "*It's a very negative effect. It is destruction of a way of life. It is a compromise in every area of life. It is a death in a certain respect*." (P3)
>
> "*Well, in some instances, it affects me significantly and in others, it's just an issue always there. You sort of work your life around* it." (P4)
>
> "*It affects every aspect of my life. It controls me and it controls my day*." (P15)
>
> "*I don't let fibromyalgia control me. I'm constantly fighting not to let it win, so regardless of how bad I feel, I don't give in to it*…" (P2)

Fibromyalgia changed the physical well-being of participants, specifically performance of activities.

> "*Before I was sick I could do a lot of physical things that I can't do*." (P10)
>
> "*Certain things you want to do a lot of times you won't do something that you are supposed to do because you are unable to do it. Sometimes it is too painful to do it*." (P13)
>
> "*But if I try to do too many things, like say I go on a trip, I went on a 3-day trip - one of those days my body will literally shut down because it's too much activity for me in such a short time*." (P8)

Most participants reported that fibromyalgia affected their emotional/psychological well-being negatively.

> "*It makes me feel depressed and angry. I feel like I'm stupid because I can't do it. You know, that it hurts then you have to remember well its*

fibromyalgia well, maybe it is, well okay let's get out of this mood." (P5)

"*It is depressing. It's frustrating. It causes anxiety. It makes you feel not as important anymore or that you can't do the things that you once did so that makes you feel a little inferior to co-workers, colleagues, and friends. It causes a lot of disappointment internally*." (P11)

Fibromyalgia also imposed social limitations and isolation on participants.

"*I couldn't go out Friday night and Saturday night on the weekend. I can't keep up with what everybody else does. If we go to a social function where most people are just waking up and ready to do whatever. I'm tired at a certain point at night.* " (P8)

"*I tend to…I tend to not want to be around anybody. I just want to be, I just tend to isolate myself. I just don't want anybody in and I don't want anybody to get too close. That type of thing. It protects me*." (P3)

4.3.3.3. Symptoms

Symptoms identified by participants focused on cognitive, emotional/psychological, and physical characteristics of the syndrome. Participants reported both comprehensive lists of classic fibromyalgia symptoms as well as specific examples of cognitive, emotional/psychological, and physical symptoms.

"*It gives me pain, it exhausts me and it gives me fibro-fog, it gives me migraines. It impairs my coordination. It affects my sleep, my relationships, my patience, my parenting, and my stamina, just about everything*." (P10)

"*I have pretty much all of the symptoms that I have read about fibromyalgia. I particularly have insomnia, headaches, pain, lack of coordination, memory impairment, and foggy brain at times*." (P2)

Specific cognitive changes recalled were difficulties with concentration, memory, thinking clearly, and decision-making.

"*It affects my concentration. I can't do this well, especially when I am stressed, tense and get overwhelmed, I can't think clearly, I can't process information, I can't make a decision, especially when I was working that was very impairing for me. I can't multitask*." (P10)

"*Loss of memory is an emotional one for me because I try to hide this from people. This is the one that I don't even like to look at, because I feel so helpless with it. With pain, you try to do little things to stop the pain. But with the memory, I mean, I tried vitamins, I try exercising, I try different things. But really, there's nothing that's helping your memory. That's the one obvious thing that you can't camouflage. I can't suck it up and get by with it. If it's not there, it's not there. So this one is very hurting. I can't hide. I can't explain it*." (P3)

The emotional/psychological effects of fibromyalgia symptoms recounted most often were frustration, anxiety, depression, and anger.

"*It's frustrating. It causes anxiety*." (P11)

"*It makes me feel depressed and angry*." (P5)

It's taking a very severe mental toll and I would say basically, it is an

exacerbation of what I have as reoccurring major depression." (P1)

The participants cited the cardinal symptoms of pain and fatigue/exhaustion most often followed by sleep issues, headaches, coordination impairments, vision changes, and gastrointestinal issues as the physical symptoms of fibromyalgia. Participants described how these symptoms changed their temperament, restricted daily routines, and created a viscous cycle of fibromyalgia symptoms.

"*The pain at times can make you sick. It can make you mean and just totally takes over your life*." (P13)

"*If I am having a lot of pain, I may not necessarily be able to do what I planned that day."* (P15)

"*It's totally exhausting*." (P1)

"*I always feel tired*." (P5)

Sleep issues were reported as cyclical and related to pain and headaches.

"*Fibromyalgia currently affects me with my sleep; I have trouble sleeping. If I don't sleep at least 8 hours, I start having a lot of pain in my back and in my joints, my hands bother me a lot, my knees and my muscles in my legs and sometimes my shoulders, and I get migraine headaches that can be pretty debilitating*." (P14)

Impaired coordination, gastrointestinal distress, and vision changes were other physical symptoms indicative of the effects of fibromyalgia.

My hand coordination is a problem; that's a real problem because I have no strength in my hands…I've had constipation quite a bit of the time, a lot of problems with GERD which I think are related to

fibro and my eyes are dry a lot of times and sometimes they hurt." (P14)

Some days I don't see as well." (P5)

4.3.3.4. Consequences

Participants identified many consequences of fibromyalgia. The consequences of this chronic syndrome represented positive changes, relationship complications, and lost capabilities.

The positive changes conveyed were management strategies namely acceptance, adaptations, and professional therapeutic interventions.

"*It took me a lot of years and when I say a lot of years I mean 5, 6, 7 years to accept my diagnosis. I don't know whether I accepted it, but I understand now*." (P15)

"*Because it does force you to look at what's important to you and what's important to your family…It's a new way of living. And in some ways it's a nicer way of living because you're more conscious*." (P4)

Participants described how they adapted their way of living since their diagnosis of fibromyalgia.

"*I think now that I have taken more control and I have had to change my life to work around the fibromyalgia. The fibromyalgia itself is not changing, so I tried to change my life to accommodate how I respond to it. Exercise is important to feel good and to be able to balance and pace yourself are important things to be able to do to manage my symptoms*." (P10)

"*I do find that I do a lot more things impromptu than I did before*

*because it's hard to plan." (*P4)

"I eat a high fiber, low-fat diet in order to try to deal with the symptoms.

I drink a lot of water and I have to go to the doctors more often than people I know. (P14)

Several participants identified professional therapeutic interventions as having a positive impact on how fibromyalgia affects their lives.

"*My doctor gives me a shot for my back to help with the back*

pain that I have, gives me tune-ups, and helps me to figure

out what I need to do next, how I can improve my situation

and that is all very helpful." (P14)

"*The physical therapist was a big help because she helped me*

find new ways of doing things that kept me moving… And the

other that I think was really helpful was my shrink, change how

you think about it, be kinder to yourself. Do what you can and

enjoy it and don't worry if you can't do other things. " (P4)

Participants reported how their relationships with family and friends were complicated because of fibromyalgia.

"*It affects most importantly my relationship with my son. He*

gets angry and bitter a lot with me because mommy is always

hurting and mommy is also tired, and he kind of gets tired of hearing it." (P15)

"*Well just because I do have pain and I am fatigued a lot of the*

time, just anytime you have a relationship whether it is with a spouse or

with my child or even you know other family and friends, when I can't do

what I used to be able to do or what other people expect to be able to do

it takes away from my ability to be who I want to be as a mother, who I want to be as a wife and who I want to be as a friend." (P10)

Lost capabilities were among the consequences for persons with fibromyalgia. Participants identified daily routine, leisure activities, and home management tasks as the specific activities affected by lost capabilities.

"*It affects me in that I have lost the capability of doing a great many things. I've lost the capability of having a normal day*." (P1)

"*Well it affects my daily routine because of the pain*." (P7)

"*It affects every single part of your being. Everything changes, it doesn't stay the same*." (P13)

"*Like I haven't played tennis in a couple of years because of it*. (P6)

I did not take a vacation this year because it's a short vacation and just packing and getting going and coming back, it is just too much effort, things like that." (P9)

"*It definitely affects what my house looks like because I am not able to keep up and keep it clean the way I like to because I am in pain so much of the time and also because I don't sleep well at night, then I'm tired and a lot of the time and I just don't have the energy to keep up*." (P15)

4.3.4. GT #2: "What triggers your fibromyalgia flares?"

Grand tour question #2 was posed to explore what participants considered triggers of their fibromyalgia flares. Overall, participants identified activity, fibromyalgia symptoms, weather, major events, cognitive tasks, food, and odors as the triggers. The three most substantial categories of triggers of fibromyalgia flares were activity, fibromyalgia symptoms, and weather.

4.3.4.1. Activity

Practically all participants reported that activity triggered a fibromyalgia flare. Activity was further differentiated into the following categories: over doing or over-exertion, activity away from home, mobility, exercise, and deviation from set routine.

> "*When I overdo. If I feel well and I overdo something, then I pay for it later*." (P7)
>
> "*Just over doing things like if I have long shopping excursions or any over physical things or over mental things or just going to the mall." (P10)*
>
> *"And interestingly enough, I think traveling would trigger it*." (P4)
>
> "*Walking will trigger you if you walk too long because your heels hurt and your feet hurt and that bothers your knees that will trigger you*." (P3)
>
> "*Other things are, if I overdo exercise because I have an elliptical trainer and if I do more than 10 minutes at a time, I pay for it later*…"(P14)
>
> "*One of the things that I know does it, is if I don't keep a standard schedule*." (P4)

4.3.4.2. Symptoms

Fibromyalgia symptoms were said to trigger flares, in particular, sleep issues, stress, and vision changes.

> "*I think the sleeping issue is like a vicious cycle. The sleeping seems to trigger the fibromyalgia and the fibromyalgia is what keeps you from sleeping well*." (P4)
>
> "*Stress is my biggest one that I have always been aware of but didn't want to accept but when I am under a lot of stress that's what flares my IBS* [irritable bowel syndrome] *and my pain flares*." (P11)
>
> "*Sometimes my eyes trigger. For some reason my eyes bother me a great deal, they say they believe it's the fibro that is triggering pressure. And that trigger, triggers your headaches, triggers the neck, triggers the back*." (P3)

4.3.4.3. Weather

Most participants reported that weather triggered a flare, specifically any change of weather, changes in temperature, changes in the barometric pressure, and approaching weather fronts.

> "*Weather changes – definitely and it doesn't really matter like -it's the change in the weather not necessarily the type of weather*." (P15)
>
> *Weather is a factor; cold, damp weather is bad*. (P10)
>
> "*The light bulb just went on yesterday; the barometric pressure bothers*

me." (P11)

I have noticed long before being diagnosed formally with fibromyalgia that I was having very difficult days on rainy days or before we would have a big storm coming in the next day, I would be severely tired." (P1)

4.3.5. GT #3: "What activities trigger your fibromyalgia flares?"

Grand tour question #3 was posed to discover which activities triggered fibromyalgia flares. In general, participants identified types of activity (i.e., those away from home, strenuous activity, outdoors activity, and everyday activity), mobility, home management, fibromyalgia symptoms, and other (i.e., not pacing, poor body mechanics, poor stress management, and cognitive tasks) as the activity triggers. The three most substantial categories of activity triggers of fibromyalgia flares were types of activity, mobility, and home management.

4.3.5.1. Types of Activity

Overall participants identified activity away from home, strenuous activity, outdoors activity, and everyday activity as types of activities that triggered a fibromyalgia flare. Activities away from home generated the most responses; with strenuous activity, outdoors activity, and everyday activity all reported equally.

"*Going to the grocery store and lifting heavy packages, that all triggers it*." (P7)

"*Okay, specific to my work, I find that going to a conference w*ould *trigger it or going on a vacation even*." (P9)

"*Being around a lot of people tends to, activities where there are uncomfortability around a lot of people might trigger me*." (P3)

"*Well like I said sometimes it is just over doing any strenuous activity*." (P10)

"*One of the worst is getting carried away in the garden*." (P1)

"*Sitting too much triggers a flare-up; too much of anything it seems*." (P15)

4.3.5.2. Mobility

In general, participants considered mobility as activities that triggered a fibromyalgia flare. Mobility was categorized as standing, climbing stairs, walking, and lifting heavy objects.

"*The most specific one is standing. If I stand too long to do anything the back gives out, the hips starts to hurt and, I get anxious."* (P4)

"*…Going up and down the steps a lot… If I walk three blocks, someone would have to carry me home*." (P5)

"*Anything you have to lift. I think heavy things like the groceries you know you have to put them up*." (P12)

4.3.5.3. Home Management

Home management tasks were usually reported as activities that triggered a fibromyalgia flare. Participants identified home management tasks such laundry, cleaning (i.e., scrubbing walls, vacuuming, making beds) and, cooking.

"*I noticed washing. I keep a big comfortable chair downstairs, even though it's just a cellar and there's nothing to look at but storage stuff all over the place. When I'm doing laundry, I do not walk the steps, because it bothers my legs so badly and even my arms will ache from carrying the basket*." (P1)

"*If I overdo the housework, like a good cleaning...*" (P7)

"*Specifically I can't say that for 8-hours I will bake for the kids making cookies and things that everybody likes or making a big dinner. We even got away from the big dinners*." (P13)

4.3.6. GT #4: "What activities have you given up due to your symptoms?"

Grand tour question #4 was posed to explore what activities participants have given up due to their fibromyalgia symptoms. The categories of activities given up were those away from home, mobility, home management, interaction with family and friends, outdoors activities at home, keyboarding, reading, and personal care. The three most substantial categories of activities given up due to fibromyalgia flares were activities away from home, home management, and mobility.

4.3.6.1. Activity away from home

When describing activities away from home that were given up, participants spoke mainly about physical sports-type activities (i.e., boating, rock climbing, tennis, golf, volleyball, skiing), leisure activities (i.e., movies, dancing, shopping, traveling, socializing), exercise, work, church attendance, and errands.

"*Tennis and volleyball because I tend to get headaches, neck pain, and muscle tension pretty bad*." (P6)

"*Going shopping, going out to go dancing, or going out with friends because in the past if I would go out with somebody they may think wow we'll go out and spend time in the evening where we could come back like at 2:00 – I can't do that*." (P14)

"*When I am in a major fibro flare, I was on medical leave probably 9 out of 12 months until just this spring and when I could return to work. I could not physically do my day-to-day duties for work*." (P11)

4.3.6.2. Home management

Several participants indicated that they have given up home management activities due to their fibromyalgia symptoms.

"*Household activities that I have not been able to do that my husband has taken over for me. Not that I miss it but laundry, shopping, vacuuming, and dishes ...*" (P10)

"*I used to do a lot more in depth cleaning of the furniture. I used to clean it and then lemon oil it down and make sure it was absolutely spotless. Never used a rag once it had anything on it. Now, if it gets dusted off with a*

Kleenex every 6 months, it's doing good." (P1)

4.3.6.3. Mobility

Some participants have given up mobility to some extent due to their fibromyalgia symptoms.

"*Walking, I used to walk all over this neighborhood. I mean I would walk for over an hour and I have actually given that up*." (P5)

"*Walking, just accessibility things that are continually a struggle and frustrating, when there are tons of steps in front of you and no way around them*." (P10)

4.3.7. GT #5: "What activities do you immediately engage in when you start to feel better after a flare?"

Grand tour question #5 was posed to query what activities participants immediately engage in when they started to feel better after a flare. The categories of activities immediately resumed were those away from home, home management, and general (i.e., reading, self-care, care giving, needle art, outdoors activity, and normal routine).

4.3.7.1. Activities away from home

Activities away from home were identified as those immediately resumed when participants started to feel better after a flare.

"*Go shopping for the day instead of the hour*." (P13)

"*I like to go sit in the park with God that's my biggest one,*

just to be or just sit and look at the night sky. Sit with God." (P3)

"*I'll go back to working out*." (P8)

4.3.7.2. Home management

Home management activities were among those participants immediately resumed when participants started to feel better after a flare.

"*I would say, cleaning projects around the house, that type of thing*." (P2)

The key word is immediately…I would do my laundry, I

would clean, vacuum, do my household things, go out and get the

necessities at the store..." (P11)

4.3.7.3. General activities

Participants reported a wide range of activities labeled as "general" that they immediately resumed when started to feel better after a flare. These activities were reading, self-care, care giving, needle art, outdoors activity, and normal routine.

"*And one of the things that I usually do early on is, taking a shower*

and shaving my legs and washing my hair. I like to do all that every

day and I can't do that on a regular basis." (P4)

"*And when I do that, I just get back to normal activity*."(P6)

"*Everything that I'm not supposed to do. Everything because right after*

the flare you feel so… when it is all done and over, the pain." (P13)

4.3.8. SIF Note Cards: 10 Most Severe Fibromyalgia Symptoms

Presented in Table 4.6 are the 10 most severe fibromyalgia symptoms, by participant. Pain was ranked the most severe fibromyalgia symptom, followed by fatigue, frequent headaches, stiffness, and poor sleep to represent the 5 most severe fibromyalgia symptoms. Thirty-five symptoms were included on the SIF with another added by a participant; 3 of the original 35 were not reported by study participants: chest pain, breathlessness, and panic attacks.

4.3.9. Weighted Rank Order Totals of Symptoms from Symptom Identification Form

Presented in Table 4.7 are the weighted rank order totals for the fibromyalgia symptoms from the SIF. The weighted rank order (WRO) totals ranged from 131 to 0. Of the 36 symptoms, the top five WRO values were: pain (131), fatigue (111), poor sleep (74), daytime sleepiness (51), and stiffness (47). WRO enables both the frequency and intensity of a response to be represented (Carroll & Lovejoy, 2005).

Table 4.6: Symptom Identification Form 10 Most Severe Fibromyalgia Symptoms, by Participant

Symptoms	Participant 1	Participant 2	Participant 3	Participant 4
1	Pain	Pain	Pain	Pain
2	Fatigue	Impaired coordination	Fatigue	Poor sleep
3	Pain after exertion	Frequent headaches	Frequent headaches	Fatigue
4	Depressed moods	Fatigue	Dry or itchy eyes	Dizziness
5	Daytime sleepiness	Poor sleep	Poor sleep	Impaired coordination
6	Swelling or bloating	Light headedness	Daytime sleepiness	Excessive fatigue for > 6 months
7	Severe fatigue after exercise	Frequent & urgent urination	Loss of memory	Pain that keeps you awake
8	Constipation	Impaired logical reasoning	Restless legs	Muscle weakness
9	Loss of memory	Excessive anxiety	Pain that keeps you awake	Stiffness
10	Awaken feeling tired	Intermittent loose stools	Depressed moods	Awaken feeling tired

Table 4.6 (continued)

Symptoms	Participant 5	Participant 6	Participant 7	Participant 8
1	Pain	Poor sleep	Pain	Fatigue
2	Fatigue	Daytime sleepiness	Muscle weakness	Awaken feeling tired
3	Muscle weakness	Depressed moods	Frequent & urgent urination	Stiffness
4	Stiffness	Frequent & urgent urination	Stiffness	Swelling or bloating
5	Tenderness of skin	Pain after exertion	Joint swelling	Constipation
6	Daytime sleepiness	Swelling or bloating	Pain after exertion	Pain
7	Dry or itchy eyes	Abdominal distension	Pain that keeps you awake	Intermittent loose stools
8	Awaken feeling tired	Premenstrual syndrome	-----	Frequent & urgent urination
9	Loss of memory	Awaken feeling tired	-----	Premenstrual syndrome
10	Excessive fatigue for > 6 months	Pain	-----	Tenderness of skin

Table 4.6 (continued)

Symptoms	Participant 9	Participant 10	Participant 11	Participant 12
1	Fatigue	Pain	Pain	Fatigue
2	Pain	Fatigue	Fatigue	Pain
3	Poor sleep	Awaken feeling tired	Daytime sleepiness	Poor sleep
4	Daytime sleepiness	Stiffness	Poor sleep	Stiffness
5	Depressed moods	Impaired logical reasoning	Pain that keeps you awake	Dry or itchy eyes
6	Awaken feeling tired	Frequent headaches	Muscle weakness	Depressed moods
7	Excessive fatigue for > 6 months	Loss of memory	Impaired logical reasoning	Severe fatigue after exercise
8	Frequent & urgent urination	Pain that keeps you awake	Frequent & urgent urination	Excessive anxiety
9	Excessive anxiety	Depressed moods	Impaired coordination	Pain that keeps you awake
10	Pain that keeps you awake	Daytime sleepiness	Joint swelling	Daytime sleepiness

Table 4.6 (continued)

Symptoms	Participant 13	Participant 14	Participant 15
1	Pain	Pain	Fatigue
2	Fatigue	Poor sleep	Daytime sleepiness
3	Pain that keeps you awake	Frequent headaches	Excessive fatigue for > 6 months
4	Loss of memory	Constipation	Pain
5	Poor sleep	Hands change color in cold	Pain that keeps you awake
6	Stiffness	Dry or itchy eyes	Poor sleep
7	Depressed moods	Stiffness	Frequent headaches
8	Awaken feeling tired	Anxiety, stress	Awaken feeling tired
9	Pain after exertion	Fatigue	Pain after exertion
10	Muscle weakness	Difficulty swallowing	Abdominal cramping

Table 4.7: Weighted Rank Order Totals of Symptoms from the Symptom Identification Form

Symptoms	Weighted Rank Order Totals
Pain	131
Fatigue	111
Poor sleep	74
Daytime sleepiness	51
Stiffness	47
Pain that keeps you awake	36
Awaken feeling tired	35
Depressed moods	33
Frequent headaches	33
Frequent & urgent urination	28
Muscle weakness	26
Pain after exertion	23
Dry or itchy eyes	22
Loss of memory	19
Excessive fatigue > 6 months	18
Impaired coordination	17
Swelling or bloating	17
Constipation	16
Impaired logical reasoning	13
Severe fatigue after exercise	8
Excessive anxiety	7
Joint swelling	7
Dizziness	7
Tenderness of skin	7
Hands change color in cold	6
Premenstrual Syndrome	5
Intermittent loose stools	5
Light headedness	5
Restless legs	4
Anxiety/stress	3
Difficulty swallowing	1
Abdominal cramping	1
Chest pain	0
Breathlessness	0
Panic attacks	0

Note. The broken line separates the 10 most severe fibromyalgia symptoms reported.

4.3.10. GT #6: "Tell me about how your symptoms change throughout the day, and if there is a pattern."

Grand tour question #6 was posed to explore fibromyalgia symptom changes and patterns as reported by the participants. Participants mainly described symptom changes and patterns relative to time of day, therefore, we categorized time of day as morning (5am to 11:59am), daytime (12:00pm to 9:00pm), and nighttime (9:01pm to 4:59am).

4.3.10.1. Morning symptom changes and patterns

Symptoms experienced in the morning were fatigue, pain, stiffness, headaches, coordination impairments, light-headedness, muscle weakness, and neuropathy. Fatigue/tiredness, pain, and stiffness were the most prominent.

> "*In the morning, I wake up usually a little tired so it takes a few minutes to get out of bed, but not long like a minute." (P8)*
>
> *I always wake up tired. Always*." (P9)
>
> "*It's an overall everything hurts. No matter what you do or no matter what you take; it doesn't get any better*." (P13)
>
> "*Okay when I first wake up in the morning, my back is always killing me*." (P12)
>
> "*For instance, the stiffness, the overall stiffness is in the morning. And then by the time, I've moved around and had a bowl of cereal or something, the stiffness is moving away*." (P4)

4.3.10.2. Daytime symptom changes and patterns

Participants cited pain and fatigue/tiredness as their most cyclic daytime symptoms. Symptoms present to a lesser extent were, stiffness, headaches, stress, coordination impairments, dizziness, and frequent urination.

"*There's a lot of pain in my low back, tremendous pain and that stays throughout the day*." (P3)

The pain gets less as the day goes on. (P7)

Fatigue that is usually late afternoon and in the evening; again, if I don't exercise, that's worst, if I exercise, it is a lot better." (P14)

"*Sometimes I don't feel very well and once I start working, the harder I work, the better I feel. And often after I've finished something and I'm completely exhausted, but I still have things to do so then I'm dragging even though I do everything, I'm really pushing. That would probably be the pattern*." (P2)

4.3.10.3. Nighttime symptom changes and patterns

Less than half of the participants spoke of nighttime symptom changes and patterns. Those experienced were fatigue, stiffness, vision changes, dry mouth, frequent urination, and tenderness of skin.

"*I mean I don't know if it is skin tenderness part, I am not sure of if it is because it bothers my neck but in the morning I will get up and like if something is on my shoulder sometimes half the time I take off my*

pajamas at night because they bother me." (P12)

"*Usually about 9:00 or 10:00, I can hardly hold my eyes open.*

That's about the time when I'm really fighting to hang in there."(P3)

"*I wake up around 3:00 or 4:00 AM and then I don't sleep well*

because my mouth is pasty and dry." (P6)

4.3.10.4. SIF Note Cards: 5 Most Severe Fibromyalgia Symptoms and the 5 Activities Most Affected by Those Symptoms

Presented in Table 4.8 are the 5 most severe fibromyalgia symptoms and the 5 activities most affected by those symptoms, by participant. Cleaning/home maintenance was ranked the activity most affected by fibromyalgia symptoms; followed by walking, socializing, shopping, exercise, working, carrying/lifting things, and cooking/meal preparation.

4.3.11. Weighted Rank Order Totals of Activities Affected by Fibromyalgia Symptoms

Presented in Table 4.9 are the weighted rank order totals for the activities most affected by fibromyalgia symptoms. The weighted rank order (WRO) totals ranged from 81 to 1. Of the 59 activities, top five WRO values were: cleaning/home maintenance (81), working (67), walking (64), exercise (49), and socializing and carrying/lifting things (44 – tied ranks). WRO enables both the frequency and intensity of a response to be represented (Carroll & Lovejoy, 2005).

Table 4.8: Five Most Severe Fibromyalgia Symptoms and Five Most Affected Activities

Participant & Symptoms	Activity 1 Affected	Activity 2 Affected	Activity 3 Affected	Activity 4 Affected	Activity 5 Affected
Participant 1					
1. Pain	Motion	Gardening	Laundry	Room cleaning	Reading
2. Fatigue	Laundry	Room cleaning	Gardening	Washing car	Motion
3. Pain after exertion	Room cleaning	Gardening	Washing car	Shopping	Laundry
4. Depressed mood	Laundry	Cleaning	Outside activities	Reading	Socializing
5. Daytime sleepiness	Monitoring diabetes	Laundry	Cleaning room	Washing car	Shopping
Participant 2					
1. Pain	Walking	Riding in car/traveling	-----	-----	-----
2. Impaired coordination	Everything	Working	Walking	-----	-----
3. Frequent headaches	Uncontrollable things	Socializing	Reading	-----	-----
4. Fatigue	Home maintenance	Heavy yard Working	-----	-----	-----
5. Poor sleep	Socializing	-----	-----	-----	-----
Participant 3					
1. Pain	Walking	Lying down	Sitting	Focus/concentration	Eyes
2. Fatigue	Memory	Focusing on things	School	Socializing	Carrying things
3. Frequent headaches	Life stops	-----	-----	-----	-----
4. Dry or itchy eyes	Opening eyes	Reading	Working on PC	Driving	-----
5. Poor sleep	Getting up in morning	Lack of alertness	Stiffness	-----	-----
Participant 4					
1. Pain	Standing	Sitting	Walking	Cooking	Shower/washing hair
2. Poor sleep	Waking when turning	Sleep positions	Coordination	Wake up tired	Quick logical thinking
3. Fatigue	Coordination	Walking	Thinking	Sitting/standing	Sleeping
4. Dizziness	Walking up steps	Carrying things	Standing projects	Reading	Eating
5. Impaired coordination	Walking	Dressing	Exercise	Writing	Computer & keyboard

Table 4.8 (continued)

Participant & Symptoms	Activity 1 Affected	Activity 2 Affected	Activity 3 Affected	Activity 4 Affected	Activity 5 Affected
Participant 5					
1. Pain	Carrying heavy objects	Walking	Shopping	Gardening/yard work	Exercise
2. Fatigue	Waking up	Living	Walking	Every day things	Exercise
3. Muscle weakness	Walking	Shopping	Climbing stairs	Carrying heavy objects	Exercise
4. Stiffness	Waking up	Climbing stairs	Repetitive motions	Every day things	Making breakfast
5. Tenderness of skin	Massage	Walking	Sleeping	Shopping	Driving
Participant 6					
1. Poor sleep	Concentration	Energy	Motivation	-----	-----
2. Daytime sleepiness	Distracted in afternoon	Shopping	-----	-----	-----
3. Depressed moods	Drive to achieve	-----	-----	-----	-----
4. Frequent & urgent urination	Diet restrictions (tea)	Running	Jumping	-----	-----
5. Pain after exertion	Lifting	Tennis	Volleyball	-----	-----
Participant 7					
1. Pain	Home maintenance	Climbing stairs	Carrying heavy objects	Shopping	Meal preparation
2. Muscle weakness	Carrying heavy objects	Bending over	-----	-----	-----
3. Frequent & urgent urination	-----	-----	-----	-----	-----
4. Stiffness	Exercise	House cleaning	-----	-----	-----
5. Joint swelling	-----	-----	-----	-----	-----
Participant 8					
1. Fatigue	Leisure activities	Shopping	Meal preparation	Exercise	Socializing
2. Awaken feeling tired	-----	-----	-----	-----	-----
3. Stiffness	Being in cold weather	Carrying heavy objects	-----	-----	-----
4. Swelling or bloating	-----	-----	-----	-----	-----
5. Constipation	-----	-----	-----	-----	-----

Table 4.8 (continued)

Participant & Symptoms	Activity 1 Affected	Activity 2 Affected	Activity 3 Affected	Activity 4 Affected	Activity 5 Affected
Participant 9					
1. Fatigue	Working	Visiting family/friends	Home maintenance	Leisure activities	Socializing
2. Pain	Home maintenance	Self-care (hair care)	Walking (exercise)	Driving a car	Shopping
3. Poor sleep	Working	Self-care	Walking	Socializing	Home maintenance
4. Daytime sleepiness	Working	Self-care	Walking	Socializing	Home maintenance
5. Depressed moods	Socializing	Healthy eating	Walking	Sleeping (too much)	Visiting family/friends
Participant 10					
1. Pain	Shopping - groceries	Walking on stairs	Home maintenance	Leisure activities	Socializing
2. Fatigue	Exercise	Thinking clearly	Socializing	Family care giving	Meal preparation
3. Awaken feeling tired	Getting breakfast	Moving on with day	-----	-----	-----
4. Stiffness	Walking	Stairs	Exercise	Meal preparation	Keyboard
5. Impaired logical reasoning	Decision making	Multitasking	Math/figures	-----	-----
Participant 11					
1. Pain	Working	Socializing	Computer use	Home maintenance	Visiting family/friend
2. Fatigue	Working	Socializing	Computer use	Visiting family/friend	Reading
3. Daytime sleepiness	Working	Socializing	Home maintenance	Meal preparation	Driving
4. Poor sleep	Working	Leisure activities	Socializing	Driving	Shopping
5. Pain that keeps you awake	Working	Driving	-----	-----	-----
Participant 12					
1. Fatigue	Exercise	Cleaning	Carrying heavy objects	Working in yard	Computer Working
2. Pain	Vacuuming	Lifting heavy objects	Exercise	Staying in one position	Reading a book
3. Poor sleep	Exercise	Cleaning	Shopping	Socializing	Traveling
4. Stiffness	Sitting	Sleeping	Carrying heavy objects	Exercise	Driving
5. Dry or itchy eyes	Computer Working	Reading	Driving	Shopping	Night vision

Table 4.8 (continued)

Participant & Symptoms	Activity 1 Affected	Activity 2 Affected	Activity 3 Affected	Activity 4 Affected	Activity 5 Affected
Participant 13					
1. Pain	Church	Cooking	Walking	Shopping	Sleep
2. Fatigue	Babysitting grand	Interacting with kids	Church	Sleeping	Cleaning
3. Pain that keeps you awake	Overall mood change	Sleeping	Daily activities	Moving in bed	-----
4. Loss of memory	Paying bills	Conversations	Daily activities	Church	Cooking
5. Poor sleep	Cleaning	Walking	Shopping	Laundry	Preparing dinner
Participant 14					
1. Pain	Walking	Sitting	Standing	Sleeping	Lifting/moving >5 lbs.
2. Poor sleep	Everything	Thinking	Moving	Exercise	All ADL
3. Frequent headaches	Thinking	Computer use	Working	-----	-----
4. Constipation	Exercise	Eating/drinking	-----	-----	-----
5. Hands change color in cold	Using keyboard	Doing dishes	Driving	House Working	Driving
Participant 15					
1. Fatigue	Working	Interacting with son	Carrying heavy objects	Laundry	Meal preparation
2. Daytime sleepiness	Working	Interacting with son	Meal preparation	Shopping	Carrying heavy objects
3. Excessive fatigue for > 6 months	Time with son	House Working	Short-term memory	Concentration	Attention span
4. Pain	Working	Playing with son	Exercise	Walking	Yard Working
5. Pain that keeps you awake	Working	Playing with son	Driving	House Working	Concentration

Note. Socializing = socializing away from home. Home maintenance described as managing things around the home (i.e., cleaning). PC = personal computer. grand = granddaughter. lbs. = pounds. Activities of daily living = ADL.

Table 4.9: Weighted Rank Order Totals of Activities Affected Most by the Five Most Severe Fibromyalgia Symptoms

Activities	Weighted Rank Order Totals
Cleaning/home maintenance	81
Working	67
Walking	64
Exercise	49
Socializing	44
Carrying/lifting things	44
Shopping	41
Driving	29
Cooking/meal preparation	27
Walking up steps/climbing stairs	26
Computer/PC/keyboard	26
Sleeping	22
Family care giving/interactions	22
Laundry	22
Gardening/yard work	20
Reading	18
Sitting	18
Shower/dressing (self-care)	17
Waking up/getting up in morning	17
Thinking	17
Every day things/daily activities/living	15
Everything/life stops	15
Focus/concentration	14
Diet	14
Leisure activities	13
Standing	11
Sports (running, volleyball, tennis)	11
Church	10
Motion/moving	9
Coordination	8
Motivation/drive to achieve	8
Visiting family/friends	8
Memory	8
Alertness	8
Washing car	7
Visual concerns	7

Table 4.9 (continued)

Activities	Weighted Rank Order Totals
Waking when turning/moving in bed	7
Monitoring diabetes	5
Uncontrollable things	5
Distracted in afternoon	5
Being in cold weather	5
Decision making	5
Traveling	5
Baby sitting granddaughter	5
Paying bills	5
Mood changes	5
Conversations	4
Multitasking	4
Bending	4
Lying down	4
Outside activities	3
Stiffness	3
School	3
Jumping	3
Math/figures	3
Repetitive motions	3
Writing	2
Staying in one position	2
Attention span	1

Note. The broken line separates the 10 activities affected most by the five most severe fibromyalgia symptoms.

4.3.12. GT #7: "How do you manage your fibromyalgia symptoms daily, compared to how you manage them during a flare?"

Grand tour question #7 surveyed how participants managed their fibromyalgia symptoms daily versus during a flare.

4.3.12.1. Daily management

The following participant responses highlight the range of strategies employed to manage fibromyalgia symptoms daily, which tended to focus on medications, pacing, and planning.

> "*Daily, I tend to ignore them or take medication that helps me ignore them*." (P2)
>
> "*Daily I go with basically how I feel as to what I do. If I feel good that day, a little might get done than a day where I am not feeling well*." (*P13*)
>
> *Well daily, I try to pace my activities. One or two things a day, one major thing maybe and then a minor thing*." (P3)
>
> "*How I manage my fibro symptoms daily is by taking my medications at the appropriate times, taking my pain medication at the maximum dose regardless whether I have pain as a preventative measure. Try to get the appropriate sleep that I need daily to keep myself replenished and rested, try to manage things at a pace, I try to pace myself. Try not to overdo it, but when I do overdo it make sure it's at a time that when I do overdo it that I'm going to be able to rest the*

next day. I just manage my schedule more clearly and appropriately, I just prepare and plan things more in advance." (P11)

4.3.12.2. Flare management

The following participant responses highlighted the range of strategies employed to manage fibromyalgia symptoms during a flare, which ranged from injections to sleep to distraction to exercise.

"*During a flare, for my primary activity, I try to keep my mind off of it. Anything, I try to feel better. I do not manage it well when I eat – trying to feel better. However, I will just try to keep my mind off of it. I will play computer games, or I will watch television. I just try not to think about it and then I definitely get m*ore sleep. If I am really in a flare, I will be in bed at 9 instead of 10." (P9)

"*When I'm in a flare I usually give it a week. So the first week if I'm having a flare, I try to pay attention to my routine, am I sleeping, am I going to bed at the same time, what am I eating, am I drinking enough water, am I getting enough exercise or is it something that I'm doing too much of or too little of. So the main things I concentrate on when I'm having a flare are exercise and sleep…Then after the first week I call my doctor and then I do whatever he tells me to the letter*." (P14)

"*When I'm in a flare I call the doctor and beg them to fit me in.*

Depending how bad the flare is I usually get injections and if the injections don't work and the pain is still so bad I can't stand it, and then he'll give me a couple courses of steroids." (P15)

4.3.13. GT #8: "If you had a friend who was just diagnosed with fibromyalgia, what would you tell her/him is the best way to manage fibromyalgia symptoms?"

Grand tour question #8 was posed to explore what participants would recommend as management strategies for a person newly diagnosed with fibromyalgia. The themes repeated most often were finding a knowledgeable and supportive physician (preferably a rheumatologist) who believes that fibromyalgia is a genuine diagnosis, incorporating pacing into their management repertoire, being their own advocate by taking control of how they manage fibromyalgia, exercising, and monitoring their nutrition.

"*I think the best thing to do – the most important thing is to find a good doctor that understands fibromyalgia and is understanding of the condition*." (P15)

"*I guess the pacing is the biggest thing. You have to pace everything. You have to pace each individual project. You have to pace your whole day. You have to pace the plans that you make. You have to pace how you think about it*." (P4)

"*To take charge of your health care and not just you know take what this practitioner tells you without asking questions, that you need to be the one in charge and get as much information as you can and I give them places either the fibromyalgia network or the National Fibromyalgia*

Awareness Association." (P10)

"*I would say to them immediately, get into a warm water exercise plan." (P1)*

"Eat good healthy food, healthy meals. At least three meals, maybe six small meals. Drink lots of water." (P2).

4.3.14. Data Triangulation

Presented in Table 4.10 are the data triangulation results for the quantitative and qualitative data: FIQ data confirmed that selection subgroup participants (i.e., FIQ low, average, high) reported differences in FIQ impact at the time of the study interview, but their group maintained its place in the hierarchy of FM impact. The grand mean data for the quantitative data (i.e., the FIQ, the FIQ VAS pain, and the CSC) and the qualitative data (activities affected by FM symptoms), indicated graduated impact effects of FM on functional status and activity performance, based on the FM subgroups. The FIQ, the FIQ VAS pain, and the CSC grand means for the low FIQ subgroup were 37.2, 4.5, 13.0, and 23.3 respectively. The FIQ, the FIQ VAS pain, and the CSC grand means for the average FIQ subgroup were 47.5, 5.4, 17.4, and 29.2 respectively. The FIQ, the FIQ VAS pain, and the CSC grand means for the high FIQ subgroup were 74.7, 7.9, 24.8, and 42.5 respectively.

Table 4.10: Triangulation of Quantitative and Qualitative Data

Subgroup/Participant	Selection FIQ†		Interview FIQ†		Interview FIQ VAS Pain§		Interview CSC‡		Interview Activities Affected	
	M	*GM*	*M*	*GM*	*M*	*GM*	*M*	*GM*	*M*	*GM*
Low FIQ Impact		30.4		37.2		4.5		13.0		23.3
2	27.4		40.9		4.9		19		11	
6	9.3		30.1		3.5		14		12	
7	44.4		37.2		4.2		6		9	
12	44.4		55.2		6.2		18		44	
13	25.7		41.5		2.8		8		28	
14	31.3		18.7		5.8		13		36	
Average FIQ Impact		47.7		47.5		5.4		17.4		29.2
4	45.9		62.4		6.3		25		31	
5	45.3		56.5		7.0		18		28	
8	45.0		35.6		0.2		12		8	
10	50.1		54.8		5.6		22		29	
11	52.0		28.3		8.1		10		50	
High FIQ Impact		62.2		74.7		7.9		24.8		42.5
1	60.0		77.7		7.3		27		41	
3	75.7		65.8		9.9		30		28	
9	56.6		80.7		6.3		24		51	
15	56.6		74.5		8.1		18		50	

Note. *M* = Mean. *GM* = Grand mean. † Fibromyalgia Impact Questionnaire (FIQ; range = 0 – 80); higher score indicates greater impact. § Fibromyalgia Impact Questionnaire Visual Analog Score Pain (FIQ VAS Pain; range 0 - 10); higher score indicates greater pain severity. ‡ Current Symptoms Checklist (CSC; range = 0 – 34); higher score indicates greater number of current symptoms.

4.4. DISCUSSION

The purpose of this study was to use mixed methods to identify clinically relevant triggers of fibromyalgia flares, experienced by three subgroups women with low, average, and high fibromyalgia impact, and explore the effect of triggers on their functional status. Using mixed methods, we were able to substantiate, quantify, and qualify the affects of fibromyalgia on the lives of person with chronic FM and the direct consequences of those affects on activity. As the manifestations of fibromyalgia are varied, to date no consensus exists as to the most appropriate management of the symptoms and consequences of FM (Adams & Sim, 2005; Okifuji & Ashburn, 2001; Oliver, Cronan, & Walen, 2001; Rossy et al., 1999; Sim & Adams, 2002). The mixed methods used in the current study yielded convergent findings on how FM affected the participants. The ethnographic techniques also provided insight into losses and gains experienced by persons with FM, activities that triggered FM flares, and management strategies that reduced the impact of FM on their daily lives.

Generally, participants reported that fibromyalgia negatively affected their lives with regard to the quantity and severity of symptoms, the intrapersonal and interpersonal challenges, and the limitations on their activity --- both in response to symptoms or to avoid the triggering of symptoms. Specifically, participants reported that FM negatively impacted their overall well-being, and left them to confront numerous unwanted symptoms and negative consequences of FM in their daily lives. Because of the overall negative affect of FM on their lives, they were acutely aware of the losses that it caused in their lives, especially in activity participation and relationships. Participant perceptions were confirmed by both the study selection FIQ subgrouping (i.e., low, average, high impact) of the participants and the interview FIQ

subgrouping, which showed decreased activity and increased symptomotology, based on subgroup, as well as fluctuations within participants, and subgroups (i.e., low, high) over time. Previous research has also found modest fluctuations in FM impact over time (Kennedy & Felson, 1996; White & Nielson, 1995) and among daily activities (Henriksson et al., 1992; Schaefer, 2005; Söderberg et al., 1999). While the most severe FM symptoms of our participants matched the classic array of FM symptoms (e.g., pain, fatigue, poor sleep), the specific activities impacted varied based on individual lifestyles. For example, activities affected by pain ranged from reading to gardening and those impacted by fatigue ranged from basic motions to doing the laundry. Our findings have added to the body of knowledge by identifying which the activities most impacted by the most common FM symptoms, and by confirming that as FM impact increases, so do the number of activities affected. Another contribution of the current study is the identification of personal gains made by participants because of how FM affected their lives. Positive consequences of FM included being forced to examine what was important in life, taking control of one's life, eating healthier, learning to balance and pace activities, and exercising.

The identification of relevant triggers of fibromyalgia flares was a critical component of the current study. Overall activity, FM symptoms, and weather were the most prominent triggers reported. The cyclical effect of activity and fibromyalgia symptoms as triggers of fibromyalgia flares is not surprising. The cycle of pain experienced by individuals with fibromyalgia has been shown to diminish physical performance, cause fear-avoidance behaviors, and limit activities of daily living (Keel, 1999). The findings of the current study parallel and complement the results by Keel. Our participants reported that over doing an activity or over-exertion during an activity, activities away from home, mobility, exercise, and deviation from a normal routine were definite

triggers of a flare. In addition to activity, sleep issues and stress were reported to trigger a flare, which is consistent with the literature (Moldofsky, 1989; Nicassio, Moxham, Schuman, & Gevirtz, 2002; Wentz, et al., 2004). Weather emerged as the other significant trigger of fibromyalgia flares, namely change in weather, changes in temperature, the barometric pressure, and approaching fronts. Waylonis and Heck (1992) reported similar findings, however, beliefs about weather as a trigger of fibromyalgia symptoms were not supported when the association between weather variables and pain were examined (Hagglund, Deuser, Buckelew, Hewett, & Kay, 1994).

Mixed methods facilitate the ability to frame and reframe research questions, and the use of mixed methods to identify specific activities that triggered FM flares offered such an opportunity. Activity as a broad category, mobility, and home management were the triggers identified most often in the interviews. Probes helped participants to become more specific, identifying activities as different as social activities, strenuous activity (i.e., gardening, exercise), lifting groceries, or sitting too long. Postures such as sitting have been reported to aggravate fibromyalgia symptoms (Waylonis & Heck, 1992), and mobility, specifically standing, climbing stairs, walking, and lifting heavy objects have been shown to denote functional limitations in persons with fibromyalgia (Mannerkorpi & Ekdahl, 1997). While mobility activities have been used to characterize levels of functional limitations, the current findings indicate that they can also trigger fibromyalgia flares. As women are the persons predominately diagnosed with fibromyalgia and typically the persons responsible for performing home management activities, the role of home management activities as a trigger of flares deserves attention. The research by Liedberg, Hesselstrand, & Henriksson (2004) confirms and supports the need to focus on home management activities as a trigger of flares, because of their findings that women with

fibromyalgia, working or not, spent between 4¾ hours to 6½ hours per day engaged in household activities. Using mixed methods, the current study has added to the body of knowledge about triggers of FM flares by identifying specific activities as well as the number of activities impacted for each fibromyalgia symptom. These new data can now be used on quantitative surveys with larger samples.

Finally, our participants were able to provide insight into the strategies they used to manage FM symptoms on a daily basis as well as during a flare. On a daily basis, participants reported that medications helped to reduce, alleviate, or prevent symptoms, which is consistent with the findings of Wassem, McDonald, Racine (2002). Our participants also stressed the importance of being flexible when confronted with symptoms -- to change plans, to pace activities, and to rest. During a flare, the ability to distract oneself, pace oneself, get plenty of rest, exercise, and water were all perceived as good management strategies, followed by calling one's physician. Participants in the study by Wassem et al. (2002) also recommended walking and exercise as self-management strategies. When our participants were asked what they would tell a friend about the best way to manage FM symptoms, at the top of the list was finding a good physician, preferably a rheumatologist who understood FM. Other suggestions focused on taking charge of their health care, pacing themselves, finding educational resources, and participating in an exercise program. This study contributes to the body of knowledge by identifying management strategies generated by persons with fibromyalgia rather than by the health professionals who serve them.

4.4.1. Limitations and Recommendations

Our study had three primary limitations. First, our sample was drawn from one academic clinical rheumatology practice, and academic health centers typically serve the patients with greater and more severe health issues. Secondly, all of our participants were female and therefore, the findings cannot be generalized to males. Third, all but one of the participants were Caucasian. However, fibromyalgia is not a syndrome exclusive to a particular ethnic or racial group (Macfarlane, 1999; White & Harth, 2001), and individuals from other health care settings or ethnic/racial backgrounds were not well represented and this is a limitation of the current study. Further studies should replicate these methods, particularly with a more diverse sample.

4.4.2. Summary

In this study, we sought to identify clinically relevant triggers of fibromyalgia flares, experienced by women with fibromyalgia, and explore their effect on functional status. Using mixed methods, we were able to glean the effects of fibromyalgia on the lives of persons with this syndrome and the negative and positive consequences of those effects on activity performance. Our findings corroborated that the clinical outcomes for three subgroups of women with fibromyalgia, those with low FIQ scores, average FIQ scores, and high FIQ scores vary based on their fibromyalgia impact, and that the greater the impact the more activities are affected. Although many negative consequences of FM were discussed, participants also identified positive consequences of the syndrome. Finally, personal methods of managing fibromyalgia

symptoms on a daily basis and during a flare were reported, as well as management strategies participants would recommend to someone who is newly diagnosed with fibromyalgia.

5. CONCLUSION

The purpose of this dissertation was to explore the functional status of subgroups of women with fibromyalgia (FM). The specific aims were to:

1. examine the effectiveness of a self-monitored cognitive-behavioral and interactive technology-based intervention to improve the clinical outcomes for two subgroups of women with fibromyalgia: those with high Fibromyalgia Impact Questionnaire (FIQ) scores and those with low FIQ scores,
2. examine the associations among symptoms of FM and objective and subjective functional status measures, and then use the functional status data to classify FM clinical subgroups, and
3. to use mixed methods to identify clinically relevant triggers of fibromyalgia flares, experienced by three subgroups women with low, average, and high fibromyalgia impact, and explore the effect of triggers on their functional status.

The first investigation examined the effectiveness of a self-monitored, cognitive-behavioral, and interactive technology-based intervention to improve the clinical outcomes for two subgroups of women with fibromyalgia: those with low FIQ scores and those with high FIQ scores. Although we expected both subgroups to be responsive to the intervention, because the high FIQ subgroup reported greater fibromyalgia impact, we hypothesized that the low FIQ subgroup would demonstrate greater changes than those in the high FIQ subgroup. Based on the

method of analysis (individual versus group), as well as the target behavior of interest, our hypotheses were not always supported. At the individual level, the intervention had a comparable impact for participants of both the low and high FIQ subgroups. Our hypothesis that participants in both the low FIQ and high FIQ subgroups would make significant changes following the intervention was supported. However, the individual trajectories of the low FIQ subgroup participants presented differently than hypothesized, because the high FIQ subgroup participants made more significant changes in the target behaviors, based on individual analyses. Therefore, our hypothesis that the low FIQ subgroup would make more significant changes than the high FIQ subgroup was not supported at the level of the individual participant. However, when we examined the impact of the intervention between the low FIQ and high FIQ subgroups, using grouped data, we found that the low FIQ subgroup did significantly better than the high FIQ subgroup for reducing fatigue and increasing physical activity. Our findings indicate that "The Efficacy of Computer and SenseWear® Technologies for Promoting Health in People with Fibromyalgia: A Randomized Clinical Trial" (FIBRO-RCT), Internet-based health promotion intervention had mixed results for two subgroups of women with fibromyalgia: those with low FIQ scores and those with high FIQ scores. The clinical response to the intervention depended on the method of analysis (individual versus group) and the target behavior of interest.

The second investigation developed profiles of fibromyalgia clinical subgroups by examining the associations among symptoms of fibromyalgia and two target outcomes: physical activity and functional status (FIQ total score). Using Exhaustive Chi-square Automatic Interaction Detector (Exhaustive CHAID), we developed two models using objective and subjective data to develop profiles of fibromyalgia clinical subgroups. While basically the same objective and subjective functional indicators were entered as predictors in each model, the

significant predictors did not overlap between models. Moreover, only objective indicators surfaced as significant predictors in Model I, with physical activity as the target outcome, and only subjective indicators surfaced as significant predictors in Model II, with functional status as the target outcome. Model I, with the target outcome of physical activity, yielded 9 distinct clinical subgroups, whose members had characteristics that were significantly associated with very unfavorable physical activity outcomes to very favorable physical activity outcomes. For all clinical subgroups, steps were the strongest predictor of physical activity outcomes, differentiating participants into four distinct clinical subgroups. Model II, with the target outcome of the FIQ total score, yielded 5 distinct clinical subgroups whose members had characteristics that were significantly associated with very unfavorable functional status outcomes to very favorable functional status outcomes. Affective distress contributed to pain emerged as the strongest predictor of functional status for all clinical subgroups. Tree-based analysis and cross validation methods reduced misclassifications and variance in the models, with Model II demonstrating stronger predictive validity than Model I. Exhaustive CHAID methods identify the objective and subjective functional indicators most strongly associated with physical activity and functional status target outcomes (segmentation) respectively, and identify predictor scores that separate the sample into homogenous clinical subgroups along the continuum of favorable to unfavorable outcomes (stratification) rather fitting data based on pre-existing or theoretical models. The present findings offer a basis for incorporating Exhaustive CHAID as an exploratory and complementary method for evidence based practice interventions by examining the interactions between relevant functional indicators of physical activity and functional status for homogenous clinical subgroups of persons with fibromyalgia.

The third investigation identified clinically relevant triggers of fibromyalgia flares, experienced by women with fibromyalgia, and explored their effect on functional status. Using mixed methods, we were able to substantiate, quantify, and qualify the affects of fibromyalgia on the lives of persons with chronic FM and the direct consequences of those affects on activities. The mixed methods produced consistent findings on how FM affected the participants. The ethnographic techniques also provided insight into losses and gains experienced by persons with FM, activities that triggered FM flares, and management strategies that reduced the impact of FM on their daily lives. Overall, participants reported that fibromyalgia negatively affected their lives with regard to the quantity and severity of symptoms, the intrapersonal and interpersonal challenges, and the limitations on their activities. As a result of the overall negative affect of FM on their lives, participants were acutely aware of the losses that it caused in their lives, especially in activity participation and relationships. Participant perceptions along with fluctuations within participants, and subgroups (i.e., low FIQ scores, high FIQ scores) over time were confirmed by both the study selection FIQ subgrouping (i.e., low, average, high impact) of the participants and the interview FIQ subgrouping, which showed decreased activity and increased symptomotology, based on subgroup. Our findings have added to the body of knowledge by identifying which activities are impacted most for the most common FM symptoms, and by confirming that as FM impact increases, so do the number of activities affected. The identification of personal gains made by participants because of how FM affected their lives, namely, an examination what was important in life, taking control of one's life, healthier eating habits, learning to balance and pace activities, and exercising offer another contribution. Another critical component of the current study was the identification of relevant triggers of fibromyalgia flares. Overall activity, FM symptoms, and weather were the most prominent

triggers reported. The cyclical effect of activity and fibromyalgia symptoms as triggers of fibromyalgia flares is not surprising. Lastly, our participants were able to provide insight into the strategies they used to manage FM symptoms on a daily basis as well as during a flare, as well as management strategies participants would recommend to someone who is newly diagnosed with fibromyalgia. Our findings offer support of the need to subgroup women with FIQ, in that the clinical outcomes for the three subgroups, those with low, average, and high FIQ scores varied based on their fibromyalgia impact, and that the greater the impact the more activities were affected.

In summary, these three studies suggest that the influence of fibromyalgia on the functional status of women manifests differently based on subgroup membership and this finding has clinical relevance. Intervention response may vary based on subgroup membership, as was seen in the different individual and group responses to an Internet-based health promotion intervention. Likewise, subgroup membership impacted the number of daily activities affected by fibromyalgia symptoms. Further study is needed to explore the efficacy of subgrouping persons with fibromyalgia using the Fibromyalgia Impact Questionnaire; to determine the utility of the Exhaustive CHAID tree-based analysis to establish fibromyalgia subgroups; and to investigate the use of mixed methods to corroborate clinical outcomes for fibromyalgia subgroups.

APPENDIX A

SAMPLE FORM

Form 1: Sample Data using Fibromyalgia Single-Subject Design Data Extraction Form

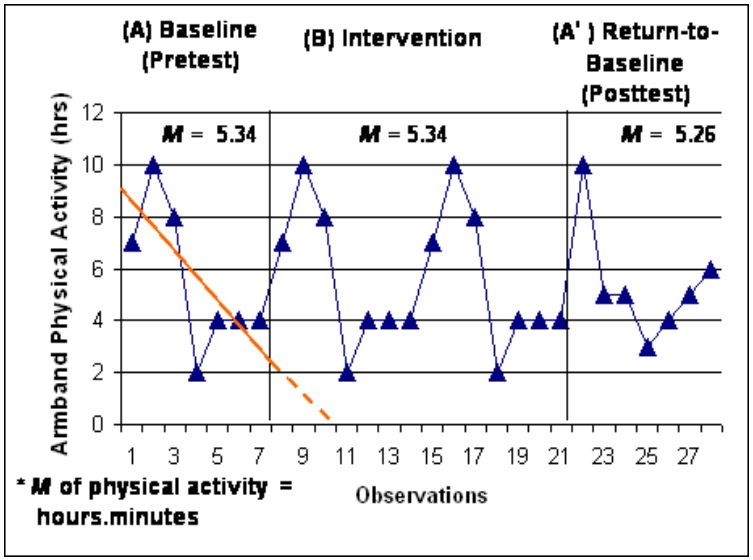
A				B					A′			
$_{pre}$HDR (7 days)		$_{pre}$Armband (7 days)		$_{tx}$HDR (6 weeks)		$_{tx}$Armband (6 weeks)			$_{post}$HDR (7 days)		$_{post}$Armband (7 days)	
Fatigue	Pain	Daily PA (Total Minutes)	Night Sleep (10p-7:59a)	Fatigue	Pain	Daily PA	Night Sleep	Day (Date)	Fatigue	Pain	Daily PA	Night Sleep
2	3.17	45	430	3	2.57	232	464		3	3.17	189	213
3	2.34	157	365	4	2.45	100	378		3*	2.34	259	415
1	1.67*	232	315	2	3.60	110	379		2	3.60	193	225
4	2.14	95	195	2	1.17	45	213		1	4.67	257	328
2	3.60	110	444	3	2.34	189	415		4	2.45	232	279
3	2.45	259	328*	3	3.17	259	225		2	2.14	89	379
1	1.57	193	279	4	2.34	193	365		2	1.00	10	213
				2	3.17	76	430					
				3	2.50	257	365					
				4	2.47	232	315					
				4	3.14	305	425*					
				2	3.60	110	444					
				3	2.45	259	328					
				2	3.00	193	279					

**Note: If data missing ~ missing value analysis utilized.*

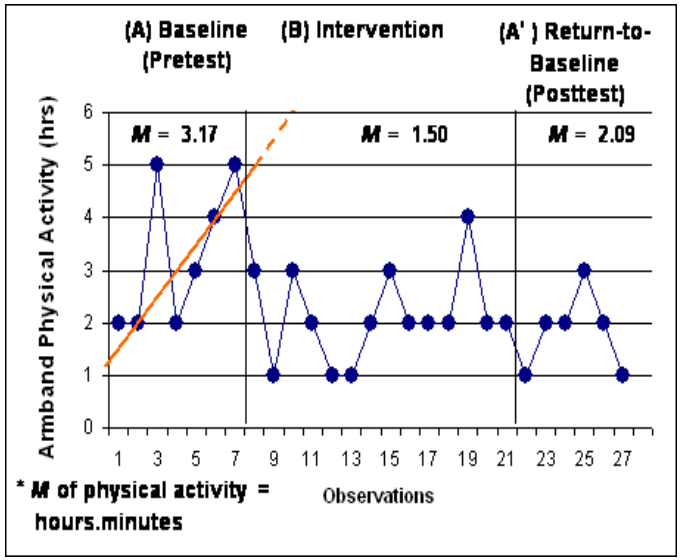
APPENDIX B

SAMPLE FIGURES

Sample 1: Armband physical activity.



Sample 2: Armband physical activity



Note. The graphs above are examples and do not represent real data.

APPENDIX C

DATA OF PARTICIPANT 1

	HDR - Fatigue	HDR - Pain	Armband – Physical Activity	Armband - Sleep
Phase A (Baseline)	3	2.50	536	347
	1	1.50	666	349
	3	2.83	689	448
	1	2.75	238	442
	2	3.75	251	427
	4	2.43	174	457
	4	2.33	399	423
Phase B (Intervention)	4	2.60	76	446
	1	4.25	94	398
	2	4.00	0	452
	3	3.00	213	480
	3	3.00	330	431
	3	2.89	353	0
	3	2.89	527	0
	4	3.33	162	447
	4	4.00	301	437
	4	2.33	24	468
	3	3.67	155	433
	3	3.00	315	448
	1	5.00	37	343
	2	4.00	0	460
Phase A' (Return-to-Baseline)	3	2.33	592	332
	3	2.67	532	443
	2	2.33	92	459
	1	2.80	77	452
	3	3.33	7	377
	2	3.33	6	449
	3	3.33	334	406

Appendix C (continued).

Data set: HDR - Fatigue	**Fatigue**	data point	data value	2. Diff scores	3. Mean diff (1)(2) etc.	3.1 sum of mean diff	4. Square mean diff	4.1. Sum of mean diff Sq	5.step 3/step 4 (r)	6. Bartlett's test	7. If 5 is < 6, autocorrelated coefficient is NS
3	Phase A	1	3	0.429	-0.673	0.102	0.184	7.673	0.013	0.756	ns autocorrelated
1		2	1	-1.571	-0.673		2.469				
3		3	3	0.429	-0.673		0.184				
1		4	1	-1.571	0.898		2.469				
2		5	2	-0.571	-0.816		0.327				
4		6	4	1.429	2.041		2.041				
4		7	4	1.429							
		1. mean	2.5714								
		count	7								

Appendix C (continued).

Data set: HDR - Pain	**Pain**	data point	data value	2. Diff scores	3. Mean diff (1)(2) etc.	3.1 sum of mean diff	4. Square mean diff	4.1. Sum of mean dif Sq	5. step 3/step 4 (r)	6. Bartlett's test	7. If 5 is < 6, autocorrelated coefficient is NOT sig
2.50	Phase A	1	2.50	-0.127	0.143	-0.085	0.016	2.643	-0.032	0.756	ns autocorrelated
1.50		2	1.50	-1.127	-0.229		1.269				
2.83		3	2.83	0.203	0.025		0.041				
2.75		4	2.75	0.123	0.139		0.015				
3.75		5	3.75	1.123	-0.221		1.262				
2.43		6	2.43	-0.197	0.058		0.039				
2.33		7	2.33	-0.297							
		1. mean	2.6267								
		count	7								

APPENDIX D

DISSERTATION INTERVIEW PACKET

Dissertation Research Study
Participant Data

Hazel L. Breland, MS, OTR/L, Principal Investigator
Margo B. Holm, Ph.D., OTR/L
Joan C. Rogers, Ph.D., OTR/L
Terence Starz, MD
Molly T. Vogt, Ph.D., DrPH

University of Pittsburgh
School of Health and Rehabilitation Sciences,
Department of Occupational Therapy
Funded by: SHRS Development Fund,
School of Health and Rehabilitation Sciences, University of Pittsburgh

Demographic Data Form

Date: _____
Age: _____

Race: ☐White ☐Black ☐Asian ☐Hispanic ☐Other

Living Situation: ☐Alone ☐With spouse/significant other ☐With Family

How many years of formal education have you completed?

☐ High school (9-12)
☐ Earned G.E.D.
☐ Trade/technical school
☐ Associate degree (2 year college)
☐ Bachelor degree (4 year college)
☐ Graduate degree/professional training
☐ Refused
☐ Missing

Are you currently employed?

1 Yes
2 No

What is your current employment status?

☐ Full-time (working at least 35 hours a week)
☐ Part-time (working less than 35 hours a week)
☐ Laid off or unemployed, but looking for work
☐ Laid off or unemployed, but not looking for work
☐ Retired, not working at all
☐ Retired, but working part-time or full-time
☐ Disabled/unable to work
☐ Full-time homemaker
☐ Student
☐ Other _____
☐ Missing

How would you describe your occupation?

☐ Professional, technical
☐ Managerial & office (state, county, etc.)
☐ Clerical & sales
☐ Crafts person or trade
☐ Operative (machine operator)
☐ Unskilled & domestic
☐ Housewife
☐ Other _____
☐ Missing

What is your total gross annual income for your household?

☐ Under $10,000
☐ $10,000 to $29,999
☐ $30,000 to 59,999
☐ $60,000 to $89,999
☐ $90,000 to $150,00
☐ Over $150,000
☐ Refused
☐ Missing

Current Symptoms Checklist

Please check your current symptoms below:

Symptom	✓	Symptom	✓
Joint swelling		Poor sleep	
Stiffness		Awaken feeling tired	
Muscle pain		Restless legs	
Muscle weakness		Hands change color in cold	
Pain after exertion		Excessive fatigue for more than 6 months	
Frequent headaches		Abdominal cramping	
Chest pain		Constipation	
Swelling or bloating		Abdominal distension	
Difficulty swallowing		Intermittent loose stools	
Daytime sleepiness		Frequent and urgent urination	
Dry or itchy eyes		Impaired logical reasoning	
Light headedness		Loss of memory	
Depressed moods		Excessive anxiety	
Breathlessness		Panic attacks	
Dizziness		Premenstrual tension (PMS)	
Impaired coordination		Tenderness of skin	
Severe fatigue after exercise		Pain that keeps you awake	

The Fibromyalgia Impact Questionnaire

	Always	Most Times	Occasionally	Never
1. Over the past week were you				
a. Do shopping	0	1	2	3
b. Do laundry with a washer	0	1	2	3
c. Prepare meals	0	1	2	3
d. Wash dishes/cooking utensils	0	1	2	3
e. Vacuum a rug	0	1	2	3
f. Make beds	0	1	2	3
g. Walk several blocks	0	1	2	3
h. Visit friends/relatives	0	1	2	3
i. Do yard work	0	1	2	3
j. Drive a car	0	1	2	3

2. Of the 7 days in the past week, how many days did you feel good?

0 1 2 3 4 5 6 7

3. How many days in the past week did you miss work because of your fibromyalgia?
(If you do not have, a job outside the home leaves this item blank.)

0 1 2 3 4 5 6 7

Directions: Mark an | on each scale at the point which best describes how you felt <u>this</u> <u>week.</u>

4. When you did go to work, how much did pain or other symptoms of your fibromyalgia interfere with your ability to do your job?

No Problem _____ Great Difficulty

5. How bad has your pain been?

No Pain _____ Very Severe Pain

6. How tired have you been?

No Tiredness _____ Very Tired

7. How have you felt when you got up in the morning?

Awoke Well Rested _____ Awoke Very Tired

8. How bad has your stiffness been?

No Stiffness _____ Very Stiff

9. How tense, nervous, or anxious have you felt?

Not Tense _____ Very Tense

10. How depressed or blue have you felt?

Not Depressed _____ Very Depressed

Qualitative Interview Field Notes

- General Information (e.g., date, time, location, persons present):
  - _____
  - _____
  - _____
- Subject's Appearance:
  - _____
  - _____
  - _____
- Subject's Facial Expressions:
  - _____
  - _____
  - _____
  - _____
  - _____
- Subject's Body Language:
  - _____
  - _____
  - _____
  - _____

Symptoms Identification Form

Q1. What fibromyalgia symptoms do you have? Rank order, 1 = most frequent

Symptoms	✓	Rank
Pain		
Fatigue		
Poor sleep		
Joint swelling		
Stiffness		
Muscle weakness		
Pain after exertion		
Frequent headaches		
Chest pain		
Swelling or bloating		
Difficulty swallowing		
Daytime sleepiness		
Dry or itchy eyes		
Light headedness		
Depressed moods		
Breathlessness		
Dizziness		
Impaired coordination		
Severe fatigue after exercise		
Awaken feeling tired		
Restless legs		
Hands change color in cold		
Excessive fatigue for more than 6 months		
Abdominal cramping		
Constipation		
Abdominal distension		
Intermittent loose stools		
Frequent and urgent urination		
Impaired logical reasoning		
Loss of memory		
Excessive anxiety		
Panic attacks		
Premenstrual tension (PMS)		
Tenderness of skin		
Pain that keeps you awake		
Other _____		

Side 1

SIF Note Card

Symptom # 1: _____

Activities Affected:

1.

2.

3.

4.

5.

6.

7.

8.

9.

10.

Side 2

SIF Note Card

Symptom # 1 Management:

Control before beginning:

_____

Manage after onset:

APPENDIX E

NU*DIST 6 GRAND TOUR QUESTIONS CODING STRUCTURE

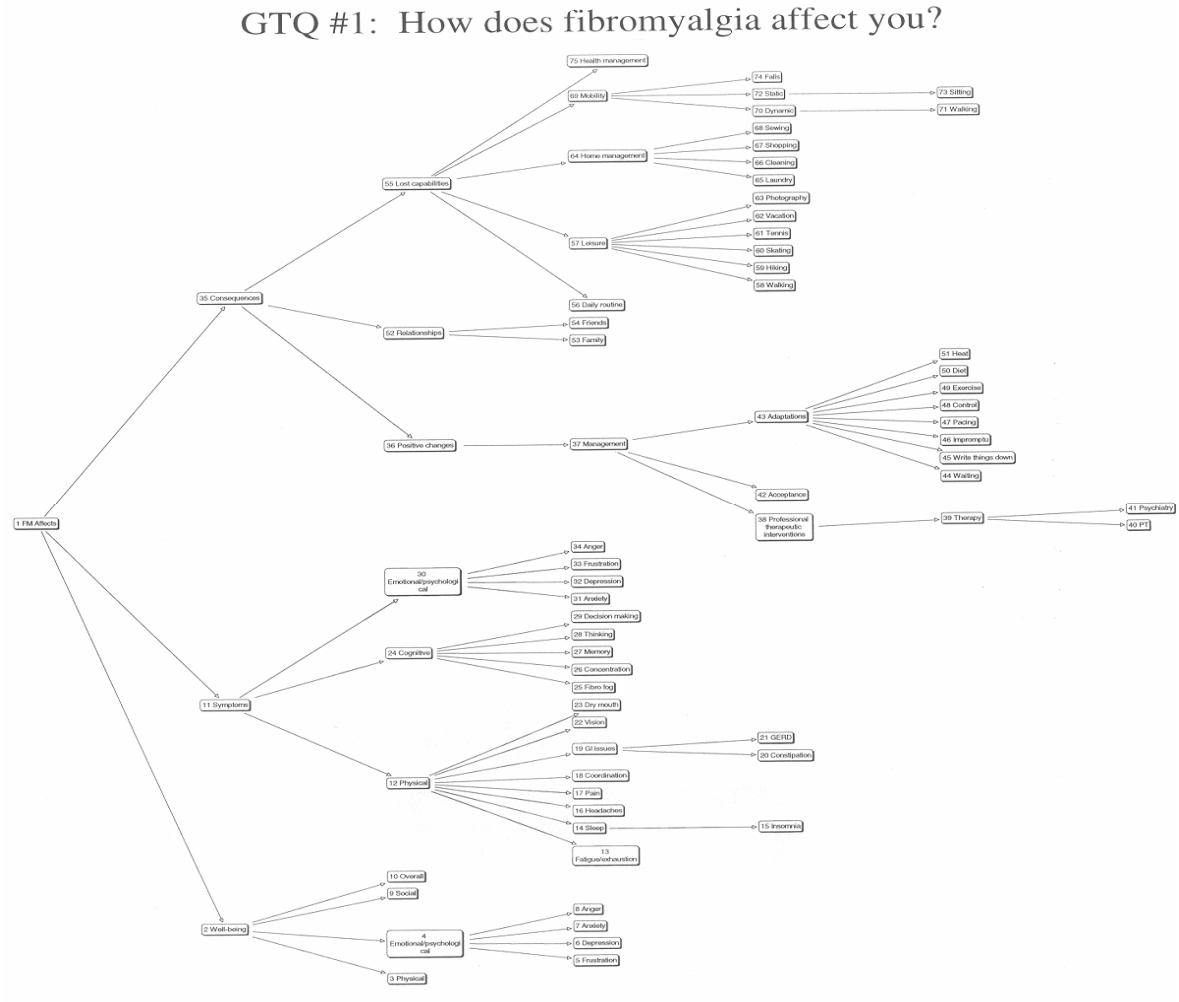


Figure 50: NU*DIST Tree for Grand Tour Question 1

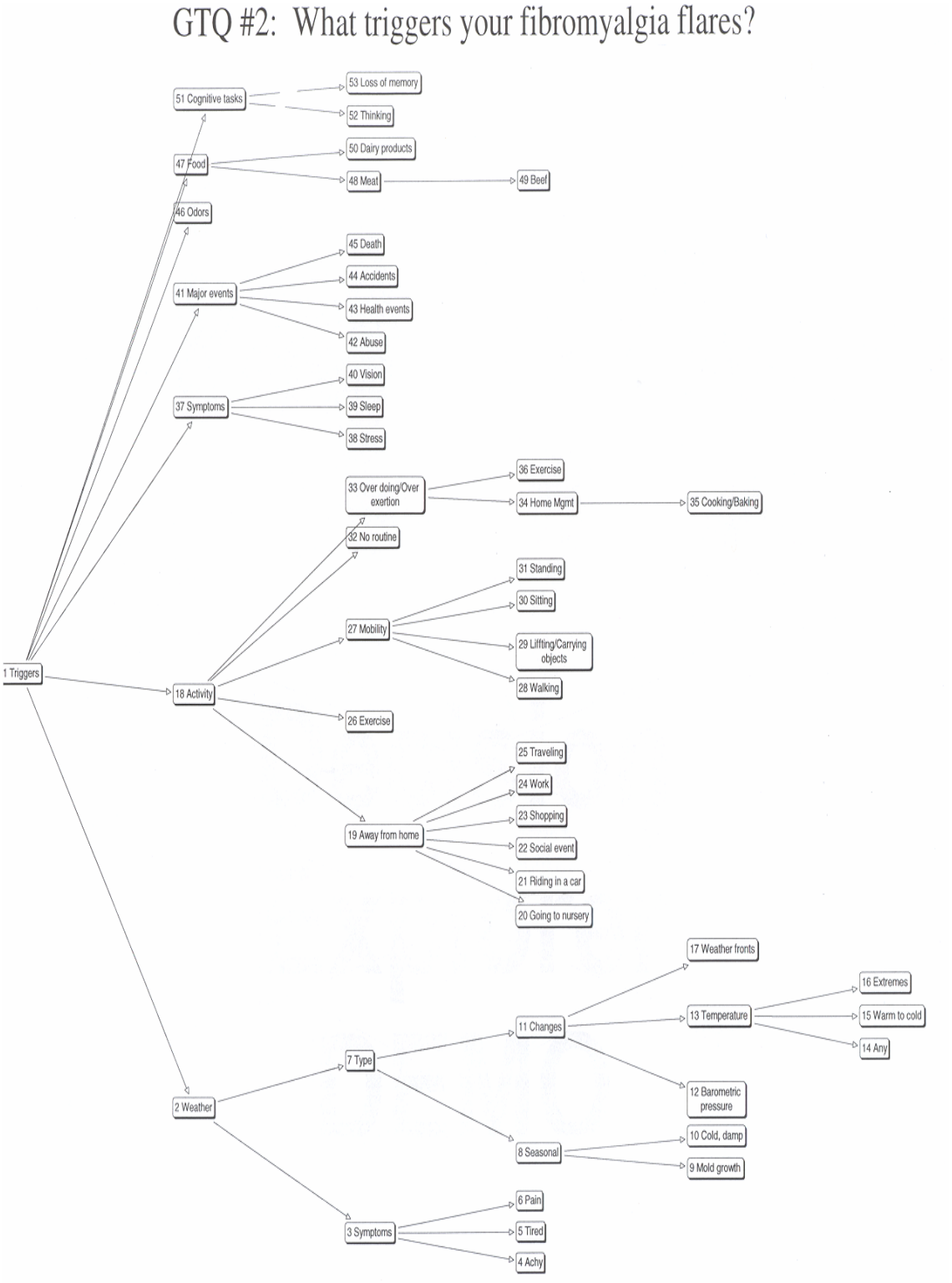


Figure 51: NU*DIST Tree for Grand Tour Question 2

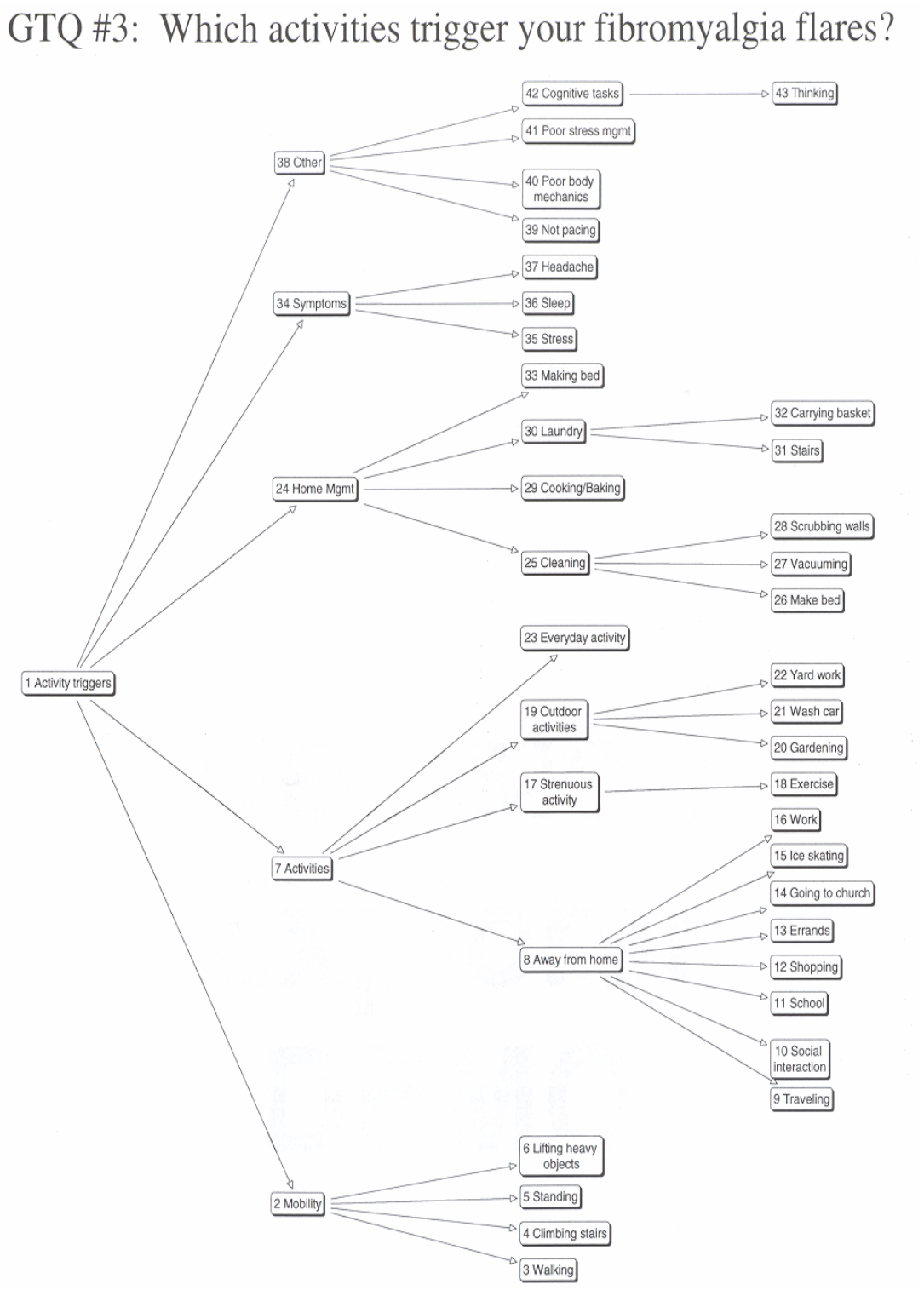


Figure 52: NU*DIST Tree for Grand Tour Question 3

GTQ #4: Which activities have you given up due to your fibromyalgia symptoms?

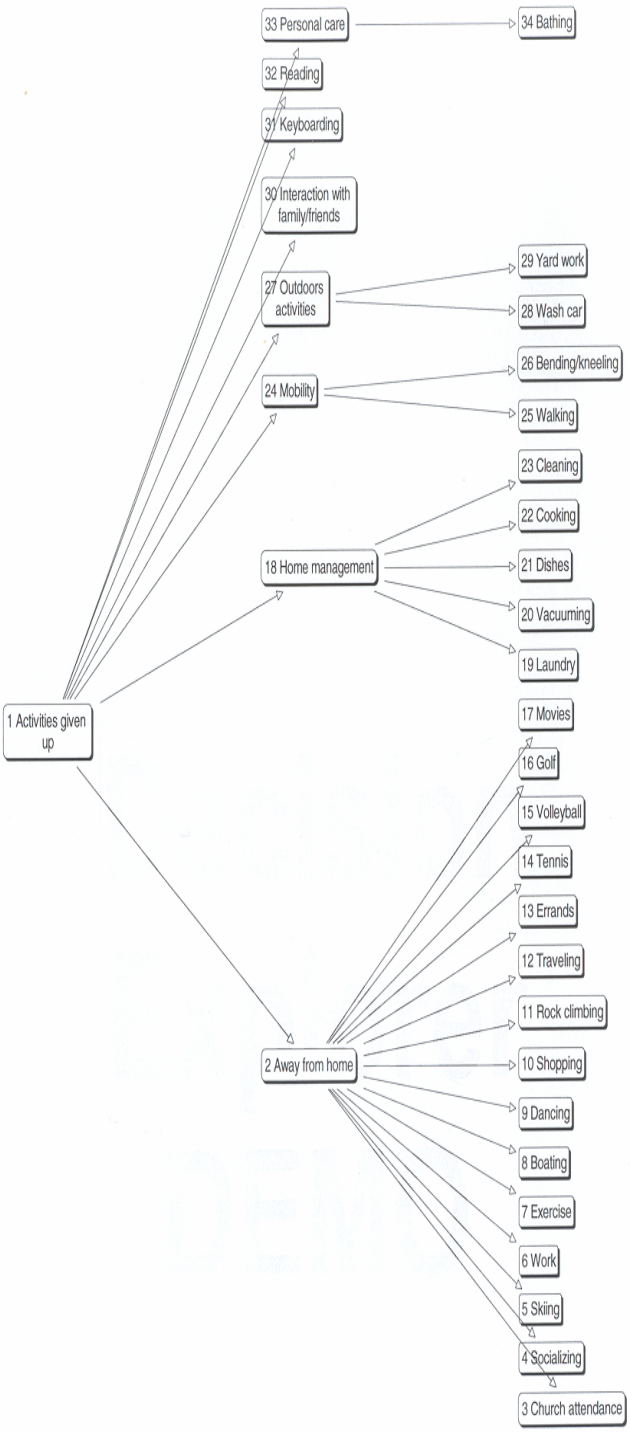


Figure 53: NU*DIST Tree for Grand Tour Question 4

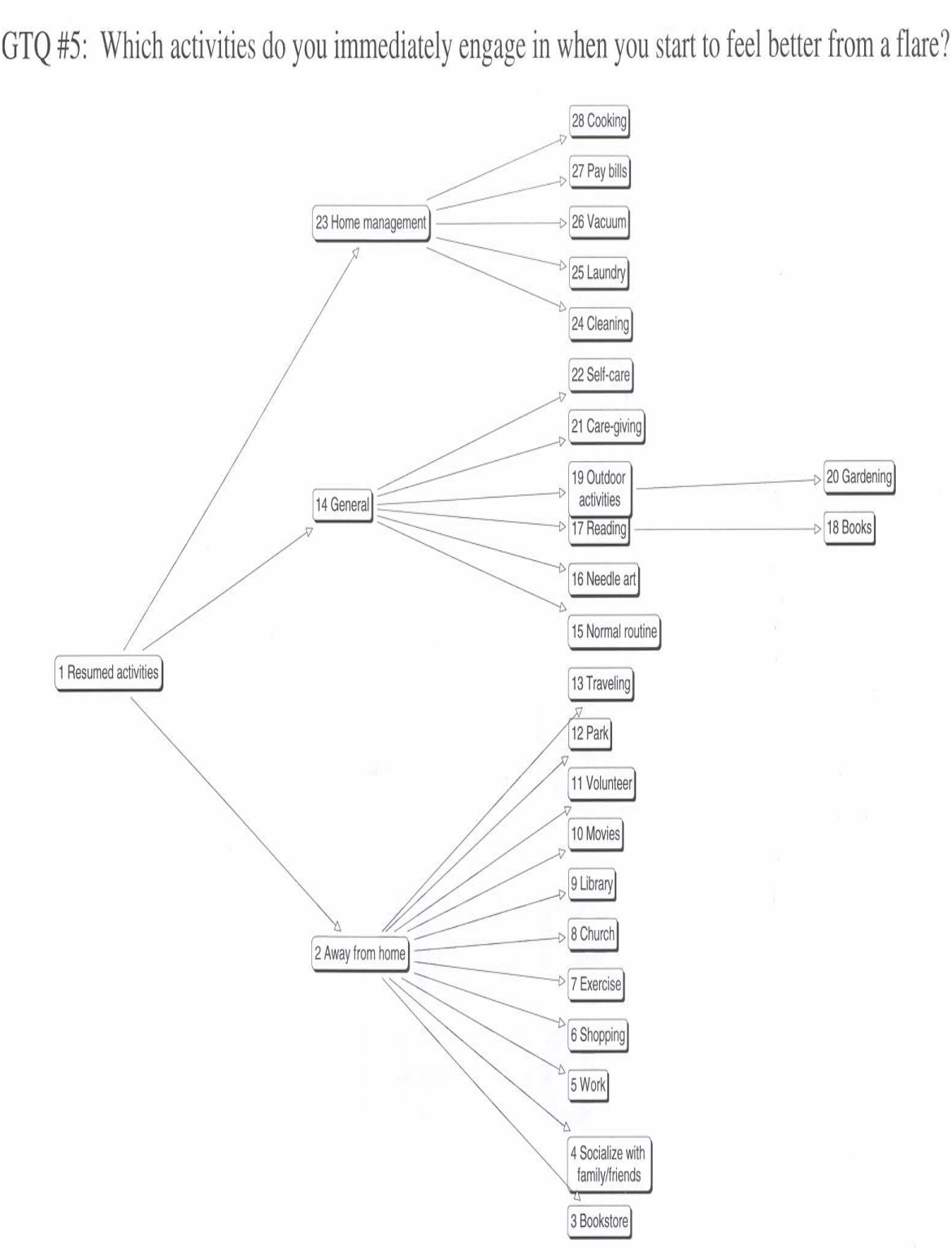


Figure 54: NU*DIST Tree for Grand Tour Question 5

GTQ #6: Tell me about how your daily symptoms and it there is a pattern.

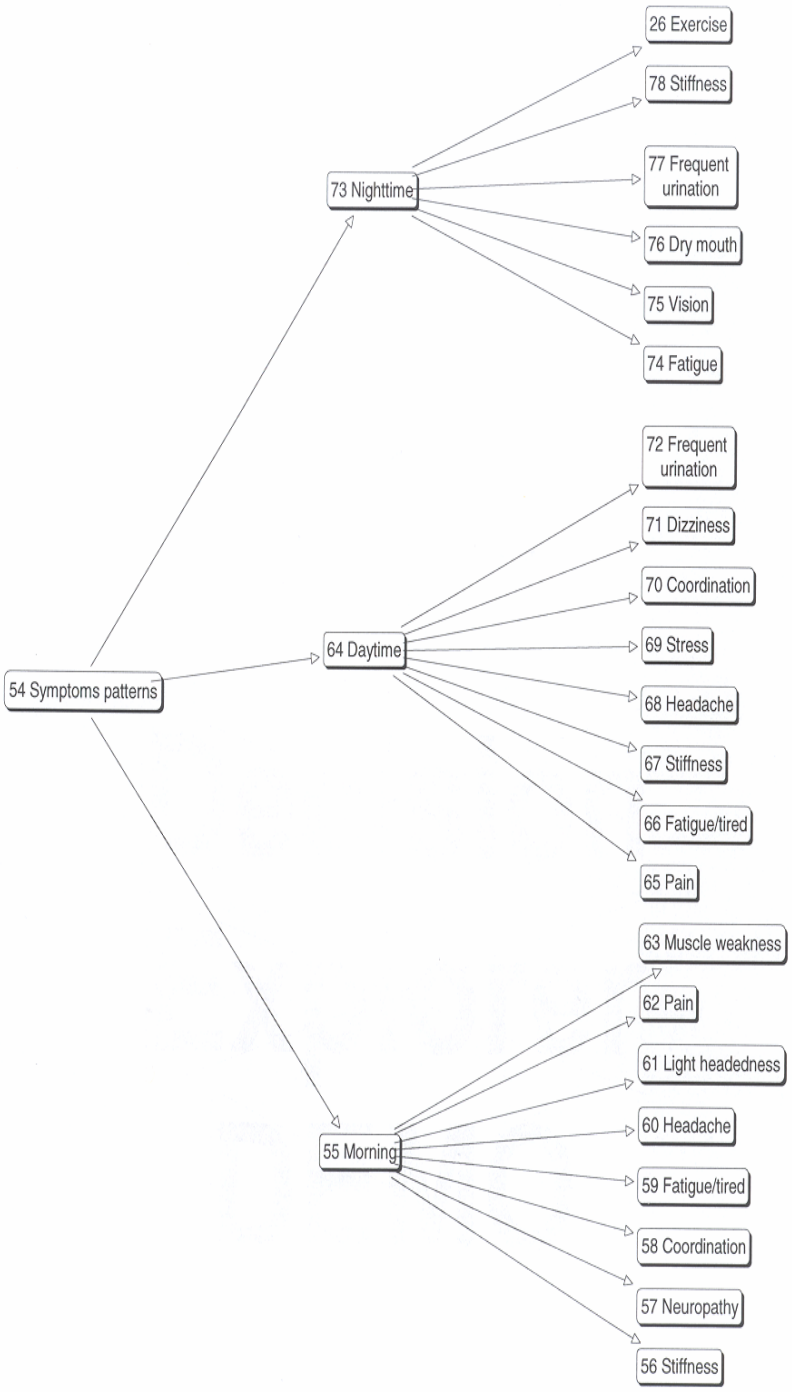


Figure 55: NU*DIST Tree for Grand Tour Question 6

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