The Impact of Fibromyalgia and Sensory Processing on Participation of Daily Activities

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THE IMPACT OF FIBROMYALGIA AND SENSORY PROCESSING ON PARTICIPATION OF DAILY ACTIVITIES

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A thesis submitted to the faculty of Dominican University of California in partial fulfillment of the requirements for the Master of Sciences in Occupational Therapy
School of Health and Natural Sciences

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This thesis, written under the direction of the candidates’ thesis advisor and approved by the chair of the Master program, has been presented to and accepted by the Faculty of the Occupational Therapy department in partial fulfillment of the requirements for the degree of Master of Science in Occupational Therapy. The content, project, and research methodologies presented in this work represent the work of the candidates alone.

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**Abstract**

Fibromyalgia (FM) is a pain disorder that involves a variety of symptoms including painful joints, fatigue, muscle stiffness, and sleep disturbances. Cognitive symptoms are also a hallmark of FM, which result in difficulties with thought articulation, concentration, and mental fatigue. There is a gap in research substantiating increased levels of sensory defensiveness symptoms in individuals with FM and the effects in daily life. Currently, only one research study has provided evidence of increased sensory sensitivity across multiple modalities in individuals with FM. The purpose of this research was to determine whether women with FM had increased levels of sensory defensiveness in daily life when compared to pain free age matched women. This research also examined whether women with FM had decreased quality of life (QOL) and participation in daily occupations. Lastly, this study investigated if there was a relationship between sensory defensiveness, participation in typical patterns of daily activities, and QOL. This study was a quantitative, multi-group, quasi-experimental comparison design. Participants were recruited from South Central Wisconsin and Northern California. A total of 20 women participated in the study, 11 in the control group and 9 in the FM group. The data was collected through the following three distinct questionnaires and one activity: Medical Outcome Survey-Short Form 36 (SF-36), Adult/Adolescent Sensory Profile (AASP), Fibromyalgia Impact Questionnaire (FIQ), and the Activity Card Sort (ACS). Data was analyzed using two-tailed t-Test and Pearson's r Correlations. Women in the FM group reported significantly more symptoms for sensory defensiveness and participation in fewer daily activities than the control group. Women with FM reported decreased QOL when compared to the control group. Symptoms of sensory defensiveness were moderately, but not significantly, correlated
with participation in daily activities. Increased symptoms of sensory defensiveness were strongly correlated with reports of poorer mental health scores in women with FM.
Introduction

Fibromyalgia (FM) gives rise to various problems in daily life, such as decreased social participation, leisure activities, restful sleep, and work. Women with FM report over sensitivity to sensations across multiple modalities, but to date there has only been one study documenting this symptom in the context of the effects on daily life (Wilbarger & Cook, 2011). Little research has examined occupational participation in women with FM, particularly from the occupational therapy perspective. Current research has not addressed whether sensory over-sensitivity was related to disruption in daily functions in people with FM.

The purpose of this study was to determine whether women with FM had increased levels of generalized sensory over-sensitivities to sensation in daily life. If sensory defensiveness was associated with decreased quality of life (QOL) and participation in patterns of daily activities. Lastly, whether correlation existed between sensory defensiveness, participation in daily activities, and QOL.
Literature Review

To date, the cause of FM is unknown. There has been a general belief that traumatic events, obesity, and genetic predisposition could increase the likelihood of a person being diagnosed with FM. This belief was not supported by any conclusive data. It has been estimated that over five million adults in the United States have FM (Lawrence, Felson, & Helmick, 2008). Fibromyalgia was initially thought to occur only in young women, but Wolfe, Ross, Anderson, Russell, and Herbert (1995) concluded that the prevalence of FM in the populations was present in women, men, and children (though it is not common in children). Fibromyalgia was estimated to be present in 2% of the American population and increased with age to as high as 7.4% in women ages 70-79 years old (Wolfe et al., 1995).

Fibromyalgia is considered a rheumatic disorder because it causes pain in joints and connective tissue (Center for Disease Control and Prevention [CDC], 2011). The CDC (2011) reported that people affected with FM often have comorbidities with other rheumatic conditions (e.g., rheumatoid arthritis, systemic lupus erythematosus, and ankylosing spondylitis).

In the past, patients with FM were often misdiagnosed because their symptomatology resembled those of other conditions. The lack of diagnostic testing for FM was problematic and physicians would often administer lab tests to rule out other conditions (National Fibromyalgia Association [NFA], 2012). In 1990, the American College of Rheumatology (ACR) established criteria for diagnosing FM. Physicians would base diagnosis of FM according to the number of tender points on the body. If a patient had more than 11 tender points for three or more months, the patient would typically be diagnosed with FM (Wolf et al., 1990). The new criteria established clinical guidelines to correctly diagnose FM or rule out other conditions. The diagnostic criteria was clarified by Wolfe et al. (2010) as widespread pain index (WPI) of $\geq 7$. 


and a symptom severity scale (SS) \( \geq 5 \) or WPI 3-6 and SS \( \geq 9 \). Combinations of these techniques, along with questions about symptoms are currently used to diagnose or rule out FM.

**Interventions**

There is no cure for FM but there are several interventions aimed at helping patients with FM manage their pain and symptoms (e.g., pharmacology, physical and occupational therapy, and complimentary alternative medicine (CAM)). The most common treatment for FM symptoms has been pharmacology. The Food and Drug Administration approved Pregabalin, Duloxetine, and Milnacipran for the treatment of FM (Traynor, L., Theissen & Traynor A., 2011; NFA, 2012). Pregabalin works by decreasing the downstream release of excitatory neurotransmitters (e.g. substance P, glutamate, and norepinephrine) and helps prevent the over activity of nerve cells involved in pain transmission (Traynor et al., 2011; NFA, 2012). Duloxetine and Milnacipran help change the serotonin and norepinephrine levels, which also helps to control pain (National Institute of Arthritis and Musculoskeletal and Skin Diseases [NIH], 2012; Mayo Clinic, 2011).

In addition to pharmacology, people with FM often try Cognitive Behavioral Therapy (CBT), physical therapy, and occupational therapy. Patients with FM who received CBT reported lower depression, higher mental health scores, and needed significantly less medication for pain control than those receiving only medication (Falcão et al., 2008). Physical therapists typically work with FM patients using muscle strengthening exercise, stretching, and aquatic exercise (Radonovich-Crum, 2007). Occupational therapists provide skilled intervention by educating the FM patient on energy conservation, pain management, sleep hygiene (e.g., avoiding stimulants or establishing bed time routine), and relaxation techniques (Radonovich-Crum, 2007). Other CAMs for FM includes massage therapy and acupuncture (NIH, 2012).
Even with the accompaniment of medications and variety of interventions, women with FM still report a number of disturbances in their daily life.

**Effects of Fibromyalgia on Everyday Life**

Fibromyalgia has significant negative effects on daily activities such as participation in social activities, leisure activities, restful sleep, and work. Wuytack and Miller (2011) found that leisure activities were disturbed in women with FM because of the pain, stiffness, fatigue, and cognitive disturbances. Pain and stiffness prevented women from participating in activities such as painting, hiking, and knitting. Fatigue would impact the patients’ frequency of traveling and exercise (Wuytack & Miller, 2011). Cognitive disturbances affected the women's ability to engage in leisure activities that required concentration, such as reading (Wuytack & Miller, 2011). Women with FM also experienced disturbances in their family dynamic due to a variety of symptoms. Lastly, Choy et al. (2010) suggested that 22% of women were unable to work due to FM. These following sections focus on the effects of FM on social participation in all areas of life, sleeping patterns, and ability to participate in work.

**Fibromyalgia and social participation**

Fibromyalgia contributes to decreased social participation in all areas of life. Arnold et al. (2008) found that women with FM struggled with the planning of social participation with friends and family because the symptoms of their disease were unpredictable. Women with FM experienced a phenomenon called *fibro fog*, which caused difficulty with thought articulation and forgetfulness (Arnold et al., 2008). Therefore, thought articulation and forgetfulness affected social participation (Arnold et al., 2008). Fatigue was another factor that contributed to the inability of women with FM to participate in social activities. Fatigue made it difficult for women with FM to talk and listen to others (Sallinen, Kukkurainen, Peltokallio, & Mikkelsson,
The study further inferred a correlation between social participation and severity of FM symptoms. Some of these women experienced loss of friendships because they were seen as unreliable (Sallinen et al., 2011).

Women with FM experienced disturbances in the daily activities of their home lives. Women often found that FM impacted their roles as mothers and wives. Wuytack and Miller (2011) discussed both the negative and positive ways that FM affected family life. The roles of mothers and wives were negatively affected because of the severe fatigue the women experienced. This fatigue prevented them from fully participating in activities of child rearing. Women also reported feeling that their children (under the age of 10) did not understand the nature of FM disease. Some participants also reported that they became estranged from their partners and had to resort to divorce. On the other hand, other women recognized the support of their partners and children as a great gift (Wuytack & Miller, 2011).

**Fibromyalgia and sleep**

Women with FM often experienced difficulty with sleep, which led to disturbances in areas of daily occupations. The researchers reported that 99% of participants experienced some kind of sleep disturbance (Theadom & Cropley, 2010). The women said they often woke up multiple times each night because of stiffness, pain, and reported feeling uncomfortable if they were in one position for too long (Theadom & Cropley, 2010). Inadequate sleep elevated the risk of accidents, which resulted in absences from work and led to increased healthcare costs (Theadom & Cropley, 2010). The disruption in regular sleep increased the feelings of fatigue during the day and affected the women’s ability to complete daily activities both at home and at work. Theadom and Cropley (2010) discussed how poor quality of sleep, affected women’s symptoms in their everyday lives. The feeling of fatigue also caused the cancellation of
activities with family and friends. Theadom and Cropley (2010) suggested that sleep disturbances in people with FM affected many spheres of their lives.

**Fibromyalgia and work**

In addition to impaired social participation and sleep, FM symptoms also affected the ability to participate in work. Sallinen, Kukkurainen, Peltokallio, and Mikkelsson (2010) inferred a relationship between FM and the ability to participate in professional activities. The researchers cited four main factors that contributed to decreased work participation, “...confusion, coping with fluctuating symptoms, being in between, and being over the edge....” (Sallinen et al., 2010, p. 21). Confusion was one of the first stages of FM during which women were unaware of what caused their symptoms. As the symptoms (e.g., pain and tenderness) became more severe and less manageable, the women participated less at work. The second stage of FM was coping with fluctuating symptoms and began to come to terms with their symptoms. In some cases, the women had to cope with fluctuating symptoms by modifying their professional environment and work tasks to be able to continue participation at work (Sallinen et al., 2010). The third stage was when women were in between being a full-time employee or on work disability. Since a great number of employers either overlooked or misunderstood the need for accommodation, women often lost their jobs. The last stage was when women were over the edge with their symptoms (Sallinen et al., 2010). This was when the pain and fatigue elevated to unmanageable levels. At this stage, women often experienced decreased energy, which made their jobs feel like a burden (Sallinen et al., 2010).

Research has established links between FM symptoms and decreased social participation, leisure activities, restful sleep, and work. The presence of increased levels of generalized sensory over-responsiveness to sensation in daily life beyond bodily or somatosensory
complaints in women with FM is widely acknowledged, but little research has been conducted to date. Women with FM have reported increased sensitivities to stimuli in the environment though no studies have looked at the relationship between sensory over-sensitivity and occupations (Wilbarger & Cook, 2011). The literature is limited and inconclusive, thus further inquiry into this matter is needed to establish a firm and clear connection between these two disorders.

**Sensory Processing and Fibromyalgia**

**Sensory processing disorders**

Sensory disorders have not been well understood or effectively treated in FM. Sensory processing disorder is defined as difficulty in perceiving, attaching meaning to and responding to sensory information received from the senses (Byrne, 2009). Sensory processing disorder includes atypical responses to tactile and body movement stimuli deficits either in sensory–motor timing or problems strongly associated with one of the processing senses (May-Benson, 2011). These difficulties have resulted in atypical behaviors because of a disconnect during the process between receiving the sensory stimulus and the response (Byrne, 2009).

One primary component of sensory processing disorder is sensory modulation, described as lack of ability to modulate responses to sensation. Sensory modulation disorders include sensory over-responsiveness (hypersensitivity) and sensory under-responsiveness (hyposensitivity). Individuals with hypersensitivity to sensation could be described as being sensory defensiveness. According to the Sensory Therapies and Research Center (2013), individuals who were under-responsive to sensory stimuli disregard or did not respond to stimuli of the usual intensity available in their sensory environment. Sensory defensiveness is defined as aversive or negative responses to non-noxious stimuli (Wilbarger, J. & Wilbarger, P., 2002). A number of daily sensations that typically do not bother most individuals are antagonizing at best
and threatening at worst to people with hypersensitivity or sensory defensiveness. Moods, thoughts, and energy levels are continuously affected because of the inconsistency of sensations (Engel-Yeger & Dunn, 2011). For example, grocery shopping can become a hassle due to bright lights or loud noises coming from a crying baby down the aisle. The functional consequences of sensory over-responsiveness include poor eating and sleeping habits, agitation by changes in plans and routines, extreme emotional states, repetitive movements, and sensitivity to sensations such as light, texture, and noise (Engel-Yeger & Dunn, 2011).

**Self reports**

Self-reports of sensory processing disruptions in FM have led researchers to speculate whether there was a relationship between FM and sensory processing disorder. Geisser et al. (2007) found that even though muscle tenderness was the hallmark of FM, patients displayed sensitivity to a number of different sensory stimuli. Participants with FM reported significantly greater sensitivity to daily sounds compared to the control group (Geisser et al., 2007). Those findings suggested that FM was associated with disruptions in the global central nervous system (Geisser et al., 2007). Current research points to atypical sensory processing in women with FM including reduced thresholds for responding across multiple sensory modalities (Wilbarger & Cook, 2011). Wilbarger and Cook (2011) concluded that both somatic and nonsomatic sensory stimuli were heightened in women with FM when compared to rheumatoid arthritis and control groups. Other reports have established that women with FM experienced difficulty coping with non-noxious stimuli were hypersensitive to all types of sensory stimuli, and may have had overactive central nervous systems (certain smells, tastes, or noises can trigger instant headaches or pain in their body) (Geisser et al., 2007).

People with FM often turn to online chat rooms to talk about their illness, find answers to
symptoms they are experiencing, and ask questions from other people with FM. A website called, Experienceproject.com - “I have FM” was opened in 2004 to allow people with FM to discuss their illness. Several subscribers discussed heightened sensitivity to taste and smell (http://www.experienceproject.com, 2013). Several people wrote back describing their related symptoms such as getting migraines triggered by perfume, nail polish, or diesel. They also reported having hypersensitivity to auditory and olfactory stimuli (http://www.experienceproject.com, 2013). There has been limited formal research done on the sensory issues, participation in the daily life of women with FM, and the effects it has on the nervous system. These reports validate Staud and Domingo’s (2008) research, which stated that oversensitivity of smells affected daily activities of people with FM. Fibromyalgia heightens all senses making daily activities difficult including shopping, daily tasks, and leisure activities. These self-reports are compatible with brain imaging, physiological, and neuropsychological studies on women with FM.

**Physiological studies**

Current research has highlighted the neurophysiological, the physiology of the nervous system, and underpinnings of the FM disorder. Headaches, restless leg syndrome, and cognitive dysfunction have also been found in women with FM (Wood et al., 2007). People with FM also had atypical pain symptoms such as chronic fatigue, sleep disturbances, disturbed bowel function, genitourinary issues, and persistent sinus congestion (Wood et al., 2007). One key finding suggested that women with FM experienced reduced thresholds for aversive or painful responses for noxious and non-noxious stimuli such as pressure, electrical, and thermal stimuli (Elkholm, Hansson, & Kosek, 1996).
Brain activity

Brain scans provided evidence that women with FM exhibited greater sensitivity to supra-threshold experimental pain stimuli (Ciccone et al., 2004). Areas of the brain most consistently implicated in pain processing were the sensory cortex, inferior partial cortex, anterior cingulate cortex, insula, lentiform nucleus, and thalamus (Ciccone et al., 2004). The individuals with FM had reduced regional cerebral blood flow leading the researchers to conclude that the FM group had an inability to modulate the ongoing abundance of incoming nociceptive signals (Ciccone et al., 2004). Ciccone et al. (2004) revealed that the group with FM showed greater responses to both painful and non-painful stimuli in multiple brain regions. The aforementioned study also revealed that FM participants were significantly more sensitive to experimental heat pain than control group (Ciccone et al., 2004). Other research has found that women with FM had abnormal information processing because of a lack of inhibitory control to repetitive non-painful somatosensory (e.g., pressure, pain, hot, and cold) information during stimulus coding and cognitive evaluation (Collado et al., 2006). Wood et al. (2007) had similar findings using the functional magnetic resonance imaging (fMRI), which confirmed that hyper-activation of the primary and secondary somatosensory, anterior cingulated, and insular cortices responded to noxious stimuli in women with FM.

In addition to increased sensitivity to pain stimuli, people with FM demonstrated increased sensitivity to assorted stimuli (e.g., auditory, visual). According to Carillo-de-la-Pena, Gomez-Perreta, Perez, & Vallet (2007) FM participants could be hyper-vigilant (enhanced state of sensory sensitivity accompanied by an exaggerated intensity of behaviors) to sensory stimuli. Hyper-vigilance indicates a defect in the inhibitory system protecting against overstimulation, and exhibits weakness in serotonergic transmissions (Carillo-de-la-Pena et al.,
For many FM patients, responses to noxious and intense auditory stimuli are delayed secondary to imbalance in serotonin (Carillo-de-la-Pena et al., 2007). Carillo-de-la-Pena et al. (2007) proposed that generalized hypervigilance of painful and non-painful sensations could be at the root of this disorder and that these sensory processing difficulties were what affected everyday life. In fact, the expanded relevance of the FM construct was that all individuals (with and without pain) had different volume control settings on their pain and sensory processing. Carillo-de-la-Pena et al. (2007) speculated that the results provided further evidence for a physiological explanation of FM pain.
Statement of Purpose

Research using self-report and physiological methodology indicated that woman with FM had disruptions in sensory processing. Little research had been done to support these two premises. This research study investigated sensory processing issues for women with FM and compared participation in daily occupations and overall QOL in comparison to healthy women. This research study asked the following questions:

1. Are there increased levels of generalized sensory over-sensitivities to sensation in daily life in women with FM compared to age matched pain free women as measured by sensory defensiveness composite score and total score of the Adult/Adolescent Sensory Profile (AASP)?

2. Do women with FM have decreased participation in daily occupations compared to age matched women without FM as measured by the percentage of retained activities on the ACS in the global score and subcategories: instrumental activities of daily living (IADL), low-demand leisure (LDL), high-demand leisure (HDL) activities, and social (SOC)?

3. Do women with FM have decreased QOL compared to age matched pain free women as measured by Medical Outcome Survey-Short Form (SF-36)?

4. A) Is there a correlation between sensory defensiveness and participation in daily activities in women with FM?

   B) Is there a correlation between sensory defensiveness and QOL in women with FM?
Theoretical Framework

The frame of reference selected was the Person Environment Occupation (PEO) Model. The PEO frame of reference was developed in the 1990s by Mary Law and several other Canadian occupational therapists in an effort to comprehensively describe the constructs that affected occupational performance (Law et al., 1996). The PEO model has three interrelated and overlapping components: the person, the environment, and the occupation (Law et al., 1996). The PEO model emphasized how occupational performance is influenced by the ability of the individual, the characteristic of the occupation, and the environmental demands (Brown & Stoffel, 2011).

The person in the PEO model is described as “...the combination of mind, body, and spiritual qualities...” (Law et al., 1996, p. 16). This model suggested that each person had their own personal experiences, beliefs, cultural background, and personality that were conveyed in a variety of situations (Law et al., 1996). In other words, all the lifetime events the person had experienced affected how they interacted and responded to the environment. The PEO model also illustrated that each person bears a variety of roles simultaneously that do not remain static (Law et al., 1996). Accompanying these dynamic roles were the qualities, spiritual beliefs, personal history, and skills that a person brings when participating in occupations (Law et al., 1996). This knowledge allowed for each person to use their intuitive and learned skills allowing them to engage in occupational performance (Law et al., 1996).

The second component of the PEO model is environment. Environment can be defined as the external, physical, and social environments that surround the client and in which the client’s daily occupations occur (American Occupational Therapy Association [AOTA] Press,
Law et al. (1996) further defined environment as cultural, socio-economic, institutional, and social construct.

Law et al. (1996) also suggested that some environments could have several different functions in which a person can have numerous different roles or occupations. For example, a space with a variety of functions could be a community center that is used for community events like bingo or as a place to hold a support group meeting.

The third component of the PEO model is occupation. Occupation is defined as “…groups of self-directed, functional tasks and activities in which a person engages over the lifespan” (Law et al., 1996, p. 16). The premise behind person, environment, and occupation model is that the overlapping parts of these three components are what affect occupational performance. The PEO model theorizes that a balance of person, environment, and occupation results in optimal occupational performance or a good fit (Law et al., 1996). Law et al. (1996) concluded that an imbalance in any of those three components could impact occupational performance or result in a “lack of fit.” The PEO model deduced that optimal performance resulted from the dynamic relationship between people, their occupations and roles, and the environments in which they live, work, and play (Law et al., 1996).

The PEO model is relevant to this study in that it depicts how occupational performance is a union of the person, environment, and occupation. Women with FM often have a difficult time interacting with their environment because of FM symptoms (e.g., chronic pain, fatigue and sensory over-sensitivity) which result in decreased occupational performance (Choy et al., 2010; Wuytack & Miller, 2011; Arnold et al., 2008). The PEO model gives equal importance to the person by acknowledging that personal abilities of motor performance, sensory capabilities, and general health are important to occupational performance (Law et al., 1996). If the environment
can be adapted to be a better fit for the person, then perhaps their occupational performance can be improved.

Methodology

Design
This study used a quantitative, multi-group, quasi-experimental comparison design to examine whether women with FM had increased levels of generalized sensory over-sensitivities to sensation in daily life. It also established if sensory defensiveness was associated with decreased QOL and participation in patterns of daily activities. Lastly, whether a correlation existed between sensory defensiveness, participation in daily activities, and QOL. The independent variables were the two separate groups of women; group one was comprised of women with FM and the second group were comprised of women without FM. The dependent variables were the scores on the AASP, SF-36, FIQ, and ACS. This research study was part of an ongoing study, which started at the University of Wisconsin-Madison and was completed at Dominican University of California.

Participants
Participants were recruited using convenience sampling from South Central Wisconsin and Northern California. Women with FM were recruited from South Central Wisconsin and portions of the healthy women were recruited from Northern California. A total of 20 women participated in the study, 11 in the control group and 9 in the FM group. In the control group, the ages ranged from 20-67 years old, in the FM group ages ranged from 19-65 years old. Participants were matched within three years of age.

Inclusion criteria for participants were women from any ethnic group ages 19-67 years old. Inclusion criteria for women with FM were based on the criteria established by the
American College of Rheumatology diagnosed by a physician. Exclusion criterion for the sample of healthy women included no history of chronic pain, orthopedic injuries, or major mental health conditions. All participants were also excluded if they were currently being treated for a significant physical or mental health condition or taking medications that would influence physiological state or responses such as antidepressant medication. Women taking GABA modulators, opiates or opioids, high doses of antidepressants/anxiety medication, and women with Axis I psychiatric disorders (e.g., major depressive episode, exacerbation of schizophrenia, or panic disorder) were also excluded. Dominican University of California and the University of Wisconsin-Madison Institutional Review Board for the use of human subjects approved this study.

**Ethics and Legal Considerations**

Researchers obtained approval from Dominican University of California Institutional Review Board (IRB) to recruit participants. Informed consent was signed by all participants and each understood the nature of the research. Participants acknowledged their right to withdraw from the study at any time. There were none or minimal risks in participation. There were no serious injuries, physiological, social, economic, or legal risks involved with participation of this study. The participants were not subjected to any invasive procedures or physiological stressors such as shock, deception, or humiliation. Researchers maintained a professional demeanor while remaining supportive and non-judgmental. Researchers monitored all participants for signs of verbal and nonverbal discomfort. Each participant was given an ID number and confidentiality was maintained for all data. No names were associated with the data or appeared on the test forms. Data was kept in a locked file cabinet and a secured computer in a room that was locked when unattended. Only key research personnel had access to the data.
Instruments

Four distinct questionnaires and one activity were used to collect data about the women’s sensory responsiveness, activity participation, FM symptoms, and QOL.

Sensory processing measures

Adult/Adolescent Sensory Profile is a self-report questionnaire that asked about responses to common sensory experiences that could be encountered in daily life. Responses to sensory experiences were rated on a scale of 1-5 of how often the experiences/behaviors occurred. The AASP yielded a total score, and scores in four patterns: (a) low registration, (b) sensation seeking, (c) sensory sensitivity, and (d) sensation avoiding; within each individual pattern, there were 15 questions. The questions (a total of 60) were further classified into individual sensory modalities for taste or smell, movement, visual, touch, activity level, and auditory (Brown, Tollefson, Dunn, Cromwell, & Filion, 2001). Scores from the sensory sensitivity and sensory avoidance subscales were combined to create a sensory defensiveness composite score. The AASP was normed on approximately 900 adolescents and adults. The AASP is reported by the authors to have a high degree of reliability and validity measuring sensory processing patterns (Brown & Dunn, 2002).

Occupational participation

The Activity Card Sort is an occupational therapy tool that measured participation in daily occupations (Baum & Edwards, 2008). The ACS contained 89 photographs designed to identify and describe participation in daily occupations (Baum & Edwards, 2008). The cards depicted a variety of activities in four areas. Instrumental activities of daily living (IADL’s) include household maintenance, groceries shopping or childcare. Low demand leisure (LDL) includes activities such as reading or sewing. High demand leisure (HDL) would consist of exercising, cleaning the house or yard work. Social activities (SOC) include spending time with
spouse or partner, visiting with friends or traveling. The majority of the people in the original ACS card set pictures are elderly. With permission from the authors, cards (2, 6, 7, 8, 9-12, 14, 17-20, 36, 38, 51-53, 63, 72, 73, 78, 80, 81, 85) from the original ACS were replaced with picture of younger to middle-aged women (D. Edwards, personal communication, November 15, 2011).

The scores were calculated for the percentage of retained activity for total activity and for each category of activity. As reported in the manual, the content, construct, and predictive validity of the ACS has been well established in both American and international samples (Baum & Edwards, 2008).

Health and quality of life measures

The Medical Outcome Survey-Short Form 36 is an assessment that measures functional health and wellbeing. The SF-36 has 36 questions that yield an 8-scale profile; the 8-scale profile is further clustered into physical health scores (PHS) and mental health scores (MHS) (Ware & Sherbourne, 1992). The scores range from 0-100, 0 being the lowest and 100 being the highest. The physical health scores (PHS) are a combination of physical functioning, role-physical, bodily pain, and general health scales. The mental health scores (MHS) consist of vitality, social functioning, role-emotional, and mental health scales. The SF-36 measure has been shown to have high degree of validity and reliability on the measurement of generic health.

The Fibromyalgia Impact Questionnaire was used to examine the impact of FM symptoms on different areas of their lives in people living with FM. Each of the 10 items had a maximum possible score of 10 with a total possible score of 100. Higher FIQ scores indicate greater impact of FM symptoms. The average FM patient typically scores at 50; severely afflicted patients usually score at 70-plus (Burckhardt, Clark, & Bennett, 1991). The FIQ has
been found a reliable and valid measure of the impact on FM on daily functioning and health (Burckhardt et al., 1991).

**Procedures**

Research assistants recruited the subjects and collected data from communities near the Dominican University of California and the University of Wisconsin-Madison. The participants then self-administered the AASP, SF-36, FIQ, and the brief background questionnaire. Every participant also completed the ACS, which was administered by a research assistant trained on administering the ACS. Each participant was informed on the study procedures risk and benefits and signed an informed consent.

**Data Analysis**

The data was recorded in an Excel file with all information de-identified to protect the participants’ confidentiality. The participants’ names and date of birth were removed and put in a separate document and the data was stored in a computer with a locked password. After data was collected, questionnaires were scored and recorded by researchers on an Excel spreadsheet. The data from Northern California was then added to previously collected data from South Central Wisconsin. Statistical Package for the Social Sciences (SPSS) version 14 was used to analyze the data. Data analysis included descriptive statistics of participant demographics and comparison of the differences between women with FM and the control group on FIQ, AASP, SF-36, and ACS measures using two tail $t$-Tests. Pearson’s $r$ Correlations examined the relationship between FIQ, SF-36, and ACS in relation to AASP.
Results

Twenty women participated in this study, 9 with FM and 11 pain free women. Both groups were matched for ages ranging from 19-67 years old. The mean ($M$) age for the control group was 46.2 and 49.2 for the FM group. Standard deviation ($SD$) for the control group was 14.1 and 13.5 the FM group. The two groups did not differ in age ($t(18) = -.473, p = .642$) Both FM and control groups completed the FIQ, which was administered to rule out that participants in the control group did not have FM symptoms. None of the women in the control group had scores on the FIQ indicating FM symptoms. The women in the FM group had significantly higher scores on the FIQ ($M = 51.9, SD = 15.7$) compared to the control group ($M =14.7, SD = 12.2$), ($t(18)=5.782, p = .001$). The FIQ measure established that the control group did not have FM symptoms.

This research addressed four questions.

1. Are there increased levels of generalized sensory over-sensitivities to sensation in daily life in women with FM compared to age matched pain free women as measured by the sensory defensiveness composite score and total scores on the AASP?

   As can be seen in Table 1, women with FM had a significantly higher total mean score than the control groups on the AASP for both the total score and the sensory defensiveness composite score. The FM group reported significantly more sensory defensiveness behaviors than the control group.
Table 1

Comparison of Scores On the AASP of Sensory Defensiveness and Total Between Women with FM and Control

<table>
<thead>
<tr>
<th>Group</th>
<th>Fibromyalgia Group</th>
<th>Control Group</th>
<th>t-Test</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
<td>M</td>
<td>SD</td>
</tr>
<tr>
<td>AASP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>168.8</td>
<td>16.9</td>
<td>147.6</td>
<td>16.7</td>
</tr>
<tr>
<td>SensDef</td>
<td>88.2</td>
<td>13.2</td>
<td>64.2</td>
<td>13.1</td>
</tr>
</tbody>
</table>

AASP= Adult/Adolescent Sensory Profile; SensDef= Sensory Defensiveness; * P<0.05 level (2-tailed).

2. Do women with FM have decreased participation in daily occupations compared to age matched pain free women as measured by the percentage of retained activities on the ACS in the global score and subcategories: HDL, LDL, IADL’s, and SOC?

A series of t-Tests were used to compare the percentage of retained activities between the women with FM and control group in the four subcategories and the global participation score of the ACS. As seen in Table 2, the FM group had significantly lower percentages of retained activities than the control group in the global participation score and two out of four subcategories on the ACS. The women with FM had fewer retained activities in HDL and IADL’s. Low Demand Leisure activity and SOC subcategories were lower in the FM group, but these differences were not significant as shown in Table 2.
Table 2

Percentage of Retained Activities on ACS as Presented From FM and Control Group

<table>
<thead>
<tr>
<th></th>
<th>Fibromyalgia Group</th>
<th>Control Group</th>
<th>t-Test</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global</td>
<td>73% 22</td>
<td>91% 7</td>
<td>2.38</td>
<td>.04*</td>
</tr>
<tr>
<td>LDL</td>
<td>77% 24</td>
<td>90% 11</td>
<td>1.44</td>
<td>.18</td>
</tr>
<tr>
<td>HDL</td>
<td>51% 20</td>
<td>88% 22</td>
<td>3.99</td>
<td>.001*</td>
</tr>
<tr>
<td>SOC</td>
<td>75% 26</td>
<td>94% 7</td>
<td>2.14</td>
<td>.06</td>
</tr>
<tr>
<td>IADL</td>
<td>76% 22</td>
<td>94% 6</td>
<td>2.42</td>
<td>.04*</td>
</tr>
</tbody>
</table>

ACS= Activity Card Sort; LDL= Low Demand Leisure; HDL= High Demand Leisure; IADL= Instrumental Activities of Daily Living; SOC= Social; SensDef= Sensory Defensiveness; *P<0.05 level (2-tailed).

3. Do women with FM have decreased QOL compared to age matched pain free women as measured on the SF-36?

The SF-36 scores were compared for PHS and MHS for both FM and control groups are reported in Table 3. The PHS and MHS related scores were significantly lower in the FM group when compared to the control group. Lower scores indicate decreased functional health and wellbeing. Higher scores indicate absence of impairments in functional health and wellbeing.

Table 3

SF-36 Scores From FM and Control Group

<table>
<thead>
<tr>
<th></th>
<th>Fibromyalgia Group</th>
<th>Control Group</th>
<th>t-Test</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-36</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHY</td>
<td>46.2 21.5</td>
<td>88.4 11.6</td>
<td>5.29</td>
<td>.000*</td>
</tr>
<tr>
<td>MHS</td>
<td>57.3 15.6</td>
<td>72.8 15.9</td>
<td>2.19</td>
<td>.043*</td>
</tr>
</tbody>
</table>

SF-36= Medical Outcome Survey-Short Form; SensDef= Sensory Defensiveness; PHY= Physical Health Scores; MHS= Mental Health Scores; * P<0.05 level (2-tailed).
4. **A) Is there a correlation between sensory defensiveness and participation in daily activities in women with FM?**

**B) Is there a correlation between sensory defensiveness and QOL in women with FM?**

Table 4 reports the correlations between the Total and sensory defensiveness scores on the AASP and the ACS. Women in the FM group showed negative moderate, but non-significant correlations between sensory defensiveness symptoms and participation in daily activities using the ACS. Women with FM who reported more sensory defensiveness symptoms had lower activity participation.

### Table 4

*Correlation Between Activity Participation in the FM Group and Effects of Sensory Defensiveness Symptoms*

<table>
<thead>
<tr>
<th>Total</th>
<th>SensDef</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACS</td>
<td></td>
</tr>
<tr>
<td>Global</td>
<td>-.26</td>
</tr>
<tr>
<td>LDL</td>
<td>-.27</td>
</tr>
<tr>
<td>HDL</td>
<td>-.25</td>
</tr>
<tr>
<td>IADL’s</td>
<td>-.05</td>
</tr>
<tr>
<td>SOC</td>
<td>-.33</td>
</tr>
</tbody>
</table>

ACS= Activity Card Sort; LDL= Low Demand Leisure; HDL= High Demand Leisure; IADL= Instrumental Activity of Daily Living; SOC= Social participation; SensDef= Sensory Defensiveness.

Table 5 reports the correlations between the sensory processing scores, FIQ, and SF-36 scales. The FM group exhibited moderate but non-significant correlations between sensory defensiveness and FM symptoms. Scores on the measures of sensory defensiveness from the AASP were strongly and significantly correlated with the MHS on the SF-36. The correlations between PHS were moderate but not significant.
Table 5

*Correlation Between Decreased QOL in the FM Group and Effects of Sensory Defensiveness*

**Symptoms**

<table>
<thead>
<tr>
<th></th>
<th>AASPTotal</th>
<th>SensDef</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF36_PHS</td>
<td>-.26</td>
<td>-.45</td>
</tr>
<tr>
<td>SF36_MHS</td>
<td>-.79*</td>
<td>-.74*</td>
</tr>
<tr>
<td>FIQ_Total</td>
<td>.49</td>
<td>.47</td>
</tr>
</tbody>
</table>

AASP= Adult/Adolescent Sensory Profile; SensDef= Sensory Defensiveness; SF-36= Medical Outcome Survey-Short Form; PHY= Physical Health Scores; MHS= Mental Health Scores; FIQ= Fibromyalgia Impact Questionnaire

** Correlation is significant at the 0.01 level (2-tailed).
* Correlation is significant at the 0.05 level (2-tailed).
Discussion

The results confirmed the hypotheses of this study. First, women with FM experienced more symptoms of sensory over-sensitivity than the pain free women. Second, women with FM had decreased levels of participation in daily activities. Third, women with FM also had a decreased QOL in comparison to the pain-free control group. Lastly, there was a moderate correlation between sensory over-sensitivity and FM symptoms, QOL, and participation in daily activities. The strong relationship between mental health, well being, and sensory defensiveness was higher than anticipated and may indicate that sensory over-sensitivity could be impacting mental health more than previously thought.

Participants with FM had increased levels of generalized sensory over-sensitivity. The FM group had higher scores overall on the AASP including the sensory defensiveness subcategory compared to control group. In contrast to previous studies, which only explored the physical symptoms (fatigue, muscle stiffness, pain, and tenderness), this study looked at sensory symptoms (auditory, tactile, olfactory, and visual) that impacted daily life. This study supported previous research done by Wilbarger and Cook (2011) reporting over-sensitivities across multiple modalities in women with FM in comparison to the control group and rheumatoid arthritis group. For example, women with FM were more likely to endorse items like “I leave or move to another section when I smell a strong odor in the store (e.g., bath products, candles, or perfume)”. Furthermore, the findings were similar to those from participants with FM who participated in studies examining physiological responses to sensation. These results also supported Giesser et al. (2007) findings that reported the FM group having greater sensitivity to daily sounds when compared to a control group. It appears that sensory defensiveness is a frequent symptom of FM. Occupational therapists have specialized knowledge in treating
sensory processing disorders and sensory defensiveness in particular. The findings of this study and others demonstrate that occupational therapists incorporate additional treatment methods to address sensory defensiveness symptoms when treating people with FM. Current treatment of FM focuses on physiological aspects such as strengthening and yoga, which neglect the sensory component. Given these findings, occupational therapy could include strategies to address the sensory defensiveness symptoms including aspects of sensory integration. Sensory integration methods may include a sensory diet and deep pressure massage. Additionally, occupational therapists could educate FM patients on environmental modifications in order to manage sensory defensiveness symptoms.

In this study, women with FM reported decreased participation in all areas of daily activities. There was a significant decrease in engagement presented in the areas of Global, IADL’s, and HDL activities from the subcategories in the ACS. This decreased participation in IADL’s is consistent with Wuytack and Miller’s (2011) findings, which reported that women with FM experienced difficulty with child rearing because of the effects of fatigue, pain, and stiffness. In addition, women with FM have also reported decreased participation in high demand activities such as traveling and exercise because of fatigue (Wuytack & Miller, 2011). Participation was lower, but not statistically significant in LDL and social subcategories. For example, it is likely that women with FM would not show a significant decrease in activities such as listening to the radio (LDL) or attending family gatherings (SOC). Although, this study did not find lower significance in SOC and LDL activities, it dovetails with two previous studies which reported that women with FM experienced decreased SOC participation because of the unpredictability of symptoms and fatigue (Arnold et al., 2008; Sallinen et al., 2011). The lack of significance may have been due to low number of participants.
Women with FM showed decreased QOL in both physical and mental health subcategories on the SF-36. The mean scores for the FM group were significantly lower in both physical and mental in comparison to the control group. The PHS may have been lower in the FM group due to women experiencing widespread joint pain, fatigue, and muscle stiffness. These symptoms could have hindered their physical and mental ability to engage in activities of daily living. These results support Arnold et al. (2008) findings that FM patients reported experiencing things such as fibro fog defined as forgetfulness, and difficulty with articulation of thoughts.

Lastly, sensory defensiveness symptoms were moderately correlated with decreased participation in daily activities. The relationships suggest that in some part sensory defensiveness symptoms are decreasing participation. The SOC participation had highest negative correlation with sensory defensiveness, which infers that higher sensory defensiveness symptoms predict lower SOC participation.

Participants also reported strong correlations between high sensory defensiveness symptoms and poor mental health. These findings are consistent with a number of studies suggesting that women with sensory defensiveness symptoms often experienced anxiety, depression, and social isolation (Kinnealey & Fuiek, 1999). This fits with this study’s findings that women with FM and sensory defensiveness have higher levels of mental health afflictions (Kinnealey & Fuiek, 1999). These findings have important implications for occupational therapists in further educating women with FM on promote mental health and maintain a high QOL. Occupational therapy treatments to address mental health could include CBT, meditation, and coping strategies.
Limitations

The sample size of this research study was small which decreased the likelihood of finding significant differences between groups or significant correlations. Having a larger sample size would improve the ability to determine if true significance existed. There were several moderate correlations that were not significant likely due to low power. The sample size also limited the ability to generalize the results to larger populations of people with FM. Limitations with self-reported data are always subject to accuracy and biases. The researchers had a small pool of participants, which may have caused a sampling bias. Another limitation included combining samples from two regions (South Central Wisconsin and Northern California), which have varying environmental factors.
Conclusion

This is one of the first studies to research how FM symptoms affect daily life and occupations. This study established that there were significant differences in generalized sensory over-sensitivity between women with FM and the pain free control group. Ranges of treatment methods are available to people with FM, but none addressed the sensory disruptions. The implications of these findings for the occupational therapy field are that (in addition to traditional occupational therapy interventions) sensory disruptions need to be addressed as well. Skilled occupational therapy services could include treatments such as a sensory diet, sensory desensitization, deep pressure, or sensory integration based treatment to address the sensory over-sensitivity symptoms. Occupational therapy can also provide treatments for the mental health aspect such as coping strategies, guided imagery, CBT, meditation, and stress management. Occupational therapists have the skills and expertise to incorporate multiple treatment approaches and environmental modifications to enable individuals with FM to live a meaningful life.

Future Research Recommendations

Further studies need to be done with a larger sample to have the ability to generalize the effect of sensory over-sensitivity symptoms in people with FM and their ability to participate in daily activity to the greater population. Researchers recommend investigating the psychological relationship between MHS and FM with sensory over-sensitivity symptoms.
References


Appendix A – Institutional Review Board Approval Letter

March 7, 2013

Ashlee Sand
340 Channing Way Apt 241
San Rafael, CA 94903

Dear Ashlee:

I have reviewed your proposal (entitled, The Impact of Fibromyalgia and Sensory Processing on Participation of Daily Activities) submitted to the Dominican University Institutional Review Board for the Protection of Human Subjects (IRBPHS Application, #10110). I am approving it as having met the requirements for expedited review.

In your final report or paper please indicate that your project was approved by the IRBPHS and indicate the identification number.

I wish you well in your very interesting research effort.

Sincerely,

[Signature]

Martha Nelson, Ph.D.
Chair, IRBPHS
Appendix B – Recruitment Flier

Healthy Women
Invitation to Participate in Research on Quality of Life and Sensory Processing

Who? Healthy women ages 20-60 to participate in research on how people respond to sensation in the environment and how it impacts daily life.

What? Participants will complete several short questionnaires on health, sensation, and daily activities.

Where? Dominican University of California, Meadowlands Lab.

Email or Call Ashlee at
707-477-0025  FMresearch2014@gmail.com
Appendix C – Recruitment Email

Sample Email to Participants

Dear Participants,

We are an undergraduate research team from Dominican University of California doing a comparison study between healthy women and women with Fibromyalgia and Sensory Processing Disorders. The nature of the study is comparing the difference of sensory processing in women with fibromyalgia and healthy women.

We are recruiting healthy women ages 20-60 with no chronic pain, no orthopedic injuries, or a major mental health disability.

If you chose to participate in this research, you will be completing questionnaires based on sensory and daily life, and sorting a set of activity picture cards. Lastly, your physical response to sensation will be measured using different touch, smell and sound.

Please contact us at FMresearch2014@gmail.com

We appreciate your time and hope to hear from you soon.

Sincerely,

Ashlee Sand, Regina Okun, and Florina Mendoza-Battle.
Appendix D1 – Consent Form

DOMINICAN UNIVERSITY of CALIFORNIA
CONSENT TO BE A RESEARCH SUBJECT

Purpose and Background:
Ashlee Sand, an undergraduate student in the Department of Occupational Therapy at Dominican University of California. The purpose of this study is to understand how healthy people respond physically to sensory experiences and how that relates to patterns of daily activity. The researcher is interested in understanding how sensory processing affects the quality of life and participation in activities of healthy women.

I am being asked to participate because I am a healthy woman that is interested in contributing further understanding of the effects of Fibromyalgia on women.

Procedures:
If I agree to be a participant in this study, the following will happen:
1. I will participate in 5 self-reported questionnaires, which will include personal life history, general health, quality of life, and sensory responses to everyday experiences.
2. I will participate in a 30-minute activity card sort, describing which daily activities I spend time doing. All personal references and identifying information will be eliminated when these results are transcribed, and all subjects will be identified by numerical code only, thereby assuring confidentiality regarding the subject’s responses. The master list for these codes will be kept by Dr. Julia Wilburger in a locked file. Only the researchers and Ashlee's faculty advisor will see coded transcripts. One year after the completion of the research, all written and recorded materials will be destroyed.
3. I will be furnished with a written summary of the relevant findings and conclusions of this project upon request. Such results may not be available for three to six months.

Risks or Discomfort:
1. I understand that my participation involves no physical risk, but may involve some psychological discomfort, given the nature of the topic being addressed in the interview.
2. I will be discussing topics of a personal nature and I may refuse to answer any question that causes me distress or seems an invasion of my privacy. I may elect to stop the interview at any time and may refuse to participate before or after the study is started without any adverse effects.

Benefits:
There will be no direct benefit to me from participating in this study. The anticipated benefit of this study is a better understanding of the effects sensory processing in women with FM.

Questions:
I have talked to Ashlee about this study and have had my questions answered. If I have further questions about the study, I may contact her at FMresearch2014@students.dominican.edu or her
Appendix D2 – Consent Form

research supervisor, Dr. Julia Wilbarger, Professor, Department of Occupational Therapy
Dominican University of California (415) 458-0125.

If I have any questions or comments about participation in this study, I should talk first with the researcher and the research supervisor. If for some reason I do not wish to do this, I may contact the Dominican University of California Institutional Review Board for the Protection of Human Subjects (IRBPHS), which is concerned with the protection of volunteers in research projects. I may reach the IRBPHS Office by calling (415) 257-1389 and leaving a voicemail message, by FAX at (415) 257-0165 or by writing to the IRBPHS, Office of the Associate Vice President for Academic Affairs, Dominican University of California, 50 Acacia Avenue, San Rafael, CA 94901.

Consent:
I have been given a copy of this consent form, signed and dated, to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. I am free to decline to be in this study or withdraw my participation at any time without fear of adverse consequences.

My signature below indicates that I agree to participate in this study.

<table>
<thead>
<tr>
<th>SUBJECT’S SIGNATURE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SIGNATURE OF RESEARCHER</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

BE SURE THAT THE MATERIAL THAT FOLLOWS IS REMOVED FROM THIS LETTER WHENcopied FOR USE
Appendix E1 – Background Questionnaire

BACKGROUND QUESTIONNAIRE

Date: ______________________ ID #____

Participants Ethnic Background: (circle one)

- American Indian or Alaskan Native
- Black, not Hispanic
- White, not Hispanic
- Asian or Pacific Islander
- Hispanic
- Other, or unknown

FAMILY/LIVING SITUATION

Were does the participant live? (With relatives, alone, etc.)

Who (name and relationship) currently make legal decisions for the participant?

EDUCATION

Highest level of education (check one)

- Less than 7th grade
- Completed 8th or 9th grade
- Completed 10th or 11th grade
- Graduated from high school
- Some college or specialized training
- Graduated from four year college or university
- Graduate degree

WORK

Does the Participant work? YES NO

Describe Job and number of hours of work per week.
Appendix E2 – Background Questionnaire

MEDICAL HISTORY
Please list all current or previous medical psychological or educational diagnoses the participant has been given by a physician, psychologist, psychiatrist or other health professional. Feel free to include any comments regarding these diagnoses.

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Date</th>
<th>By whom</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Please list all medication taken during the last month:

Does the participant have a history of any of the following? If yes, please describe

- Vision or hearing problems
- Physical limitations
- Mental Health problems
- Seizures
- Head injury/loss of consciousness
- Neurological difficulties
- Difficulty with drugs or alcohol

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RESEARCH STUDIES
Has the participant been in any other research studies? Please list all previous research studies.