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The Effect of an Online Coping Skill Application on Relapsing-Remitting Multiple Sclerosis Sufferers

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Abstract

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by

Jennifer Garrison

MS, Wilmington College, 2002

BS, Wesley College, 2000

AS, Central Texas College, 1998

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Many individuals with multiple sclerosis (MS) are classified as having relapsing-remitting MS (RRMS), a form of the illness that requires constant symptom management for suffers to achieve optimum outcomes. There are only a few community-based educational programs that exist to help RRMS sufferers cope with their illness; the effectiveness of those that have been fielded has not yet been adequately assessed. The research questions of this study were to determine if an online training development module would increase the coping skills of those affected by RRMS and if the online educational module would be more effective at improving the coping skills of mild RRMS sufferers versus severe RRMS sufferers. The theoretical foundation was based on a stress-coping model commonly utilized for chronic disease management. The research design employed 2 groups, nonrandom selection, and use of a pretest/posttest applied to the target population from the Georgia MS Chapter. SPSS was used to perform statistical analysis as well as to perform the Mann-Whitney test on study data/results. According to findings from this quantitative study, the application of the online education development module to RRMS sufferers does provide a mechanism of significantly improving their coping skills. This positive social change improvement of coping strategies helps the patients as well as family, friends, and coworkers, and this module would serve as the complement to augment coping strategy improvement efforts for RRMS suffers. This study supports improvement of RRMS sufferer coping skills in the short term, and a future area of research focus would address the long-term improvements in coping skills for RRMS sufferers from the application of this online module.

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Dedication

I would like to dedicate this study to all of the researchers before me. Their work enabled me to conduct this research study in order to see clarity in the dilemma of MS not having leadership effectiveness aspects related to MS community awareness.

Keep your thoughts positive because your thoughts become your words. Keep your words positive because your words become your behavior. Keep your behavior positive because your behavior becomes your habits. Keep your habits positive because your habits become your values. Keep your values positive because your values become your destiny. (Gandhi, 2012, p. 14)

When it comes to examining the prognosis for multiple sclerosis (MS), there's some good news and some bad news. Let's start with the bad news: there is currently no cure for MS. However, there is good news about life expectancy. According to the Multiple Sclerosis Foundation (MSF), MS is not a fatal disease. In fact, those with the condition have essentially the same life expectancy as the general population. (Healthline, 2013, p. 12)

More than 2.5 million people worldwide are thought to have some form of multiple sclerosis. An estimated 400,000 people in the United States are thought to have MS. Most people are between 15 and 60 years of age when diagnosed with MS, although it can also occur in young children and significantly older adults. (MSlifelines, 2013, p. 57)

Acknowledgments

I would like to dedicate this journey of writing, rewriting, and my frequent absence, to my family and my best friend, Greg Garrison, all of whom have given me courage and peace of mind through some significant life changes. Greg has taught me what a true friend is and his daily voice, comfort, and support is why I still persevere. I want to acknowledge my dear Mother, Irene Milne, who has been a blessing when I needed a good laugh or just helping out. I am most grateful for my two children, Samantha and Adam. They are my heart and soul, my flesh and blood and are forever with me as I worked through the darkest moments of my journey – this PhD is for them…and…kudos to my dad and brother, who have been my backbone.

There is not a day that goes by that I am not inspired and blessed to know every single one of my Airmen stationed at Shaw Air Force Base, South Carolina. I am aware and cognitively in-tune with what goes on – the strain of their lives that are nothing short of being challenged on a daily basis. I am in awe of their resilience and strength to keep on going in times of stress and disorder. To Dr. Lawrence Fulton, my chair who has inspired, supported and grounded me when there was one more thing to do, and Dr. Mary Lescoe-Long, who reminded me of the "little engine that could" finding a backup plan just in case.

I am forever humbled by this process and journey – that which has kept me up day and night thinking about how, why, where, and who.

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Chapter 1: Introduction to the Study

Introduction

Multiple sclerosis (MS) is the most prevalent neurological disability today in developed countries. The relapsing remitting course of MS is the most debilitating and eventually affects 85% of MS sufferers (Kasper, Kopke, Muhlhauser, & Heesen, 2006, p 56). Within 10 years of initial diagnosis with MS, sufferers will often develop a secondary progressive course of the disease (Kasper et al., 2006). Those afflicted with MS must deal with daily challenges to leading a normal life. The health care systems must grapple with the challenges of preventive care and treatment of those affected by MS. Health promotion and education are areas that need to be addressed in order to properly care for MS sufferers. The unique aspects of MS result in a disease with the ability to impact health care customers, which necessitate a look at maximizing coping skills of sufferers. The health care system does not always provide adequate education on MS or address leadership effectiveness aspects related to MS community awareness. An online tool can be used to fill help this gap for MS sufferers.

Background

Preventive medicine is the cornerstone for all diseases in the healthcare system. According to the Robert Wood Johnson Foundation (1999),

> Investing in disease prevention, health promotion and health education initiatives are the most effective and common-sense way to improve consumer health quality such as, developing preventable illnesses programs designed to reduce health care

costs and programs designed to improve the productivity of the American workforce in order to be competitive with the rest of the world. (para 3)

There is a need for continuous awareness of a positive health-related quality of life (HRQoL) for a person with MS. Research should be pursued for this research initiative. MacLean and Russell (2005) claimed that there must be more innovative ways of responding to the health information sharing of those connected with MS, such as cognitive programs tailored to their individual requirements or programs delivered in different formats within a time-frame to suit the MS sufferer (e.g., access through a web-based framework from the convenience of home and career environments).

There exist access and financial barriers to receiving proper care and support for MS sufferers. These barriers make it difficult for MS sufferers to obtain support from costly nonprofit, agency-based, in-house workshops to aid with MS coping skills. For the MS sufferer, a potential alternative to this traditional method is via existing free, virtual, online learning workshops. According to the National Multiple Sclerosis Society (2014), some MS patients cannot afford access to available MS treatments. MS patients may not be able to afford to attend educational in-house workshops. Given the logistical and geographic barriers that MS sufferers can face, a more readily accessible tool for increasing coping skills for MS sufferers is worth pursuing. Such a tool might be found through an online forum.

In addition to existing organizations to include the National MS Society, nonprofits and government agencies an online resource may also help MS patients to better cope with their disease. One such source is QualityHealthCareusa-QHCusa. The

QHCusa center for research and virtual health education framework is designed to reach

those with MS across 52 states or MS chapters that are in need of free and unlimited

access to quality leadership skills, personal development, and coping strategies. The

QHCusa center is a resource for further study in increasing coping skills for MS

sufferers.

Problem Statement

One of the diseases that has far reaching results and affects people at various

levels is MS. This disease has classified 85% of sufferers identified with MS have RRMS

(Minden, Marders, Harrold, & Dor, 2007, p 547). Minden et al. (2007) acknowledged

that MS patients suffer from exacerbations from this disease. McLean and Russell (2005)

identified that gaps do exist for MS awareness regarding coping skill mechanisms for

those suffering with the disease. In this study, I will capitalize on the need for increased

leadership engagement and community involvement. MacLean and Russell identified that

there should be ways to respond to health information sharing of those with MS. Some

examples are cognitive programs that are geared towards individual requirements.

Another example would be programs delivered to MS sufferers in different formats, such

as web-based frameworks.

Investing in disease prevention, health promotion, and health education initiatives

are the most effective ways to improve consumer health quality (MacLean & Russell,

2005). Researchers must develop preventable illnesses programs designed to reduce

health care costs and programs designed to improve the productivity of the U.S.

workforce. The American Association for Retired Persons in 2009 (2011) confirmed that

family caregivers (42.1 million) provide support to those with limitations in daily activities (para 2). MS-related burden/stress and coping strategies are connected (Minden et al., 2007). The connection opens the gates for analysis and further research to MS coping strategies (Feinberg & Houser, 2012). For instance, Minden et al. (2007) piloted a longitudinal study on the MS populace and quoted the subsequent as access barriers to self-care: 19,400 or 10.5% persons lack access to prescription medication, 7,600 or 4.1% persons experience barriers to medical care, and 4,500 or 2.4% persons are unable to get continuing cognitive development related to mental health services. There is a need for an increase in coping skills mechanisms to help MS sufferers. My quantitative research plan could help fill the gap in services available in mental health for MS cognitive development.

Purpose of the Study

The purpose of this quantitative study was to better understand the Multiple Sclerosis Online Training Module (independent variable) by quantifying and analyzing the coping response (dependent variable) for the Georgia National Multiple Sclerosis Society Chapter site participants. This online training module was developed by a group of students from Humber College, located in Toronto, Ontario (Kashyap, 2009). The goal of this investigation was to examine the effectiveness of this online MS education module to increase the coping skills of individuals with RRMS.

Research Questions

The following research questions were addressed in this experimental design study to quantify the impact of an online MS education module on RRMS sufferers.

1.   Will the online training development module increase the coping skills of those affected by RRMS?

2.   Is the online educational module more effective at improving the coping skills of severe RRMS sufferers versus mild RRMS sufferers?

Hypothesis

Based on the research questions listed above, I hypothesized that the use of the online MS education module would improve the coping abilities for RRMS sufferers.

$H1_a$: The online training development module will increase the coping skills of those affected by RRMS.

$H2_a$: The online training development module will be more effective at improving the coping skills of severe RRMS sufferers versus mild RRMS sufferers.

$H1_0$: The online training development module will have no effect on the coping skills of those affected by RRMS (null hypothesis)

$H2_0$: The online training development module will not be more effective at improving the coping skills of severe RRMS suffers versus mild RRMS sufferers

Theoretical Foundation

MS is universally recognized within the medical and nonmedical community as a debilitating disease with far-reaching consequences for suffers. MS is a degenerative disease that affects an individual by creating challenges to performing normal daily activities (Peeters, Boersma, & Koopman, 2008). These challenges have a marked effect on MS sufferers both physically and psychologically. Their inability to accomplish normal daily tasks makes them dependent upon others for daily caregiver support, and the

individual's inability to accomplish tasks directly affects their feelings of life fulfillment and overall individual accomplishment (Peeters et al., 2008). Depression can eventually result, and this depression can also affect those caring for individuals (Peeters et al, 2008).

One aspect worth mentioning is that of the theory of cognitive appraisal created by Lazarus and Folkman (1984). In this theory, stress is defined as a two-way process made up of stressor production followed by stressor response. The cognitive appraisal occurs when an individual considers two contributory factors to his or her stress response: the extent of threatening tendency of the stress and the individual's estimation of capability to reduce or tolerate the stressor, as well as the subsequent stress it produces (Peeters et al., 2008). The next step is to evaluate potential harm or benefit (primary appraisal) and then to make a decision on the appropriate course of action (secondary appraisal). The stress level during the primary appraisal can affect the ability of an individual to reach the point of making a secondary appraisal. The use of coping strategies can ease this transition enabling the individual to better reach the secondary appraisal step (Peeters et al., 2008).

Derived from this cognitive-appraisal model, an extended model for coping with a chronic disease was developed by Maes, Leventhal, and de Ridder (1996; Figure 1). Maes et al. developed an extended stress-coping model. According to Peeters et al. (2008) based on this stress-coping model:

Other life events, disease characteristics, disease-related events, and demographic characteristics are linked to the appraisal of demands and goals. Furthermore, all

factors are directly or indirectly related to coping behavior, which is also moderated by external and internal resources. All these factors contribute to psychological, social, and physical consequences (HRQoL) through coping. (p. 7).

Maes et al.'s approach to cognitive appraisal, stress, and coping is the theoretical framework on which the stress-coping model is based. I used this model for the research of the MS sufferers.
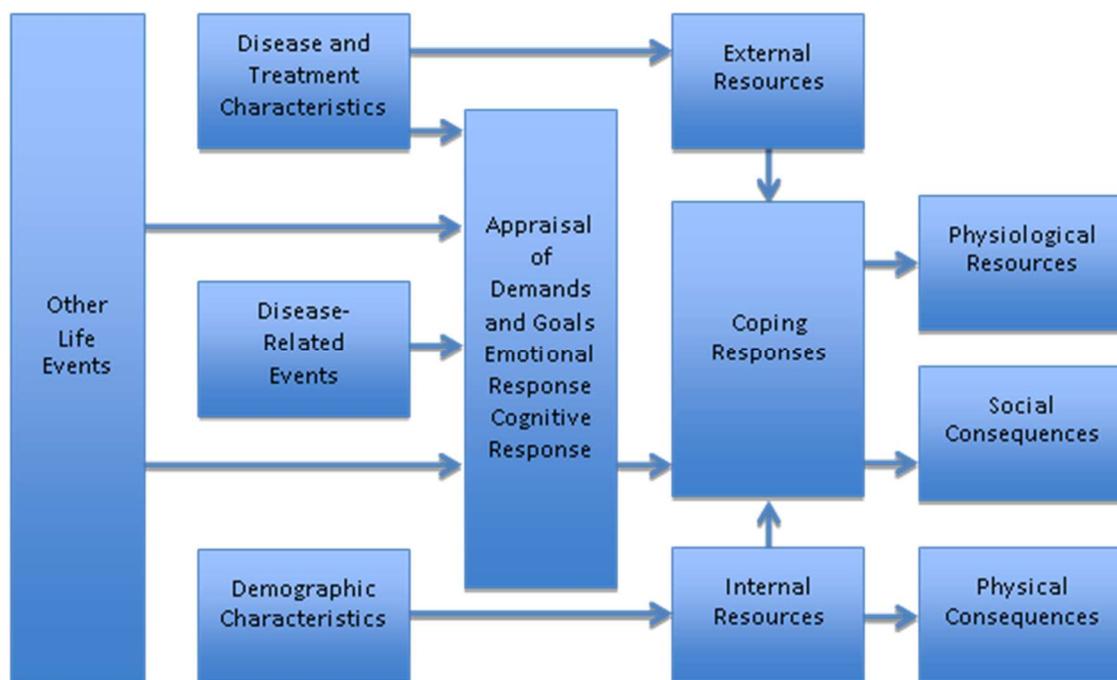
Figure 1. A flowchart depicting the stress-coping model developed by Maes et al. (1996).

Through formal organizations such as the Multiple Sclerosis Society (and its individual state chapters), MS sufferers have resources at their disposal to include hands-on and online programs. There are practical challenges associated with hands-on

programs (i.e., geographic access), which often makes the online programs an advantageous resource. However, the existing online programs lack discussion on aspects and strategies to increase coping skills.

Nature of the Study

I conducted my research study using a quasi-experimental quantitative design. This design has inherent advantages applicable to my study's subject area. The design enabled me to identify a catchment of study participants and randomly assign them to various groups based on treatment type (Frankfort-Nachmias & Nachmias, 2008). The two major groups were the experimental groups. The experimental groups were exposed to the independent variable (in this case the online program for coping with MS), and were divided based on mild or severe RRMS. Establishment of a control group for this experiment was problematic due to the ideal intent of establishing a control without the online program intervention. Rather than establish a control group, a deliberate attempt was made to statistically control as many threats to internal validity as possible. The dependent variable was the degree of coping realized based on pre/post questionnaires. The target population included those suffering from MS who were members of the Georgia MS Society. I chose this state based on my personal proximity being stationed at Shaw Air Force Base, South Carolina. The overall focus of my research study was to quantify and evaluate the effectiveness of the online educational training platform for mild and severe RRMS sufferers.

The measurement instrument of my research study was a questionnaire. This questionnaire was applied to study participants during, before, and after the experimental

period. The experimental period entailed the period in which the online education tool was applied. The method of application by use of the tool will help improve the coping skills. I personally briefed the Power Point tool to study participants by focusing on key areas throughout my experimental briefing period. This was a much more effective method for independent variable application than simply placing participants in front of a computer and asking them to review the online tool themselves. Resident experts in the field of RRMS were consulted to provide expert presurvey questionnaire review. The goal of this evaluation was to ensure that the tool addressed all clinically identifiable coping benchmarks in a quantifiable fashion.

Operational Definitions

Exacerbation: Defined as intensification of old symptoms lasting 24 hours at the same time with relapse or new symptoms (MSlifeline, 2013).

Multiple sclerosis (MS): An autoimmune disease of the central nervous caused by neurological defects in the early years of the disease and gradually worsening in later years (MSlifeline, 2013).

RRMS: Defined as MS developing new symptoms or worsening of old symptoms (relapses or exacerbations; MSlifeline, 2013).

Remission: Decreased severity of MS symptoms (MSlifeline, 2013).

Severe RRMS: Having MS symptoms with limited mobility and complex symptoms, making one dependent upon others for care and support (MSlifeline, 2013).

Assumptions, Scope, Limitations, and Delimitations

Within the confines of this research study are assumptions and limitations. In research, construct validity in measurement is the aspect of measurement validity focused on the "general theoretical framework within which they conduct their studies in order to determine whether the instrument is logically and empirically tied to the concepts and theoretical assumptions they are employing" (Frankfort-Nachmias & Nachmias, 2008, p. 152). I showed construct validity in my experimental research by demonstrating through preliminary research that an existing online education platform does impact the coping skills of those affected by RRMS (Got-MS, 2008). My research can at least nominally demonstrate this, and I have a theoretical basis of construct validity to ascertain that the online education module can also provide an increase or decrease in the coping skills of the MS population, and the research questionnaire used can also accurately capture and quantify these changes in coping skills. Research cost and practical limitations, coupled with power analysis results, were the guiding factors in the size of the sample I chose to study. Practical limitations included facets such as the population in Georgia of each of the two populations, feasibility in fielding the questionnaire to the sample subsets, and the required workload to obtain increasing levels of subset samples.

Significance of the Study

My aim was to promote free public services for leadership engagement and coping strategies for burden and stress among the 161 million chronically ill populations and the growing 60 million family caregivers who care for them (Feinberg & Houser,

2011). Specific to RRMS, I evaluated the promotion of such a free public service. This public service was in the form of an online education tool for RRMS sufferers.

Summary

A review of the background of RRMS sufferers, as well as the need for a tool for maximizing coping for RRMS sufferers, has been discussed. I outlined my problem statement, purpose, hypothesis, and various aspects of the study I conducted in order to ascertain and quantify the effectiveness of an online educational tool for increasing coping skills for RRMS sufferers. Results from this study have the potential to support more widespread use of online education tools for RRMS sufferers, whereby providing an effective and more readily accessible platform resource for increasing coping skills. Chapter 2 provides an overview of the literature review.

Chapter 2: Literature Review

Introduction

Continuous awareness associated with MS is an essential element in my research study. This awareness is directed towards those afflicted with MS. In this study, I have identified numerous past research works with applicability to my chosen research study subject. I believe these bibliographic works provide a basis to justify a foundational need for the research initiative I undertook. The major source of my research has been articles from the Walden Research Library. Searches were conducted in the Walden Research Library with the primary focus being on recent articles in journals, websites, and books published primarily in the past 10 years on MS and RRMS. For this study specific search terms used included *MS*, *RRMS*, *quality of life*, *coping*, and *control strategies*.

MS Symptoms Leading to RRMS

Individuals with MS symptoms can suffer from attacks as new symptoms appear or fade away. Eighty-five percent of MS sufferers are classified with RRMS, which can lead to suffering from exacerbations from having the MS disease. (Mslifelines, 2011, para 1-3). As symptoms partially or never go away, relapses are immediately followed by a period of remission. These MS sufferers can become depressed as progressive-relapsing takes its course. MS sufferers experience periods in which they may never get better or get worse (Mslifelines, 2011, para 1-3).

Leadership engagement, community involvement, and more research are warranted with respect to MS. In 2009, the American Association for Retired Persons (2011) noted that, at any given time, 42.1 million family caregivers were providing some

type of care to adults with limitations on their daily activities (para 2). In addition,

approximately 61.6 million persons were the actual providers of that care during any

given year (American Association for Retired Persons, 2011, para 2). The overall care

provided amounted to $450 billion dollars annually (American Association for Retired

Persons, 2011, para 2). This was identified as a spike in cost as compared to $375 billion

identified just 2 years previous (American Association for Retired Persons, 2011, para 2).

The facts above explain the reason for more research in the MS disease. MS sufferers

lack the education on how to cope with day to day living with the MS disease. This is due

to the lack of research and online education given to MS sufferer. If MS societies had

more community leadership engagement in each state educating how to cope with the MS

disease, the cost for healthcare may decline due to an understanding of how to cope with

the disease.

Improvements for coping with the MS disease are underway in the healthcare

community. The need for, and improvement in, the sharing of health information was

identified as paramount by MacLean and Russell (2005). This improvement includes

innovations such as cognitive health programs adapted to the individual needs of patients,

along with time-sensitive health care delivery programs. These delivery programs should

be presented in varying formats to improve their effectiveness; these programs should

include web-based access. This type of access allows for application in various

environments, including the home and occupational application.

Current barriers to rewarding living must be broken down for those affected by

MS. Specifically, these barriers include areas such as uncontrolled costs as well as a

general lack in nonprofit level assistance through in-house workshops. These in-house workshops are prime targets for augmentation or even replacement with other more cost-effective and easily accessible options (Hendley, 1997). Online workshops would provide a reduction in costs for treatment both initially and in the long term. Free and unlimited accesses to leadership skills tools are already available in libraries and online. Along with leadership tools, local MS Society centers can offer assistance with personal development and coping strategies.

The purpose of this quantitative study was to analyze theories related to MS from Georgia Chapter site participants. In this study, I used Clark's (2007) theory of a "quantitative methodology and validity of a population" (p. 2), and Creswell's (2009)

> Strategies of inquiry from a post positivist theory of analysis, and the writing from an investigators data collection from world views and the investigators writings in support of experimental strategy of inquire of a narrative study design such as various types of the open ended interviews, specifically pre and post measures of behavioral traits of the specific population being studied. (p. 16)

Maes et al.'s (1996) extended stress-coping model was the theoretical framework on which the stress-coping model is based; I applied this model towards the research of the MS sufferers.

There are reasons why instilling positive learned behavior for MS sufferers is critical to improve coping skills. Orem (2012) claimed that self-care "is a learned and purposeful behavior based on group cultural and behavioral characteristics because one learns from one's own environmental experiences as well as observing others within

one's culture and the outcomes of a person's actions and behaviors" (p. 984). Goetzel,

Roemer, Levinson, and Samoly (2008) stated that workplace health promotion programs

"should be cohesive to employer-sponsored initiatives and directed at improving the

health and well-being of all employees" (p. 985). Goetzel et al. (2011) explained that

"families and retirees should be included in this initiative and in some cases, include the

surrounding local communities such as nurses where businesses are located" (p. 986).

The workplace provides for an atmospheric setting to address the introduction and

maintenance of community sponsorships for long-term health promotion programs. The

MS program in the Georgia MS Chapter is central to crafting and instilling positive

learned behavior for participants in this quantitative research study. According to the

Centers for Disease Control and Prevention

> The President's budget proposed a competitive and cooperative agreement for
>
> disease-specific programs into a more streamline approach, also known as the
>
> comprehensive chronic disease prevention program. Chronic disease is among the
>
> most prevalent, costly, and preventable of all health problems." (2011, para 2)

The next article of relevance to this study is the "Balancing Qualitative &

Quantitative Methodology in Health Services Research: Continue: Three Abbreviated

Research Plans"; Clark's (2007, p.2, 4) theory of a "quantitative methodology and

validity of a population" (p.2) supported my research study. Creswell (2009, p. 16, 12,

13) noted,

> Strategies of inquiry from a post positivist theory of analysis, and the writing from
>
> an investigators data collection from world views and the investigators writings in

support of experimental strategy of inquire of a narrative study design such as various types of the open ended interviews, specifically pre and post measures of behavioral traits of the specific population being studied. (p.16)

Orem (2012) is relevant to theoretical framework of the present study. Orem cited,

The true importance of self-care is in this notion is a learned and purposeful behavior based on group cultural and behavioral characteristics because it is learned from one's own environmental experiences as well as observing others within one's culture and the outcomes of a person's actions and behaviors. (p. 124)

My research plan for MS sufferers may improve the lives of individuals in the state of Georgia and potentially create positive health outcomes.

Stress of the MS Sufferer

Stress is considered overtaxing when it exceeds the resources of an individual and has a negative effect on the well-being of an individual (Lazarus & Folkman, 1984). In order to best cope with stress the MS sufferer must maximize their cognitive and behavioral response when encountering threatening situations (Silver & Wortman, 1980).

In 2007, Klauer, Schneider, and Zettle concluded, "preventive psychological intervention has frequently been recommended, at least for MS sufferers in the early stages of the disease" (p. 107). Such preventive intervention programs arm the MS sufferer with the skills to better cope with the consequences of their debilitating illness.

Sufferers to deal more effectively with the consequences of their illness. The concept of coping plays a central role for such preventive approaches (Klauer et al., 2007).

Sá (2008) recognized that the management of the disease in MS sufferers is based on standard psychiatric treatment guidelines to strengthen the sufferer's coping strategies (p. 877). According to Mohr (2007), accumulating evidence summarized in a recent systematic meta-analysis support the hypothesis that there is an association between stressful life events and an increased risk for MS exacerbations (p. 65). Events in life that evoke stress in the MS sufferer often come from family and work conflicts. Research has demonstrated that these events and the ensuing stress are directly associated with a significant increase in the risk of the occurrence of a new gadolinium enhancing (Gd+) MRI brain lesion 8 weeks later (Mohr, 2007, p. 65). There existed several limitations in the current literature. First, for the MS sufferer there existed an association between stress and exacerbation, but evidence was lacking to support direct causality between the two. Second, an examination of biopsychosocial models was also lacking to explain the association between stress and exacerbations (Mohr, 2007, p. 65).

Coping Strategies of the MS Sufferer

According to Mohr (2007), distraction is considered a generally adaptive coping strategy in which a person consciously shifts attention away from a problem that is not resolvable to something else, such as something pleasurable or something that is resolvable (p. 66). In 2010, Goretti, Portaccio, Zipoli, Razzolini, and Amato concluded the notion of coping has acquired a variety of meanings and different terms are often used in an equivalent manner, such as mastery, defense and adaptation (p. 227). Coping can

occur in anticipation of a stressful confrontation or in reaction to a present or past stressful situation. Coping may serve one of two functions: problem solving or emotion regulation. Problem-solving functions involve dealing with internal or environmental demands that create a threat, such as studying for an exam. Emotion regulation functions involve efforts to modify the distress that accompanies threat, for example, by denying that the threat exists or by drinking in excess (Kasl & Cooper, 1995). Goretti et al. (2010) advised that there are two general coping strategies that have been distinguished, problem-focused coping (PFC) and emotion focused coping (EFC). PFC strategies are efforts to do something active to alleviate stressful circumstances: for example, trying to find out strategies to concretely solve specific problems, seeking information, and instrumental social support. On the other hand, EFC strategies involve efforts to regulate the emotional consequences of stressful events. Denials, seeking emotional social support, turning to religion or resignation are some examples.

More recently, Goretti et al. (2010) concluded the style of coping has a crucial importance in sufferers facing a chronic disease, such as MS, and contributes to determining the subject's Quality of Life (QoL; p. 228). Generally speaking, active coping strategies, whether behavioral or emotional, are considered to be better ways to deal with stressful events, whereas avoidant coping strategies appear to be a risk factor for adverse response to stressful events. To date, disease-related variables that can influence the style of coping in MS sufferers are poorly understood. From existing evidence, however, the presence of depression and neurotic or psychotic personality traits are significantly associated with dysfunctional coping strategies and worse QoL (p. 228).

Coping Strategies as a Mechanism for MS Sufferers

In 2009, Patti et al. showed that impaired cognitive function is significantly associated with lesion load in sufferers with relapsing-remitting MS (p. 780). Treatment with natalizumab has demonstrated significant reductions in the number and volume of MRI lesions ($p<0.001$) and a reduced amount of brain atrophy ($p=0.004$) compared with placebo, which may reflect a longer term benefit of natalizumab in preventing the formation of new lesions in sufferers with relapsing MS (Miller et al., 2007, p. 1391). Despite these findings, which indicate that natalizumab has a substantial positive effect on both clinical and MRI progression in sufferers with relapsing MS, the effect of natalizumab on the neuropsychological impairment associated with MS has not been investigated (MacAllister, 2005). Addressing this issue is of particular importance due to the prevalence (40-70%) of cognitive impairment in sufferers with MS, which, regardless of disease severity, impacts social integration, employability and a person's capacity to perform everyday tasks (Chiaravalloti & DeLuca, 2008, p. 1140).

In 2010, Goretti et al. conducted a study that investigated MS coping strategies and related demographic and clinical features in a clinic-based sample of MS sufferers, with a specific focus on the possible impact of cognitive functioning (p. 127). The goal was to assess the impact of cognitive impairment (CI) on coping strategies in MS sufferers. Methods included 63 sufferers (40 women, 55 relapsing-remitting, and eight secondary progressive, age 42.6±10.1 years, Expanded Disability Status Scale 2.2±1.7) who were assessed using the Coping Orientation for Problem Experiences-New Italian version Inventory, the Beck Depression Inventory, and the Rao's Brief Repeatable

Battery. The results showed that MS sufferers were less likely to use positive and problem-focused strategies, whereas avoiding strategies were adopted more frequently. Twenty-three (36.5%) cases were CI. Goretti et al. (2010) found no differences in the type of coping between CI and cognitively preserved sufferers. Scores on the Stroop test (beta=−0.91, p 0.04) and on the Word List Generation (beta=1.15, p=0.04) were associated with poorer coping strategies. Goretti et al. (2010) concluded that cognitive functioning must be accounted for as one of the factors contributing to successful coping in MS sufferers.

According to Ennis, Thain, Boggild, Baker, and Young (2006), "health promotion activities are defined as behavioral, cognitive and emotional efforts to sustain health and well-being" (p. 784). Health promotion activities are part of an individual's lifestyle. Skills fall into several areas: physical activity, nutrition, interpersonal support, self-actualization, stress management, and health responsibility (Ennis et al, 2006).

The objective of Ennis et al., (2006) was to evaluate the effectiveness of a health promotion education program for people with multiple sclerosis (the OPTIMISE program) in terms of increasing the level of health-promoting activity undertaken, improving self-efficacy, and enhancing quality of life (p. 783). The design was a randomized controlled single blinded trial. Nonparametric analysis was undertaken to test for significant differences between treatment and control groups change scores. The subjects and setting was sixty-two adults (32 treatment and 30 control subjects) with multiple sclerosis of any type, Expanded Disability Status Scale (EDSS) 1 7. The intervention was an 8-week multidisciplinary outpatient health promotion education

program aimed at increasing knowledge, skills, and confidence in undertaking health promotion activities. The outcome measures were the Health Promoting Lifestyle Profile, Self-Rated Abilities for Health Practices Scale, and the Short Form 36 Item Health Survey. The results following completion of the program revealed treatment subjects had significantly higher levels of health promotion activity undertaken (PB 0.01) and self-efficacy for health promotion activities (PB 0.01). These benefits were sustained for at least three months after the program ceased. Certain domains of quality of life also improved in treatment subjects more than controls (physical P_ 0.03, mental health and general health PB 0.01), although only mental health and general health showed further improvement at three months. Participants provided positive feedback regarding the usefulness of the intervention and demonstrated observable changes to their health promotion behaviors. Based on the study results, the researcher concluded that the OPTIMISE program produced significant changes in health-promoting behaviors. The research completed by Ennis et al. (2006) demonstrated the limitations of the study and showed that it was impossible to blind subjects as to whether they were treatment or control subjects, due to the subjects being involved in attending an intervention. While self-selecting samples are often considered potentially biased, the intervention was aimed at subjects who wanted information on health promotion activity, thereby making self-selection an intrinsic element of the study. With regard to decliners, it was not felt that subjects declining due to work and childcare/family commitments introduced bias, as within the study sample there were subjects with similar commitments. As the data collection method was that of self-report questionnaire, there is considered to be a

minimum influence of the researcher. Finally, primary measures have evidence of their reliability, validity, and test/retest properties, but all published normative data are from the USA. Replication of the study is required with larger numbers to provide more confidence in the results and allow analysis of the influence of demographics, multiple sclerosis type, and disease duration. Identification of the characteristics that benefit least from this type of intervention may inform the development of alternative methods of delivering health promotion education. Studies investigating the long-term benefits from two different perspectives are required. First, measurement of the level of maintenance, improvement and decline in scores is required, thereby evaluating the benefits of the intervention over time. Second, work is required to evaluate the influence of the intervention on the consequences of neurological levels of health-promoting activity undertaken disability over the longer term, such as weight, fitness/activity levels, and use of health screening services. Ennis et al. (2006), in a study evaluating the benefits of health promotion education for people with multiple sclerosis in a British population, suggested that OPTIMISE is effective in increasing levels of health promotion activity undertaken, confidence and belief in ability to undertake health promoting activity as well as certain domains of quality of life.

Summary

Although health promotion and wellness have been part of the larger vision of serving multiple sclerosis sufferers, relatively few studies have been published on this topic have been demonstrated (Matuska, Giles-Heinz, Flinn, Neighbor, & Bass-Haugen, 2003). Gutman (2008) also noted that this topic was "greatly underrepresented (p. 620).

Minden et al. (2007, p. 547-558) stated the gap of a quantitative research study using an online training module to increase coping skills of MS sufferers and their caregivers is underutilized. There should be a new community action plan for Health Promotion through an online education platform that demonstrates an increase in MS learning to help the coping skills for both family and consumers within the RRMS population.

All of the extensive research completed in this chapter on coping strategies to increase the coping skills of MS sufferer showed little information for continuous awareness for a positive health-related quality of life (HRQoL) for the MS person via an online training module.

For my research study I assessed the effectiveness of an existing online education module with hope to increase the coping skills for sufferers afflicted with RRMS (MSLifelines, 2011). My expectation was that the use of this online education module would increase the effectiveness of RRMS coping skills for the populations studied. To accomplish my research, each of the four levels of measurement were demonstrated and applied: nominal level, ordinal level, interval level, and ratio level. It is materially essential that each of the four levels be applied in order for me to adequately address and quantitatively assess the research study topic and method I have chosen. Chapter 3 discusses the methodology used in this study.

Chapter 3: Research Method

Introduction

For my research study, I assessed the effectiveness of an existing online education module with the hope to increase the coping skills for sufferers afflicted with RRMS (MSLifelines, 2011). My expectation was that the use of this online education module will increase the effectiveness of RRMS coping skills for the population studied.

Research Design and Rationale

I chose a research design using two groups, nonrandom selection, using a pretest, posttest because this design matches with my predetermined experimental objectives and research execution strategy. The purpose of my research was to test deductive quantitative theories that compared the independent variable to the dependent variable and controlling variables for the Georgia site participants. The dependent variable was the coping response. The independent variable was the Multiple Sclerosis Training Module. The goal was to see the effect of an online existing education module on RRMS participants in the state of Georgia.

The purpose of this study was to determine if an increase in MS learning would help the coping skills for sufferers within the RRMS population. Experimental research allows the researcher to control the incident. This research permitted the investigator to identify cause and affect relationships between variables meaning research can differentiate between imitation effects from treatment effects. This design supported the ability to limit other explanations and conclude direct relationships in the study.

Research Questions

The basis for the research questions was to address better ways for development for MS coping skills for those suffering from exacerbations with RRMS. The ultimate goal was to strengthen the significance for the MS sufferer in order to improve the quality of life and requisitely to stimulate community awareness for a social change movement from leading healthcare consortiums from across the current healthcare delivery system.

The following research questions below will be addressed in this experimental design study to quantify the impact of an online MS education module on RRMS sufferers.

RQ1:   Will the online training development module increase the coping skills of those affected by RRMS?

RQ2:   Is the online educational module more effective at improving the coping skills of severe RRMS sufferers versus mild RRMS sufferers?

Hypothesis

Based on the research questions listed above, I hypothesize that the use of the online MS education module will improve the coping abilities for RRMS sufferers.

$H1_a$: The online training development module will increase the coping skills of those affected by RRMS.

$H2_a$: The online training development module will be more effective at improving the coping skills of severe RRMS sufferers versus mild RRMS sufferers.

$H1_0$: The online training development module will have no effect on the coping skills of those affected by RRMS (null hypothesis)

$H2_0$: The online training development module will not be more effective at improving the coping skills of severe RRMS suffers versus mild RRMS sufferers

Participants

The participants were sufferers affected by the most debilitating form of Multiple Sclerosis called RRMS. My population was divided into two main groups for study and analysis: (1) those suffering from mild RRMS and (2) those suffering from severe RRMS.

Setting

The selected site of study was the state of Georgia. The study was conducted with the support from the Georgia Chapter of the National MS Society. At the time of the study, this society served over 17,000 individuals who were living with MS and residing in the state of Georgia (National Society, 2014). For my study, I employed a questionnaire and applied it before and after the experimental period. I attempted to maintain content validity during the construction of this questionnaire by creatively and scientifically capturing coping skills as the primary objective.

Sampling Strategy

I used probability sampling in order to obtain a true representative sampling of those coping with RRMS. By using the probability type design in my research study I maximized my ability to provide experimental repeatability and more accurately extrapolate my research study results to larger populations. Within the construct of the probability type design I used a stratified sampling approach. For the type of experimental research I undertook stratified sampling in order to ensure that the two

different population groups were "represented adequately in the sample so as to increase the level of accuracy when estimating parameters" (Frankfort-Nachmias & Nachmias, 2008, p. 171). To meet this objective, I first obtained a preliminary sample population based on working with the Georgia MS Chapter. From there I further divided this preliminary population into two initial groups: Those suffering from regular MS and those suffering from RRMS. Since my research focused on RRMS coping skills, I focused on those suffering from RRMS only. This population was then further divided into two distinct subgroups: those suffering from mild RRMS and those suffering from severe RRMS. Whichever of these subgroups was the lowest generally defined my initial stratified sample subset level. In order to obtain a manageable (and numerically consistent) sample pool for each of the two groups I excluded members with certain qualities or characteristics. At a minimum to be eligible for inclusion in this study, residents were within the two above mentioned groups of study and had the ability to communicate verbally or in writing during the survey or focus group. Once the sample list containing the two groups was narrowed down the Georgia MS Society emailed each of the prospective participants an invitation to participate. Positive e-mail responses from prospective participants determined my pool of sample research study participants.

The total number of samples taken was equally represented between each of the two above mentioned groups. The samples for each respective group were considered subsets of the entire sampled population. Using G*Power3.1.9.2 and the input parameters of power of 0.95 and effect size of 0.5 I determined a total sample size for each group of at least 34 participants. Each sample subset (group) consisted of the same number of

participant samples. The Georgia Multiple Sclerosis Society sent out "The Ways of
Coping Questionnaire" via Survey Monkey to all eligible RRMS sufferers and asked for
participants in a case study to increase their coping skill mechanisms.

Instrumentation

The dependent variable in this study was coping response and the independent
variable was the participation of MS sufferers using the online training module. To
measure the dependent variable, I used the Ways of Coping Questionnaire (Folkman &
Lazarus, 1988). The Ways of Coping Questionnaire is a research study instrument to
conduct coping process studies. In the past, researchers used the questionnaire for
investigating the mechanisms and causes of coping in a variety of studies. The
questionnaire was conceived as an evolving strategy for measurement. This questionnaire
measured coping processes that assess coping styles with the instrument. I needed to
assess an individual's coping process in a range of stressful encounters, then evaluate
consistencies in those processes across encounters. This questionnaire could be used as a
stimulus for discussion in clinical, training, and workshop settings and used as a research
tool in clinical settings. For example, in relation to types and degree of pathology, or in
measuring the effects of interventions.

Since my research study was on RRMS coping skills, I focused on those suffering
from RRMS only. This population was then further divided into two distinct subgroups of
equal number: those suffering from mild RRMS and those suffering from severe RRMS.
Whichever of these subgroups had the lowest number defined my initial stratified sample
subset level. I had four sample subsets overall of the same quantity from which I applied

my measurement questionnaire initially and at a second time after RRMS suffers had

reviewed the online training module on the same day.

Procedures

Prior to conducting the study, literature was placed in common areas such as the

patient waiting room or the bulletin board to inform MS patients of the upcoming study.

This study was conducted on a Saturday. Participants were notified in writing of their

confidentiality rights, volunteer options, and the purpose of the research study.

Quantitative Data Collection and Analysis

In order to log the data for analysis, I created a codebook using SPSS software to

describing each data type. Outputs from this codebook included the variable name,

description, format, variable location, instrument used to collect the data, date and time

collected, participant number, randomization number, and notes on the data collection

processes and attempts.

Descriptive statistics were used to describe the basic characteristics of the data. A

frequency distribution was used to summarize the values of individual variables. To

measure dispersion and central tendency of the variable, the mean, median, mode,

standard deviation, variance, and range were computed using the descriptive tab in the

SPSS program. For my research study the dependent variable was the degree of coping

skills for sufferers with RRMS. The independent variable was the existing online

education module meant to increase coping skills for MS sufferers. I utilized the Likert

scale during my research study. This scale enabled me to obtain a more accurate measure

of any increase or decrease in coping skills of my captured study population. The

feasibility of use associated with the Likert Scale stemmed from its inherent measure of attitudes. This was precisely what I was looking for my in research study to quantify the attitudes of my study participants specific to their interpretations of the associated strengths and weaknesses to cope with RRMS.

The Likert Scale was designed to measure attitudes, and in my research the attitude I measured was the attitude of study participants regarding their strength or weakness in their ability to cope with RRMS. I also utilized the Ways of Coping Questionnaire (Folkman & Lazarus, 1988) for my research. This scale enabled increasing levels of results data analysis, and to make this happen I ensured the questions in my questionnaire measuring instrument were crafted and ordered to meet the Guttman Scale attributes. These attributes included being cumulative and unidimensional while at the same time maximizing the coefficient of reproducibility (CR of 0.9 or greater). Utilizing the Guttman Scale with the appropriate coefficient of reproducibility increased the validity of the scale (Frankfort-Nachmias, & Nachmias, 2008, p. 426). I demonstrated the reliability of my chosen scale by utilizing the test-retest method.

The most appropriate test for my research plan was the norm-referenced test in order to compare the coping skills of various populations against each other. Upon early examination of my experimental study I decided to apply the criterion referenced test to measure increase in coping skills of the two affected RRMS populations. I also applied the standards-referenced test and compared the change/increase in coping skills of the two populations studied utilizing the online education module as compared to the standard I chose to use: the coping level from the existing on-site health promotion

education to those affected by RRMS. I also used the coping level from the existing on-site health promotions education for those affected by RRMS in my chosen Likert and Guttman Scales.

Mann-Whitney Test

There were two groups for this research study based on disease severity. For the test, the overall dependent variable was the degree of coping based off comparison of the pre and posttest of study participants. The Mann-Whitney Test was used to analyze and compare results from the pre and posttests for the two groups (data sets). Comparisons of the variance in specific questions of the pre and posttests were undertaken and analyzed to determine if specific test question-based facets of coping are affected by the online health promotions tool as compared between the two groups.

The first assumption for the Mann-Whitney Test is that for a given experiment and/or dataset, the cases represent random samples from the populations and the scores on the test variable are independent of each other. Sample randomness means that the researcher cannot specifically choose the samples to choose in the experiment or study group, as this would imply that the researcher is biasing the dataset to yield a particular result or conclusion. Likewise, for this assumption of the Mann-Whitney Test, the actual test variables for which the test is being applied must be independent and not related to each other. This does not mean the test variables are independent variables in the true statistical definition of an independent variable, rather for the Mann-Whitney Test this means that the test variables are merely measured or registered. Dependent variable dependency does not occur across multiple groups or cases; instead the dependent

variable depends on the conditions and manipulations specific to that particular group or case.

The second assumption for the Mann-Whitney Test is that all observations in an experiment are numerical or ordinal. For this experiment this assumption was met by the dependent variables (observations) being ordinal in rank correlating with the degree of use for coping on a zero to three point scale.

Test Significance

In social science research, statistical and experimental data is often further studied in order to test significance of the tests. This can be accomplished by using two types of tests of significance: parametric tests and nonparametric tests. Each of these groups of tests is separate in its own ways, and primarily their distinctions relate to the basic assumptions underlying each group of tests. The parametric statistical test is based on two general assumptions related to the parameters of the population drawn for the sampling activity. These assumptions are as follows: (a) research observations must be obtained from a population that is normally distributed, and (b) the variables measured in the experiment are measured on an interval scale. Such assumptions can be validated and patterns/trends may be discovered using a posthoc test.

Validity

Content validity as a principle type validity of measurement can be broken down into face validity and sampling validity (Socialresearchmethods, 2012), Face validity "rests on the investigator's subjective evaluation of the appropriateness of the instrument

for measuring the concept rather than whether the instrument measures what the researcher wishes to measure" (Frankfort-Nachmias, & Nachmias, 2008, p. 150).

Empirical validity in measurement is outcome focused (Psychassessment, 2012). High measurement validity would mean that results obtained from the instrument of measure in an experiment (in a controlled environment) are reasonably similar to instruments of measured found in the real world (Frankfort-Nachmias, & Nachmias, 2008, p. 150). Just as for the face validity aspect of content validity, I ensured I could obtain and maintain empirical validity through the careful crafting of my questionnaire measuring tool using the resources previously discussed.

In research construct validity in measurement is the aspect of measurement validity focused on the "general theoretical framework within which they conduct their studies in order to determine whether the instrument is logically and empirically tied to the concepts and theoretical assumptions they are employing" (Frankfort-Nachmias, & Nachmias, 2008, p. 152). I believe that I demonstrated construct validity in my experimental research study by the use of the preexisting Ways of Coping Questionnaire designed specifically to measures coping skills. Had I not used the Ways of Coping Questionnaire and created my own questionnaire I would not have been able to demonstrate such a degree of construct validity.

The test-retest method involves administering the measuring instrument to the same group determining the correlations between the results from each application. I used this method for my research. My approach was to deliberately apply the questionnaire as an instrument of measure in the research study.

Validity was a key aspect that was addressed in my study. For my study I employed The Ways of Coping Questionnaire through the experimental period. I maintained content validity during the construction of this questionnaire by creatively and scientifically capturing coping skills as the primary objective. Evidence of construct validity was found in the fact that the results of the studies were consistent with theoretical predictions, namely, that (a) coping consisted of both problem-focused and emotion-focused strategies, and (b) coping was a process. That is, how people cope varied in relation to the demands and constraints of the context and also in relation to changes in those demands and constraints as an encounter unfolds. Cronbach's Alpha was used to assess the reliability of the scale to capture results from this experiment. The scale was essentially the survey questionnaire and the questions contained within it.

For internal validity there should be direct causality between changes in the dependent variable (coping skills) as related to the independent variable (questionnaire). Threats to internal validity were minimized by applying the questionnaire to RRMS sufferers immediately after reviewing of the online educational tool. This way any change in RRMS sufferer responses on the second questionnaire were a direct result of utilization of the online training resource. External validity threats were reduced by random participant selection coupled with maximization of study populations as feasible. These two practices maximized the generalization of results from my study to larger populations of RRMS sufferers.

Reliability

Internal consistency estimates of coping measures generally fall at the low end of the traditionally acceptable range. As Billings and Moos (1981) pointed out, those who are constructing coping measures attempt to minimize item redundancy within each coping category, resulting in groups of relatively independent clusters of coping strategies within each category. The use of one coping response may produce the desired effect, which lessens the need and probability that other coping responses from the same category will be used. The alpha coefficients for the eight scales, shown in Appendix F, were higher than the alphas reported for most other measures of coping processes.

Ethical Concerns

No direct ethical concern issues were experienced through the course of this research project. The IRB approval number for this study was 09-25-14-0240182. Upon initially meeting with the Georgia Chapter of the MS Society representatives I explained the purpose of my research and especially highlighted its possible utility in improving coping skills for those afflicted with this disease. Since the Georgia MS Society was my primary link and base for obtaining research subjects for my study, I ensured that I effectively answered any questions related to the ethics of my research project and I explained my intention to use an informed consent for all research subjects to ensure each participant was fully cognizant of the study's purpose and their involvement in the study.

I ensured all data I obtained from my study remained confidential. All data was included in the study report that was stored on my personal computer in password-protected format. The data was shared with no one except for my Walden University

dissertation committee. I upload completed questionnaires and saved them electronically the same way. Once scanned all hardcopy questionnaires were immediately shredded. Data will be stored for a minimum of 5 years.

Summary

The prevalence of online forms of assistance in dealing and coping with health related concerns has been increasing. Even as a parent before I ever consider taking my children to the doctor I consulted an online medical website for advice. I checked the medical symptoms of my child against an online symptoms checker to initially determine what type of medical concern I was dealing with. Though dealing with common parental concerns associated with childhood health such as the common cold is fairly simple medicine, the internet is a valuable resource for knowledge and education to enable parents to cope with and/or improve the health of their children. Likewise, the internet holds true as an effective means of enabling coping with RRMS. Coping tools in prevalent use today focus more on the one-on-one person-to-person aspect of teaching coping skills. An online program, such as the one in this project, had the potential to provide similar positive coping skill improvements to RRMS suffers. Through my research study I was able to prove that the existing online education module increased coping skills of those suffering from RRMS. This was true for sufferers of both mild and severe RRMS. These characteristics support the fact that the online education module may be fielded even more to help the RRMS community. Providing an additional coping mechanism such as a research tested online education module can have infinitely far reach results to improve the lives of countless individuals in the state of Georgia (and the

United States) contributing to healthcare's basic tenant of creating positive health

outcomes. Chapter 4 will provide a discussion of the results from this research.

Chapter 4: Results

Introduction

The purpose of this study was to measure the effect of an online training

development module on the coping skills of sufferers affected by RRMS. The two

populations studied were those with mild and those with severe RRMS. The Mann-

Whitney Test was identified as the most applicable test for the type of data in this study.

Two formal hypotheses were established. The first hypothesis was that

participants with severe RRMS would exhibit a greater improvement in their coping

skills than participants with mild RRMS. The second hypothesis was that participants

overall would exhibit substantial improvement in their coping environment after

participating in the online education development module. This chapter summarizes the

results of analyses performed on study participants.

All questionnaire data were from the Ways of Coping Questionnaire (Folkman &

Lazarus, 1988) in keeping with my originally planned research design. The questionnaire

was applied in the study using the planned pretest/posttest method with a gap of

approximately 1 week been tests for each survey participant. This questionnaire was

made up of 66 individual questions. These individual item questions are divided into

scale groups to include accepting responsibility, planful problem solving, escape

avoidance, confrontive coping, and seeking social support. These actual scales were used

to compare coping improvement results between the mild and severe RRMS sufferer

groups. Each question had four possible responses (0, 1, 2, and 3) correlating with the

following: 0 = *does not apply or not used*; 1 = *used somewhat*; 2 = *used quite a bit*; and 3 = *used a great deal*.

Sample Demographics

Through coordination with the National Society Georgia MS chapter informed consent was obtained from all study participants. The National Society Georgia MS chapter distributed study invitations to 800 members of their chapter. Of the 800 invites 70 participants (8.75%) volunteered for the study and completed the initial questionnaire, viewed the online MS training module developed by a group of students from Humber College, located in Toronto, Ontario (Kashyap, 2009), and completed the final questionnaire. These subjects were equally distributed with 35 members suffering from severe RRMS and 35 members suffering from mild RRMS. Out of the 70 study participants 41 (59%) were male and 29 (41%) were female. Table 1, on the next page, summarizes the demographic data on the study sample.

Table 1

*Demographic Characteristics of RRMS Members by Membership Status (*N = 70)

Characteristic	N	%
Age bracket (years)		
21-30	10	14.2
31-40	17	24.3
41-50	18	25.7
51-60	21	30.0
61-70	4	5.7
Ethnicity		
Caucasian	30	42.9
Hispanic	21	30.0
Asian	7	10.0
African American	12	17.1
Education background		
Some/no college	25	35.7
Bachelor's degree	40	57.1
Master's degree	4	5.7
Doctoral degree	1	1.4

Note: 2014 RRMS Member Survey. Compiled by Georgia National Multiple Sclerosis Society.

As far as the age demographic is concerned, 80% of the participants were between the ages 31 and 60 years. The lowest numbers were found in the oldest age group of 61 to 70 years (5.7%). From an ethnical diversity standpoint the largest subset of participants were Caucasian (42.9%) and the smallest subset were of Asian descent (10%). The education background of study participants included a majority of participants with a bachelor's degree (57.1%) with the next highest category of participants being those with

some/no college, including those with associate's degrees (35.7%). Only one of the 70

participants had a doctoral degree (1.4%).

Hypothesis 1 and Statistical Significance

The first hypothesis predicted that severe RRMS suffers would experience a

greater increase in their coping skills after reviewing the online educational development

module. Means were compared to test this hypothesis. Specifically, for each group

(severe and mild) the mean change in scores for each of the five scale groups was

calculated (ex. for a particular score on a scale for one respondent a change from 0 to 3

was counted a 3 point increase, which was then used to calculate the overall mean scale

change for that group). The mean coping increase for mild RRMS respondents was

0.1433 while the mean coping increase for severe RRMS respondents was 0.1653. By a

simple comparison of overall mean increases clearly severe RRMS sufferers

demonstrated the greater increase in coping skills overall as compared to mild RRMS

sufferers after completion of the online education development module. To further

support this conclusion a Mann-Whitney test was performed to compare the overall

change in coping skills by group without consideration to the scale. The results of this

analysis using SPSS are located in Tables 2 and 3.

Table 2

Mann-Whitney Test Ranks

Scale	*N*	Mean Rank	Sum of Ranks
Mild RRMS	175	130.28	22799.50
Severe RRMS	175	220.72	38626.50
Total	350		

Table 3

Mann-Whitney Test Statistics[a]

Statistic	Score (0-3)
Mann-Whitney U	23225.50
Wilcoxon W	22799.50
Z	-1.839
Asymp. Sig. (2-tailed)	.047

Note: Maximum score = 350, p = 0.047, $p < 0.05$
[a]Grouping Variable: Scale

The value for $p = 0.047$ which is less than 0.05. From this a conclusion can be made that the data used in the SPSS calculation provides statistically significant evidence of a difference in increase in coping skills between severe and mild RRMS sufferer groups did not occur by chance. These results together support the first hypothesis that severe RRMS sufferers would receive greater coping benefits than mild RRMS sufferers in this study.

As exemplified in Figure 2 below, of the five scales analyzed as part of this study the severe RRMS suffers had higher levels of improvement in coping over mild RRMS sufferers in the two areas of Planful Problem Solving and Confrontive Coping. The magnitude of improvements in only these two areas overshadowed the mild RRMS group improvements in the other three areas contributing to the severe RRMS group overall improvement.
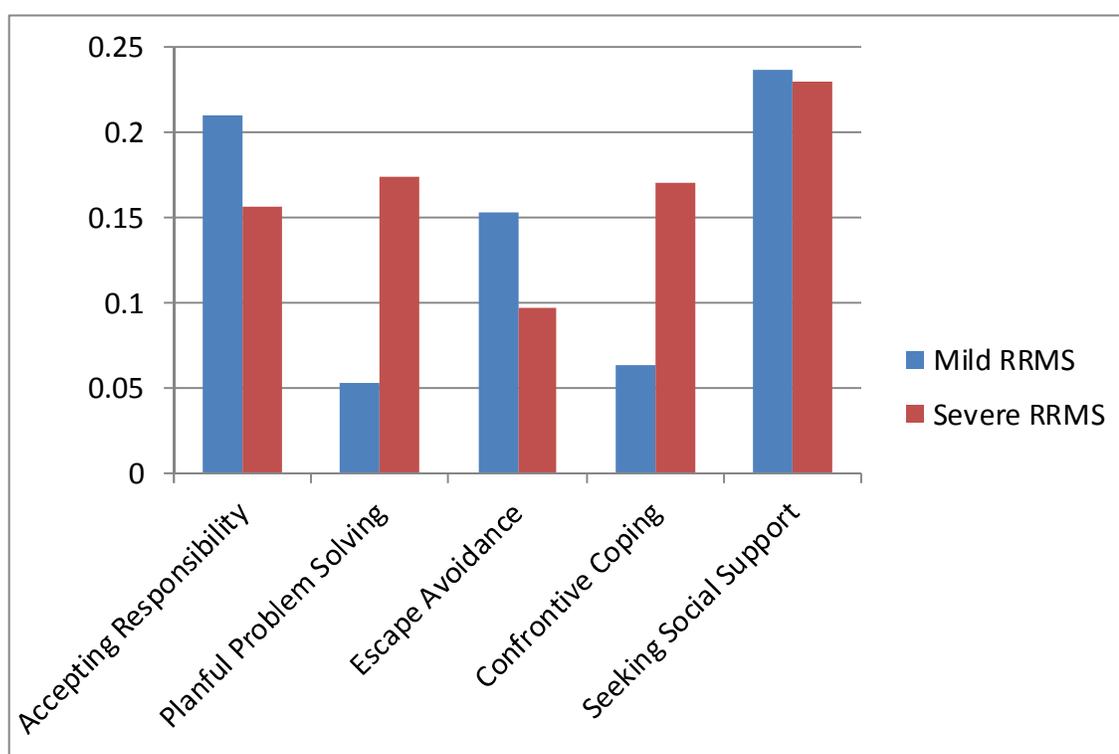
Figure 2. Bar graph showing the results of mild and severe RRMS members' coping relationships. Derived from answers to the Ways of Coping Questionnaire administered to members of the Georgia National Multiple Sclerosis Society.

Hypothesis 2 and Statistical Significance

Hypothesis 2 predicted that the use of the online education development module would result in substantial improvement in the overall coping skills of RRMS suffers.

Again referring to Figure 2, the results of this study do in fact support this hypothesis due

to the fact that both mild and severe RRMS sufferer groups had increases in their coping

skills as a result of utilizing the online education development module. There is difficulty

in establishing through this study whether these incremental scale increases in coping

skills could be defined as substantial. The argument of a substantial improvement is

supported based on the fact that both groups increased their coping skills in all five scale

areas. Conversely based on the score range per scale of 0-3, increases in the

neighborhood of 0.1433 for mild RRMS sufferers and 0.1653 for severe RRMS sufferers

can be viewed as relatively small improvements. Increases in the range of 0.25-0.5 or

greater might be a more realistic example of substantial improvements.

As a statistical validator the Mann-Whitney test was performed in SPSS within

each of the five scales (ex. Accepting Responsibility scale for the mild RRMS group

versus the same scale for the severe RRMS group). Table 4, on the next page,

summarizes the P values obtained from each Mann-Whitney test.

Table 4

Severe and Mild RRMS Members' Coping Skills Within the Five Groups

Scale	P value	< 0.05?
Accepting Responsibility	.095	No
Planful Problem Solving	.042	Yes
Escape Avoidance	.047	Yes
Confrontive Coping	.049	Yes
Seeking Social Support	.068	No

Table 4 shows that from a within scale comparison there is evidence of a difference in increase in coping skills between severe and mild RRMS sufferers, but it is not statistically significant within all five groups. Statistical significant evidence is present only in three of the five groups containing p values less than 0.05 ($p = 0.042$, $p = 0.047$ and $p = 0.049$). The increase in coping skills was not by chance, and was identified in the scales of Planful Problem Solving, Escape Avoidance, and Confrontive Coping. Therefore, there was an enhancement in coping skills but it was not conclusively considered statistically significant with all five groups.

Summary

The statistical analyses of the survey data for both the mild and severe RRMS supported both Hypothesis 1 and Hypothesis 2. Overall increases in coping were realized in survey participants in both groups after reviewing the online education development module. Utilizing the scales for each group the improvement in coping skills was not necessarily consistent for the mild and severe groups on a scale basis, but overall the survey and data support the overall goal of improving coping for RRMS sufferers.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

This study was carried out to evaluate the suitability of an online education development module in increasing the coping skills of patients suffering from mild and severe RRMS. In order to accomplish this Georgia MS Society was targeted into order to provide a pool of interested survey participants. These participants were voluntarily selected, and through the Ways of Coping Questionnaire were able to address their coping abilities both before and after viewing the online education development module. Since coping plays an major role in allowing RRMS sufferers to manage their affliction and carry on a normal life, identification and application of a tool to aid in this regard is essential.

Through research MS education has been successful in improving the coping and quality of life of MS sufferers. This was previously noted in a study by Ennis et al. (2006) where the objective was to evaluate the effectiveness of a health promotion education program for people with MS (the OPTIMISE program) in terms of increasing the level of health-promoting activity undertaken, improving self-efficacy, and enhancing quality of life (p 783). The results of the study concluded that the OPTIMISE education program produced significant changes in health-promoting behaviors. The study for the OPTIMISE program produced positive results for MS sufferers, just as positive results were realized for RRMS suffers through this study.

Summary and Interpretation of Findings

In the current study, the goal was to assess the impact of cognitive impairment on coping strategies in RRMS sufferers. The expectation was that there would be some marked improvement of coping skills for RRMS sufferers, but the specific degree of increase was of interest to the unique application mechanism in an online format. Mohr's (2007) meta-analysis revealed there are a lack of studies into the long-term of accumulating evidence that there is an association between stressful life events and an increased risk for MS exacerbations (p. 65). In addition, stressful life events, primarily in the form of family and work conflicts, are associated with a significant increase in the risk of the occurrence of a new gadolinium enhancing (Gd+) MRI brain lesion 8 weeks later (Mohr, 2007, p. 65). Goretti et al. (2010) recommended a study that investigated MS coping strategies and related demographic and clinical features in a clinic-based sample of MS sufferers, with a specific focus on the possible impact of cognitive functioning (p 127). These major conclusions hold true today for MS and RRMS sufferers.

The findings of this study demonstrated that the application of the online education development module to RRMS sufferers does provide a mechanism of improving their coping skills. Specific to this study a closer comparison of results with the demographics of the study participants provides some valuable insight. First, increases in coping skills as a result of the online education development module are gender neutral. Increases were realized both for males and females, but the data did not demonstrate any particular improvement in coping overall and by scale specific to a particular gender.

Survey participant age in the study also provides an opportunity for introspection. First, RRMS prevalence in today's society is not limited to just the young or the old, and the ages of study participants are representative of the prevalence across age groups, with 80% of the study participants between 31 and 60 years of age. Compared to older adults, the younger generation is more tech-savvy and is more accustomed to learning via online means (citation?), and for this study the education development module was accessed online. It might be reasonable to expect that overall coping increases would not occur simply due to the small proportion of younger study participants. This assumption does not hold true though based on this study. The results of this study demonstrate that the online method of education development to improve coping skills of RRMS sufferers is effective both for the young tech-savvy generation as well as the older generation of adults in their 40s and 50s.

Limitations

There are three particular limitations within this study worth noting. One is related to the education level of study participants. A majority of participants (64.4%) had completed some type of college degree, which raises the question of whether there is a link between coping skill improvement via the online education development module and education level. If the majority of participants had been non-college-educated, would the results have demonstrated improvement in coping skills for both mild and severe RRMS sufferer groups? This is a question worth exploring in future research but provides a potential limitation for application to future study populations.

The second limitation of this study centers on the true applicability of this online education development module to support long-term increase in coping for RRMS sufferers. The period of the pre/posttest for this study was only 1 week, so survey participant results did demonstrate improvement in the short term. Would this improvement in coping skills maintain itself at longer intervals such as one month later, six months later, or even 1 year later?

The final limitation of this study was the low survey response rate. Using GPower, 34 participants for each group (mild and severe RRMS) were determined. This number of participants was in fact used in the study, but had the number of participants been more that 34 per group it is possible the results of this study would not have been the same. Had there been double (68) or even triple (102) the respondents per group the results may have been the same or even shifted.

Implications for Social Change and Recommendations for Action

Now for a moment "put yourself in the shoes" of an individual suffering from mild or severe RRMS. RRMS affects your ability to function effectively and productively in society and possibly even in the workplace. As the RRMS sufferer it is reasonable to believe that your interest would lie in finding strategies to enable you to better cope with your affliction. To do so look to other RRMS sufferers, your doctor(s), family, friends, and the local branch of the state MS society. The state MS society can provide support to help increase coping. Individual instruction is challenging due to scheduling, availability of staff, and especially the logistics of visiting the location. This is especially true when the state MS society is over 1 hour drive time from home.

Now consider the potential for having tools available to augment and help increase your coping as an RRMS sufferer at your fingertips without ever having to consult a friend, doctor, or MS state society. This is precisely the benefit of the online method of application to support increase in coping strategies for RRMS sufferers.

Based on the study results, the online education development module used in this study might serve as a perfect complement to augment coping strategy improvement efforts for RRMS suffers. The state MS societies would benefit from educating their members on this tool as a means to help them. This education could be accomplished by onsite discussions during period state meetings and expositions, or by posting the resource online on their state MS society website. Further, periodic e-mails and newsletters to state MS society members would also help.

The results of this research study have demonstrated that an online education development tool does in fact have the ability to improve coping skills of mild and severe RRMS suffers in the short term. Another area of further research might include the tracking of coping skills over longer periods to determine if there is a lasting improvement in coping skills. Similarly, initial application of the module followed by periodic reapplication might be worth investigating to determine the optimal application forum, level, and frequency. These are all valuable facets of coping strategy improvement via an online means that warrant further research.

Optimizing the coping strategies of RRMS sufferers is a win-win proposition for all involved to include the patient as well as family, friends and coworkers. Whether stand-alone or augmenting other coping strategies, the online method using this study's

online education development module is one worthy of further research as well as

immediate application to affected RRMS sufferers.

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Appendix A: Letter of Cooperation

National MS Society, Georgia Chapter

███████████████████████████
█████████████
███████

Date: 20 September 2014

Dear Jennifer Garrison,

Based on my review of your research proposal, I give permission for you to conduct the study entitled "The Effect of an Online Coping Skill Application on Relapsing-Remitting Multiple Sclerosis Sufferers" within the National MS Society, Georgia Chapter. As part of this study, the National MS Society, Georgia Chapter will assume oversight of the Multiple Sclerosis Online Training Module as well as the pre and post administration of the Ways of Coping Questionnaire (WCQ) that will be completed as part of the training. The National MS Society, Georgia Chapter will then release deidentified pre and post WCQ scores to you for analysis for the dissertation.

I understand you will be using an online training module titled "Multiple Sclerosis" to see if the effect of an online coping skill application on relapsing-remitting multiple sclerosis sufferers does in fact increase the coping skills of the MS members. I understand that the data will be released to you will be for your dissertation. Individuals' participation will be voluntary and at their own discretion.

I confirm that I am authorized to approve research in this setting and that this plan complies with the organization's policies.

I understand that the data collected will remain entirely confidential and may not be provided to anyone outside of the student's supervising faculty/staff without permission.

Sincerely,

Ms. Carole Anderson, M.A.
National MS Society, Georgia Chapter

███████████████████████████

Appendix B: Data Use Agreement

DATA USE AGREEMENT

This Data Use Agreement effective as of 1 Oct 2014 is entered between Jennifer Garrison (Data Recipient) and Mrs. Carole Anderson (Data Provider). The purpose of this Agreement is to provide Data Recipient with access to a Limited Data Set ("LDS") for use in research in accord with the HIPAA and FERPA Regulations.

1. Definitions. Unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the "HIPAA Regulations" codified at Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time.

2. Preparation of the LDS. Mrs. Carole Anderson shall prepare and furnish to Data Recipient a LDS in accord with any applicable HIPAA or FERPA Regulations.

3. Data Fields in the LDS. No direct identifiers such as names may be included in the Limited Data Set (LDS). In preparing the LDS, Mrs. Carole Anderson shall include the **data fields specified as follows**, which are the minimum necessary to accomplish the research: all 66 data sets from each participant from the Ways of Coping Questionnaire from the pre/posttest.

4. Responsibilities of Data Recipient. Data Recipient agrees to:

   a. Use or disclose the LDS only as permitted by this Agreement or as required by law;

   b. Use appropriate safeguards to prevent use or disclosure of the LDS other than as permitted by this Agreement or required by law;

   c. Report to Data Provider any use or disclosure of the LDS of which it becomes aware that is not permitted by this Agreement or required by law;

   d. Require any of its subcontractors or agents that receive or have access to the LDS to agree to the same restrictions and conditions on the use and/or disclosure of the LDS that apply to Data Recipient under this Agreement; and

   e. Not use the information in the LDS to identify or contact the individuals who are data subjects.

5. Permitted Uses and Disclosures of the LDS. Data Recipient may use and/or disclose the LDS for its Research activities only.

6. Term and Termination.

    a. Term. The term of this Agreement shall commence as of the Effective Date and shall continue for so long as Data Recipient retains the LDS, unless sooner terminated as set forth in this Agreement.

    b. Termination by Data Recipient. Data Recipient may terminate this agreement at any time by notifying the Data Provider and returning or destroying the LDS.

    c. Termination by Data Provider. Data Provider may terminate this agreement at any time by providing thirty (30) days prior written notice to Data Recipient.

    d. For Breach. Data Provider shall provide written notice to Data Recipient within ten (10) days of any determination that Data Recipient has breached a material term of this Agreement. Data Provider shall afford Data Recipient an opportunity to cure said alleged material breach upon mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within thirty (30) days shall be grounds for the immediate termination of this Agreement by Data Provider.

    e. Effect of Termination. Sections 1, 4, 5, 6(e) and 7 of this Agreement shall survive any termination of this Agreement under subsections c or d.

7. Miscellaneous.

    a. Change in Law. The parties agree to negotiate in good faith to amend this Agreement to comport with changes in federal law that materially alter either or both parties' obligations under this Agreement. Provided however, that if the parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either Party may terminate this Agreement as provided in section 6.

    b. Construction of Terms. The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.

    c. No Third Party Beneficiaries. Nothing in this Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

    d. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

e. <u>Headings.</u> The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Agreement.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

DATA PROVIDER   **DATA RECIPIENT**

Signed: _____   Signed: _____

Print Name: _____   Print Name: _____

Print Title: _____   Print Title: _____

Appendix C: Description of the Coping Scales

Description of the Coping Scales

Confrontive Coping: Aggressive efforts to alter the situation and suggests some degree of hostility and risk-taking. (Ways of Coping Questionnaire, 1988)

Distancing: Cognitive efforts to detach oneself and to minimize the significance of the situation. (Ways of Coping Questionnaire, 1988)

Self-Controlling: Efforts to regulate one's feelings and actions. (Ways of Coping Questionnaire, 1988)

Seeking Social Support: Efforts to seek informational support, tangible support, and emotional support. (Ways of Coping Questionnaire, 1988)

Accepting Responsibility: Acknowledges one's own role in the problem with a concomitant theme of trying to put things right. (Ways of Coping Questionnaire, 1988)

Escape Avoidance: Wishful thinking and behavioral efforts to escape or avoid the problem. Items on this scale contrast with those on the Distancing scale, which suggest detachment. (Ways of Coping Questionnaire, 1988)

Planful Problem Solving: Deliberate problem-focused efforts to alter the situation, coupled with an analytic approach to solving the problem. (Ways of Coping Questionnaire, 1988)

Positive Reappraisal: Efforts to create positive meaning by focusing on personal growth. It also has a religious dimension. (Ways of Coping Questionnaire, 1988)

Appendix D: Humber College Multiple Sclerosis Education Module

Multiple Sclerosis
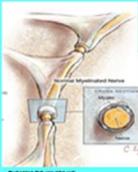
Group
Presentation
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Introduction

- Brief Overview of disease condition
- History of MS
- Epidemiology and world wide distribution
- Types of MS
- Signs and Symptoms
- Factors causing Disease
- Diagnosis
- Treatments
- Research Themes
- Conclusion
- References

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Overview

- MS is predominantly a white a matter disease and a neurodegenreative disorder of the central nervous system that includes the brain, spinal cord and nerves.

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Multiple Sclerosis - Introduction

- It is an inflammatory and demyelinating disease.
- Inflammation: body's own immune cells attack the nervous system.
- Demyelination: myelin (protective covering of the nerves) is destroyed leaving multiple areas of scar tissue or sclerosis.
- It is progressive disease
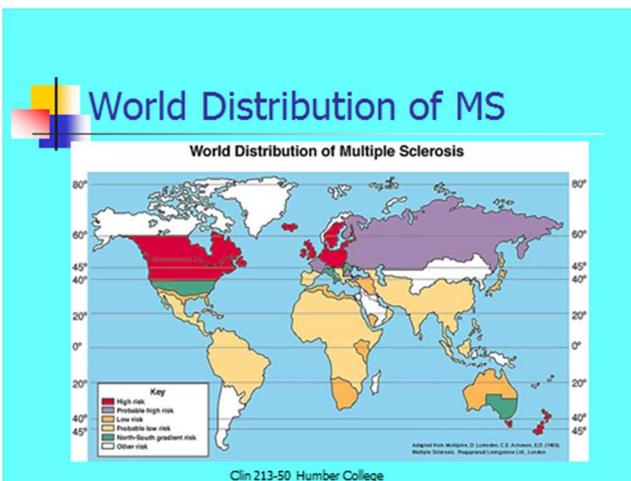- Most common age of occurrence – between 20 and 40

History of Multiple Sclerosis

- The earliest description of MS was recorded in Holland on August 4, 1421 but the history of the disease really begins in the 19th century with the first clear illustrations and clinical description of the disease beginning to appear in 1838" Ref : (Barnes, David. Multiple Sclerosis Questions and Answers, Merit Publishing International, Florida, 2000).
- The first actual case was diagnosed in 1849. It was Dr.Jean-Martin Charcot who is credited with giving us the first signs and symptoms of Multiple Sclerosis.

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Multiple Sclerosis - Epidemiology

- Worldwide occurrence:1.1 – 2.5 million cases
- MS in women is 2-3 times more prevalent than in men.
- It is not contagious
- In Canada an estimated that 55,000-75,000 people have multiple sclerosis

World Distribution of MS

World Distribution of Multiple Sclerosis

Key
- High risk
- Probable high risk
- Low risk
- Probable low risk
- North-South gradient risk
- Other risk

Adapted from McAlpine, D. Lumsden, C.E. Acheson, E.D. (1965).
Multiple Sclerosis. Reappraisal Livingstone Ltd, London

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Multiple Sclerosis - Types

There are 4 types of MS
- Relapsing-remitting MS (RR-MS)
- Primary-progressive MS (PP-MS)
- Progressive-relapsing MS (PR-MS)
- Secondary-progressive MS (SP-MS)

Multiple Sclerosis - Types

Relapsing-remitting MS (RR-MS)
- More than 80% of the cases
- Defined clinical exacerbation of neurological symptoms
- Followed by complete or incomplete remission during which the person fully or partially recovers from the deficits acquired during relapse

Multiple Sclerosis - Types

Primary-progressive MS (PP-MS)

- 10 to 20% of individuals with MS are diagnosed with PP-MS
- Gradual progression of the disease from its onset
- No overlapping relapses and remissions

Multiple Sclerosis - Types

Progressive-relapsing MS (PR-MS)

- Rare
- Initially presenting as PP-MS however, during the course of the disease the individuals develop true neurologic exacerbations
- Steady progression of clinical neurological damage with superimposed relapses and remissions.

Multiple Sclerosis - Types

Secondary Progressive MS (SP-MS)

- SP-MS is characterized by a steady progression of neurological damage with or without superimposed relapses and minor remissions
- Individuals with SP-MS will have experienced a period of RR-MS, which may have lasted from 2 to 40 years
- Any super-imposed relapses and remissions fade over time

Factors Contributing for MS

Genetic Factors
- **Gender:** Women are 2 to 3 times more likely to get the disease.
- **Family history of MS:** A family history increases the risk of developing MS
- **Race:** MS appears more commonly in Caucasians than in groups

Environmental factors: MS occurs most commonly in those living in northern climates
- **Infections:** Researchers believe that many autoimmune diseases are provoked by some kind of infection that strikes people who have a certain genetic makeup
- **Socioeconomic status:** Least common in rural and lower class
- **Migration :**The age at which you may move may also be an important factor. "If you move before the age of 15, your risk is that of the people in the country you move to. If you move after the age of 15, your risk stays fixed at that of the country you grew up in" (Ref:O'Connor)

Multiple Sclerosis Signs and Symptoms

- The symptoms of MS may occur in isolation or in combination
- A clinical attack is considered if the symptoms are present for a minimum of 24 hours.

Multiple Sclerosis - Causes

- The exact cause of multiple sclerosis is not clear
- In MS patients, a higher number of immune cells is seen which suggest there might be an immune response; this is suspected to be due to a virus or genetic defect
- Other causes are environmental and hereditary

Multiple Sclerosis - Diagnosis

- MS is a clinical diagnosis.
- It is diagnosed by neurological examination and brain MRI scans. Family history and lumber puncture are also used for diagnosis.
- If MS is present, very high percentage of protein IgG (oligoclonal antibody) bands can be seen in spinal fluid which is an additional confirmatory test. IgG banding is seen in other diseases as well such as, Syphilis.

Coping Strategies of RRMS Patients

- Physical therapy may help relieve muscle spasms.
- A diet low in saturated fat and trans fat
- Eating more foods with healthy omega-3 fatty acids may be especially good because these nutrients are believed to fight inflammation.
- Talking with a counselor can help with depression.
- Avoid situations that cause you to become overheated.
- Getting a moderate amount of exercise and enough sleep may help reduce relapses.

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Possible v/s Definite MS

General Physical Examination

- History of all complaints of patients general health.
- MRI (Magnetic Resonance Imaging)
- CSF (Cerebrospinal fluid)

  Fluid examined for cells, proteins, and electrolytes

  Proteins examined for presence of oligoclonal bands.

  NOT COMMON IN EARLY CASES
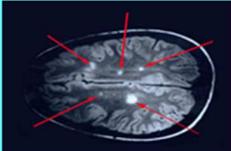
Oligoclonal Bands in CSF

normal   abnormal
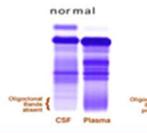
Oligoclonal Bands absent { CSF Plasma
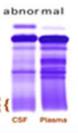
Oligoclonal Bands present { CSF Plasma

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MRI as Surrogate marker of disease process in MS

- Brain lesions
  - Character
    - Large ≥ 3 mm
    - Ovoid
    - Oriented perpendicular to ventricles
    - Enhancing
      - Open-ring enhancement
      - Multifocal homogeneous
- Location
  - Multiple white matter
  - Brainstem, infratentorial
  - Juxtacortical
  - Corpus callosum
   - Pointing away
    - Moth eaten
    - Callosal atrophy

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Multiple Sclerosis - Diagnosis

Challenges

- Early diagnosis of MS is a challenge as immediate access to imaging and scans is not available in many parts of the country.
- Sometimes, family physicians may not diagnose the problem and hence won't be able to send the patient to the right place.
- Due to similar symptoms in other diseases, MS can often be misdiagnosed.

How Does it work?

Normal Conduction of Myelinated Nerve Fibers
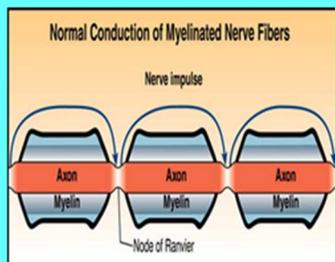
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Demyelination of Nerve Fibers in MS
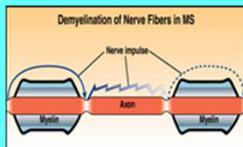
The destruction of the myelin sheath leads to impaired communication between nerve cells and neurological symptoms such as abnormal sensations, vision problems , and weakness
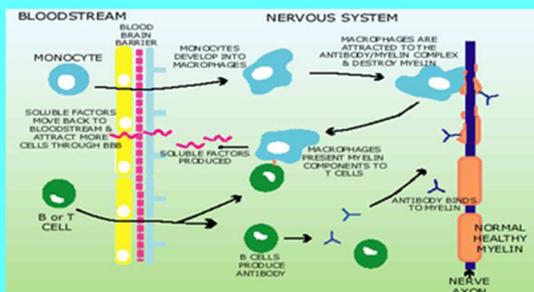
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Mode of Action

- **The immune system attacks axons**, causing destruction of the myelin sheath resulting in a **Conduction Block** which leads to permanent loss of function.

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How Autoimmune response cause MS

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Pathophysiology

- ❖ Autoimmune response results in damage and lost fibers.
- ❖ Nerves can regain myelin, but process is not fast enough to avoid the deterioration that occurs
- ❖ Astrocytes form scars where myelin formerly existed
- ❖ Inflammation, loss of myelin, and nerve fibers, and the scarring that follows result in reduced transmission of nerve signals within the CNS.
- ❖ Types of symptoms and severity vary widely due to the location of the scar tissue and extent of demyelination

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Clinical Tools for MS Diagnosis
Schumacher Clinical Criteria -1965

- Age (onset 10-50 years)
- CNS white matter disease
- Lesions disseminated in time and space
- Objective abnormalities on exam
- Consistent time course
  - Attacks lasting > 24 hrs., spaced at least 1 month apart
  - Slow or stepwise progression for > 6 months
- No better explanation
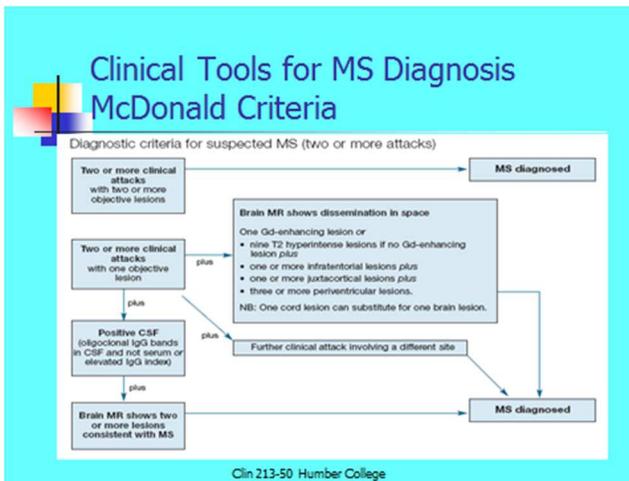- Diagnosis by experienced clinician.

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Clinical Tools for MS Diagnosis
Poser Criteria for the 1983

- Widely used for last 20 years
- Definite or probable
- Laboratory supported MS
- Replaced by McDonald criteria 2001
  - Technical advances enable quicker diagnosis
  - Controversial

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Clinical Tools for MS Diagnosis
McDonald Criteria

Diagnostic criteria for suspected MS (two or more attacks)

Two or more clinical attacks with two or more objective lesions	→ MS diagnosed

Two or more clinical attacks with one objective lesion *plus*

Brain MR shows dissemination in space

One Gd-enhancing lesion or
- nine T2 hyperintense lesions if no Gd-enhancing lesion *plus*
- one or more infratentorial lesions *plus*
- one or more juxtacortical lesions *plus*
- three or more periventricular lesions.

NB: One cord lesion can substitute for one brain lesion.

Positive CSF (oligoclonal IgG bands in CSF and not serum or elevated IgG index) *plus*

Further clinical attack involving a different site

Brain MR shows two or more lesions consistent with MS → MS diagnosed

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Clinical Tools for MS Diagnosis
Expanded Disability Status Scale

- Kurtzke's Expanded Disability Status Scale (EDSS) - Primary clinical outcome measure
- It is based on the measurement of mobility related abnormalities

Clinical Tools for MS Diagnosis
EDSS - Issues

Disadvantages of EDSS
- Not a linear scale
- Heavily favors issues related with mobility
- Does not assess cognitive function
- Does not capture subtle changes

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Clinical Tools for MS Diagnosis
EDSS - Issues

- EDSS is normally used against placebo-controlled arm.
- Now as more effective treatments are there it is unethical to use placebo as a control
- To judge the efficacy of investigational drug against the active arm, bigger sample size is required and more responsive outcome measures needed.

Clinical Tools for MS Diagnosis
Multiple Sclerosis Functional Composite

- To overcome these issues, a new multidimensional outcome measure, the Multiple Sclerosis Functional Composite (MSFC) was proposed.
- MSFC includes clinical dimensions of arm, leg and cognitive function.

Clinical Tools for MS Diagnosis
Multiple Sclerosis Functional Composite

- MSFC is more sensitive to change than EDSS
- Change in MSFC over the first year of observation predicted subsequent change in the EDSS.

Treatment of Multiple Sclerosis

- Although no cure exists for MS, treatment aims to reduce the number of relapses or attacks and to lessen their severity when they do occur.
- **Medications**
- **Chemotherapy**
- **MRI devoted to neurological imaging**: using three-dimensional imaging that determines whether a patient's condition is worsening.

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Treatments available in Canada

Treatment involves managing the symptoms of multiple sclerosis as well as treating the disease before permanent damage occurs.

Since 1995
- Four medications have been approved by Health Canada for the treatment of relapsing-remitting MS (RRMS).
- One is approved for secondary-progressive MS (SPMS).
- One is approved for people at high risk of developing MS.

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Alternative Treatments

- Acupuncture
- Aromatherapy
- Cannabis (Marijuana)
- Chiropractic
- Cold Immersion
- Dietary Supplements
- Herbal Medication
- Homepathy
- Injection of Venom such as snake and bee
- Massage
- Meditation
- Reflexology
- Tai Chi
- Yoga

REF (Multiple Sclerosis: Hope Through Research, 06 April 2003)http://intelihealth.com/IH/ihtIH/WSIHW000/8120/21154/199415.htm?d=dmtContent

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Medications used for MS

- **Spasticity** (involuntary muscle spasms) - Baclofen, Tizanidine, Diazepam, Dantrolene
- **Optic Neuritis**- Methlyprednisolone, Oral steroids
- **Fatigue**- Antidepressant, Amantadine
- **Pain**- Codeine, Aspirin
- **Sexual Dysfunction**- Viagra, Pravatine
- **Tremor**- Isoniazid, Primidone, Propranolol
- **Disease-Modifying Drugs**- Interferon beta 1a and 1b, and Glatiramer acetate

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Current Treatments

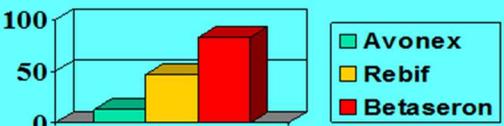Interferon use in MS

Discovered in 1957

•A protein substance naturally produced in the body and believed to function to modulate the immune system where one infection with one virus interferes with a subsequent infection with another virus

•Interferon's interact with receptors on non-infected cells to promote the synthesis of antiviral proteins that prevent further infection. They belong to Cytokines, which are hormones of the immune system

•Significant antiviral agents

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Current Treatments

•Avonex altered long-term course of MS in patients who began treatment immediately after initial attack
•35% decrease in the rate of developing second attack
•42% reduction in new or enlarging T2 hyper intense lesions

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Current treatments cont'd: Disease Modifying Drugs

Interferon Beta 1a (Avonex and Rebif):

- Protein that is a replica of human interferon.
- It suppresses the immune system and helps to maintain the blood-brain barrier.
- Avonex injected into the muscle once a week and Rebif is injected under the skin three times a week.
- This drug is useful to people who have definite progressive MS.
- One side effect of the drug is a flu like symptom

Interferon Beta 1b (Betaseron):

- Different from our own interferon.
- This medication does the same thing as beta 1a, but is injected just under the skin every two days.
- This is also given to people who have definite progressive MS.
- Side effects include irritation, bruising, and redness at the site of injection and the flu like symptoms.

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Current Treatments cont'd:
INTRAMUSCULAR INTERFERON BETA-1a THERAPY
(LAWRENCE,D. JACOBS et al, SEPTEMBER 28, 2000)

- Objective: Initiating treatment at the time of a first clinical demyelinating event is of value.
- Method : A randomized, double-blind trial of 383 patients who had a first acute clinical demyelinating event.
- 193 patients were randomly assigned to receive weekly intra-muscular injections of 30 µg of interferon beta-1a and 190 were assigned to receive weekly injections of placebo.
- Study end points: were the development of clinically definite multiple sclerosis and changes in findings on MRI of the brain.
- Results :During three years of follow-up, the cumulative probability of the development of clinically definite multiple sclerosis was significantly lower in the interferon beta-1a group than in the placebo group (rate ratio, 0.56; 95 percent confidence interval, 0.38 to 0.81; =0.002).
- Conclusions : Initiating treatment with interferon beta-1a at the time of a first demyelinating event is beneficial for patients with brain lesions on MRI.

Current Treatments cont'd: Alemtuzumab

- Reduces the number of attacks experienced by people with relapsing-remitting multiple sclerosis.
- Alemtuzumab appears to be reasonably well tolerated despite the fact that it kills T cells.
- One serious side effect was that one third of the trial subjects developed autoimmune thyroid disease (Graves's disease)
- Relatively easily managed with thyroxin supplementation and most people with MS would exchange multiple sclerosis for Graves's disease.

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Antidepressants Efficacy Trial

Michael A. Posternak, M.D.
et al, *(Am J Psychiatry 2002; 159:191–200)*

- Method: After reviewing 31 antidepressant efficacy trials published between 1994 and 1998,
- A computerized MEDLINE search and a manual search were used to identify studies evaluating the efficacy of antidepressants
- Antidepressant efficacy trials routinely exclude ,subjects believed to have high placebo response rates.
- Exclusion of these subjects significantly increases recruitment costs.
- The generalizability of antidepressant efficacy trials to a narrow population of "pure" depressed patients.
- eligibility is ascertained through a sequence of screening stages, and many ineligible subjects may not even be referred to such trials.
- No standard inclusion and exclusion criteria set exists.

Safety and Efficacy Issues

Interferon beta-1a and hepatic injury.

- In March 2005, the prescribing information and medication guide were updated to include important new safety information including precautions for patients and pregnancy.

Reference: Communication from Biogen dated 1 March 2005, posted on http://www.fda.gov/medwatch.

A Randomized, Placebo-Controlled Trial of Natalizumab for Relapsing Multiple Sclerosis

A total of 942 patients, 627 were randomly assigned to receive natalizumab (at a dose of 300 mg) and 315 to receive placebo by intravenous infusion every four weeks for more than two years. (α4 integrin antagonist in a new class of selective adhesion molecule inhibitors).

Natalizumab reduced the risk of sustained progression of disability by 42 percent
Over two years (hazard ratio, 0.58; 95 percent confidence interval, 0.43 to 0.77;P<0.001). The cumulative probability of progression (on the basis of Kaplan–Meier analysis) was 17 percent in the natalizumab group. Ref:(ClinicalTrials.gov number, NCT00027300.)

Nataluzimab: marketing withdrawal pending evaluation

- Suspended marketing of nataluzimab (Tysabri®) while two serious adverse events are evaluated.
- One confirmed fatal case
- One possible case of progressive multifocal leukoencephalopathy ,a rare, serious progressive neurologic disease usually occurring in immunosuppressed patients.
- FDA News, P05-07. 28 February 2005. http://www.fda.gov/cder/drug/advisory/natalizumab.htm.

Multiple Sclerosis and Epstein-Barr Virus Ref: Lynn I. Levin, PhD, MPHet al, *JAMA*. 2003;289(12):1533-1536 (doi:10.1001/jama.289.12.1533)

- **Objective** To determine whether antibodies to EBV are elevated before the onset of MS.
- **Design, Setting, and Population** Nested case-control study conducted among more than 3 million US military personnel with blood samples collected between 1988 and 2000.
- **Result :** Average time between blood collection and MS onset was 4 years.
- The date of onset of MS is difficult to establish accurately,
- Increased antibody response to EBV occurs early in relation to pathological process that leads to demyelination and clinical disease.
- **No association was found between cytomegalovirus antibodies and MS.**
- Strongest predictors of MS were serum levels of IgG antibodies to VCA(viral capsid antigen) or EBNA(nuclear antigen) complex.

Research Themes for Multiple Sclerosis

MS research has generally taken two forms :
- Studies that focus on the mechanisms associated with nerve damage and nerve repair.
- Focusing on symptoms
- Clinical Trials is distinctly divided into five phases i.e.,conceptualization, planning,implementation, analyzing and reporting.

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Focus on current trends

- Hookworms
- Stem cells
- Vitamin D

Hookworms In MS

- Aims to determine whether infection with a small and harmless number of the worms can lead to an improvement on the severity of MS over a 12 month period.
- The trial is a multi-Centre study being carried out in UK
- Intended recruitment is 72 patients - 36 on hookworms and 36 on placebo.
- Method : 25 worms are introduced painlessly through a patch in the arm.
- They are then flushed out after nine months
- If the trial is successful, the worms have the potential to provide a simple, cheap, natural and controllable treatment for MS.
- Final result of the trial will be available in 2011/2012

Ref : Source: Professor Cris Constantinescu , University of Nottingham(UK)
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Stem Cells in Multiple Sclerosis

- History
  - 1945 – Nuclear explosions over Hiroshima and Nagasaki
  - 1950s – First studies involving HSC
  - 1960s – Till and McCulloch establish the existence of pluripotent HSC
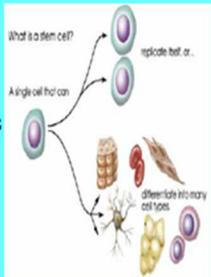
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Stem Cells in Multiple Sclerosis

- How are Stem Cells different from the other types of cells?

They have two important properties:

- they are unspecialized cells capable of self renewal

- under certain conditions they can be induced to differentiate into other types of cells

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Stem Cells in Multiple Sclerosis

- Sources of Stem Cells
  - Embryonic stem cells
  - Fetal stem cells
  - Umbilical cord stem cells
  - Adult stem cells
    - Bone marrow
      - Hematopoietic stem cells
      - Mesenchymal stem cells
    - Peripheral blood

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Stem Cells in Multiple Sclerosis

- Hemopoietic stem cells
  - Give rise to all blood cells
  - Collected from:
    - Bone marrow
    - Peripheral blood

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Stem Cells in Multiple Sclerosis

- Method used to harvest HSC
  - Bone marrow is stimulated using a cytokine
  - As a result the blood is enriched with HSC
  - Fluorescence Activated Cell Sorting is used to separate the different blood cells
  - Cell Surface Marker Combinations (usually CD34) are used to achieve further purification

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Stem Cells in Multiple Sclerosis

- Number of HSC transplantations performed annually worldwide:
  - Aoutologous transplantations >30,000
  - Allogeneic transplantations >15,000

  - Used to treat such conditions as non-Hodgkin Lymphoma, multiple myeloma, Sickle cell anemia, lymphoid and hematologic cancers

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Stem Cells in Multiple Sclerosis

HSC transplantation for MS timeline
- 1997 – A. Fassas at al - *Peripheral blood stem cell transplantation in the treatment of progressive multiple sclerosis: first results of a pilot study*
- 2003 - R. K. Burt at al - *Hematopoietic stem cell transplantation for progressive multiple sclerosis: failure of a total body irradiation-based conditioning regimen to prevent disease progression in patients with high disability scores*
- January 2009 - R. K. Burt at al - *Autologous non-myeloablative haemopoietic stem cell transplantation in relapsing-remitting multiple sclerosis: a phase I/II study*

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Stem Cells in Multiple Sclerosis

Autologous non-myeloablative haemopoietic stem cell transplantation in relapsing-remitting multiple sclerosis: a phase I/II study

- Study hypothesis:

An autologous HSC transplantation will reset the immune system of patients with MS, by replacing the autoreactive lymphocytes with ones that are self-tolerant

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Stem Cells in Multiple Sclerosis

- Study method:

This is accomplished by a process in which the patient's autoreactive lymphocytes are destroyed by an initial course of chemotherapy, followed by HSC transplantation

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Stem Cells in Multiple Sclerosis

- Inclusion criteria:
  - Age between 18-55
  - Had relapsing-remitting MS
  - Met the McDonald criteria for MS
  - Met the Poser criteria for MS
  - Were treated with interferon beta for 6 months without response
  - EDSS scores measured at least 3 months after the last attack - 2.0-5.5 points
  - Normal levels for renal, hepatic, cardiac and pulmonary function

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Stem Cells in Multiple Sclerosis

- Study method description:
  - Peripheral blood cells mobilized with cyclophosphamide, followed from day 5 by filgrastim
  - Once the neutrophils recovered the activated HSC were collected using apheresis and cryopreserved
  - Conditioning regimen - cyclophosphamide given in four equal fractions between days -5 and -2, followed by alemtuzumab and methyl-prednisolone on day -2

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Stem Cells in Multiple Sclerosis

- Study method description cont'd:
  - HSC re-infused on day 0
  - Filgrastim from day 5 till neutrophil recovery

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Stem Cells in Multiple Sclerosis

- Post-chemotherapy prophylaxis:
  - Atibacterial - cefepime, piperacillin–tazobactam
  - Antifungal- fluconazole
  - Antiviral - valaciclovir , aciclovir
  - *Pneumocystis jirovecii* prevention - trimethoprim-sulfamethoxazole, nebulised pentamidine

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Stem Cells in Multiple Sclerosis

- Study results
  - Mobilization and transplantation procedures were considered well tolerated as there were no non-hematological toxicities of grade III or higher

  - Relapse in 5 patients (23%) - these patients were treated with immunosuppressants and achieved remission and further neurological improvement

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Stem Cells in Multiple Sclerosis

- Study results cont'd:
  - 81% of patients improved by 1 or more points on EDSS score

  - None had a score lower than the baseline

  - All patients improved their EDSS score after the HSC transplantation

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Stem Cells in Multiple Sclerosis

- Study results cont'd:
  - Using Scripps neurological rating scale (NRS), it was determined that 19 patients improved by 10 or more points and none of the patients had scores lower than their baseline scores
  - Scores on the timed 25-foot walk, right-hand peg test and left-hand peg test all improved in comparison to baseline
  - Patients felt that their health and quality of life has improved after the transplantation.

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Stem Cells in Multiple Sclerosis

- Study results cont'd:
  - at the time of publication the progression-free survival was 100%
  - Reversal of neurological symptoms with improved EDSS score from baseline was observed in 81% of the patients

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Stem Cells in Multiple Sclerosis

- Study results cont'd:

  - Neurological function continued to improve for up to 2 years after the transplantation

  - It was observed that some improvement occurred after a delay of 1 or more years

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Stem Cells in Multiple Sclerosis

- Study results cont'd:

  - The authors conclude that the autologous non-myeloablative haemopoietic stem cell transplantation is a procedure that can benefit patients with relapsing-remitting MS because it appears to stop progression of neurological symptoms as well as reverse neurological deficiency

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Stem Cells in Multiple Sclerosis

- The results of this study are very encouraging because in contrast to the currently used therapies which aim to slow down the progression of MS without offering a cure for the disease, the autologous non-myeloablative haemopoietic stem cell transplantation promises to deliver a treatment that could not only delay the progression of the disease but also reverse the existing neurological damage.

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Stem Cells in Multiple Sclerosis

- A new phase III study is on the way that will asses the efficacy of the tested method against any of the FDA-approved medication

- A Canadian center will take part in the trial

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Stem Cells in Multiple Sclerosis

- There is hope that a cure for the early stages of MS could be developed in the very near future

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Vitamin D – the basics

- Vitamin D is a lipid soluble vitamin
- It is needed for the absorption of calcium which aids in the formation and maintenance of strong bones
- It also aids in proper regulation of calcium and phosphorous levels in the blood
- Many disorders can arise because of vitaminD deficiency such as rickets and osteomalacia
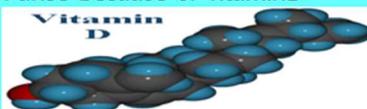
Sources of Vitamin D

- The dermal layer of the skin can manufacture vitamin D from UV rays of the sun, from there the liver and kidney help convert vitamin D to its active hormone form
- It can also be obtained form dietary sources such as cod liver oil, fortified butter and margarine.
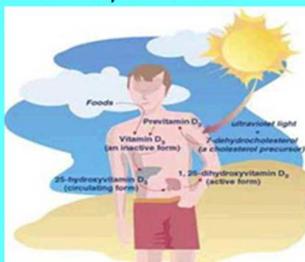
Vitamin D and Multiple sclerosis

- Some of the latest findings in research done in patients with multiple sclerosis (MS) is that, there is a correlation between vitamin D deficiency and MS. Vitamin D deficiency afflicts most MS patients, as demonstrated by their low bone mass and high fracture rates (Nieves et. Al)
- We will be discussing 2 research papers on this topic and their findings.

Neives et. Al cont'd

- The bone mass density (BMD) from the femoral neck and the lumbar spine and the total body mineral samples were obtained from subjects in both groups through dual x-ray absorptiometry.

Neives et. Al cont'd (Results)

- Discovered that the mean BMD for the patient group was 0.905 g/cm2 in the lumbar spine and 0.676 g/cm2 in the femoral neck, which causes them to be twice at risk for bone fractures specifically in the female population. The level was 1 to 2 significant digits lower in women with MS than their healthy counterparts. They also found that the chronic progressive MS had the lowest BMD and relapsing-remitting MS had the highest.

Table 3. Bone mineral density of the spine and femoral neck and total body bone mineral (TBBM) for female MS patients categorized by pattern of MS and EDSS score

| | Bone mineral density | | |
	Lumbar spine (g/cm²) Mean ± SEM	Femoral neck (g/cm²) Mean ± SEM	TBBM (g) Mean ± SEM
MS pattern			
Relapsing-remitting (n = 13)	0.983 ± 0.036 (−0.59)	0.724 ± 0.034 (−1.47)	2,510 ± 104
Relapsing progressive (n = 34)	0.913 ± 0.032 (−1.13)	0.697 ± 0.025 (−1.84)	2,384 ± 94
Chronic progressive (n = 28)	0.873 ± 0.040 (−0.93)	0.632 ± 0.036 (−2.02)	2,289 ± 101
EDSS score			
0-6.5 (ambulatory) (n = 46)	0.931 ± 0.026 (−0.82)	0.711 ± 0.021 (−1.38)	2,412 ± 62
≥7 (nonambulatory) (n = 34)	0.871 ± 0.034 (−1.23)	0.626 ± 0.029* (−2.27)*	2,287 ± 110

MS pattern could not be determined in five patients.

The z score is shown in parentheses below bone mineral density values.

* $p < 0.02$ versus ambulatory.

Neives et al. cont'd

- A lower bone mass density triggers fractures as well as osteoporosis specifically in females. Their findings suggested that a continued supplementation of vitamin D to the MS patients would reduce bone fractures and osteoporosis, which is common for them.

Cytokine Profile in Patients with Multiple Sclerosis Following Vitamin D Supplementation.
B.D. Mahon, S. A. Gordon, J. Cruz, F. Cosman, and M.T. Cantorna

In the next trial discussed, patients diagnosed with MS who also had a baseline 25 hydroxyvitamin D levels <25 ng/ml, were placed in a randomized, double blind design study in two groups (this study incorporated males and female subjects from a variety of age groups) :

Cytokine Profile in Patients with Multiple Sclerosis Following Vitamin D Supplementation.
B.D. Mahon, S. A. Gordon, J. Cruz, F. Cosman, and M.T. Cantorna

1. Vitamin D supplemented group (800 mg supplemental calcium plus 1000 IU Vitamin D)
2. Placebo group (this group was assigned 800 mg supplemental calcium plus placebo)

Cytokine Profile in Patients with Multiple Sclerosis Following Vitamin D Supplementation.
B.D. Mahon, S. A. Gordon, J. Cruz, F. Cosman, and M.T. Cantorna

- The subjects were given their supplements for 6 months
- After that blood samples were obtained and the levels of 25 hydroxyvitamin D were measured
- Radioligand-binding assay was used to measure the level of 25 hydroxyvitamin D

Cytokine Profile in Patients with Multiple Sclerosis Following Vitamin D Supplementation.
B.D. Mahon, S. A. Gordon, J. Cruz, F. Cosman, and M.T. Cantorna

- As expected, the vitamin D supplemented group displayed an increase in the 25-hydroxyvitamin D level, and the placebo treatment did not affect 25-hydroxyvitamin D levels.
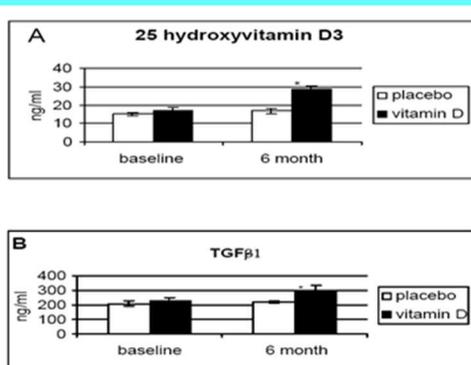

Cytokine Profile in Patients with Multiple Sclerosis Following Vitamin D Supplementation.
B.D. Mahon, S. A. Gordon, J. Cruz, F. Cosman, and M.T. Cantorna

Conclusion (vitamin D)

- Based on the findings from both studies, vitamin D deficiency is significantly common in patients with MS.
- MS is also more prevalent in environments where vitamin D level are lowered either by lack of sunlight or dietary intake.
- This deficiency among MS patients can be reduced by providing them with vitamin D supplements

Issues with Trial Design:

- Some clinical trials are observational studies in which investigators do not manipulate the patient or disease but simply gather data in order to learn about the course of the disease. Most clinical trials, though, are interventional trials, in which investigators attempt to intervene in a disease process to alter the disease course. Drug treatment trials are among the most common of interventional clinical trials.

- Clinical studies of multiple sclerosis have used many different types of study designs and statistical analyses with subtle differences that may influence the results of their interpretation. The most common design for multiple sclerosis clinical studies is a randomized double-blind study.

Issues with Trial Design Cont'd:

- In order to discern the effect of a drug, patients are assigned to different treatment groups, or arms. At least one arm will receive investigational treatments, and at least one arm will function as a control group. Clinical trials may compare treatment with an experimental drug to no treatment (placebo control), or to an approved, standard of care (SOC) treatment (active control).

- MS clinical drug trials for relapsing-remitting MS (RRMS) increasingly utilize active-control or superiority/non-inferiority trial designs, as it could be considered unethical to treat patients with placebo for an extended duration when approved therapies for RRMS exist.

Issues with Trial Design Cont'd:

- Smaller, short-duration phase I or II trials and older phase III trials in RRMS, some of which are ongoing, may still employ a placebo-controlled design. Clinical trials for progressive forms of MS may still be placebo-controlled since there are no established therapies for primary progressive MS (PPMS) or for secondary progressive MS (SPMS).
- Placebo controlled trials are common; even though there are major ethical issues surrounding using placebos as the comparator :

    - It is evident that a placebo comparator provides the most solid evidence of efficacy, but it is also very clear that it is unacceptable when an effective therapy already exists

    - As there is a growing amount of approved effective therapies, especially for relapsing multiple sclerosis patients and an increasing need for early treatment, placebo-controlled clinical trials raises more of a predicament

Ethical Considerations:

- Placebo-controlled MS trials
- **The Challenge:** As there is a growing amount of approved effective therapies, especially for relapsing multiple sclerosis patients and an increasing need for early treatment, placebo-controlled clinical trials raises more of a predicament
- **The Goal:** Future RRMS clinical trials will most likely be designed as active-control or superiority/non-inferiority trials. There would be more effective therapies allowing the same for progressive MS and the placebo-controlled trials will no longer be the standard.
- **The Solution:** Society's International Advisory Committee on Clinical Trials in MS - bandage solution

Guidelines 2001:

- It was determined that if placebo-controlled trials would be conducted, it should only be offered with a rigorous informed consent and only if the patients have refused to use the existing treatments or if existing treatments are unavailable to them for certain reasons, or that the patients have not positively responded to them

- It was this panel that provided guidelines in 2001, for conducting placebo-controlled MS trials ethically. It states six terms in which placebo-controlled trials are permitted

Six terms for Placebo-Controlled Trials

1. When there is no established effective therapy available
2. Those who refuse the established effective therapy
3. If the patient has not responded to the reputable effective therapy

Six terms for Placebo-Controlled Trials Cont'd

4. When the effective therapy is not available and resources are restricted
5. No evidence that short-term withdrawal (6 months or less) of MS therapies can cause long-term differences in clinical outcomes
6. Does not cause serious or permanent harm as in clinical trials of symptomatic treatments.

Informed Consent

- Informed Consent seems to be the best resolution for now

- Improving informed consent procedures allows for greater constraints for placebo-controlled trials in "resource-restricted" environments where existing therapies may not be available.

Conclusion

World wide 2.5 million people live with MS.

- **MRI as an out come of MS trials** - widely used in trials of relapsing-remitting and progressive multiple sclerosis add little if anything independently to the clinically relevant relapse and disability outcomes
- **Disability as outcome of MS Trials**
- **Reducing possibility of False positive**
- **Online tool for individual for easy assessment for non commercial purpose** -Prognosis of the individual course of disease
- **Research Methodologies**- possibilities of publishing false positive results
- **Microarray-based classification and clinical predictors** - in MS research e.g. to identify genes that are differentially expressed depending on the disease course or to refine the prediction of patient outcome
- **Launch of website**-for treatment guidelines and available treatments

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- Multiple Sclerosis Society @ http://www.mssociety.org.uk/
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Curriculum Vitae

Jennifer H. Garrison

EXPERIENCE

Administrator, 20th Medical Group   **2 July 2013-Present**
Shaw AFB, SC

   Provides administrative oversight of all medical operations and support activities while coordinating the health care delivery to 23,000 beneficiaries and supporting the missions of the 20th Fighter Wing, Headquarters 9th Air Force and associated units. Additional Duties: Medical Wing Division Inspection Team Chief, Management Internal Control Toolset (MICT) Administrator/Compliance Officer and Risk Manager.

Air Combat Command Surgeon General's Office   **29 June 2010-1 Jul 2013**
Langley AFB, VA

   Medical Readiness Planner; provides overall support to 15 bases as Air Combat Command Functional Area Manager for all readiness programs including medical plans, deployment operations, exercises, training, Unit Type Code (UTC) management, inspections and acquisition. Identifies medical units for Aerospace Expeditionary Force (AEF) apportionment, deployment and contingency operations. Identifies command training requirements to be accomplished under exercise objectives. Ensures Joint Mission Essential Task Listing (JMETL) is accomplished. Prepares formal tasking messages and produces/publishes exercise programs. ACC/SG Crisis Action Team (CAT) officer representative. Executes deliberate and crisis action planning activities, and coordinates medical forces deployments in support of all ongoing operations. Validates Time-Phased Force Deployment Data (TPFDD) for all expeditionary force deployments.

10th Medical Group   **October 2009-29 June 2010**
United States Air Force Academy, CO

   Senior Group Practice Manager; responsible for business management of 26 clinics, 74 providers, 188K Out Patient Visits, $54M in patient care delivered annually. Facilitates provision of high-quality, accessible & cost-effective healthcare services for clinic serving 29K patients. Leads business planning team; responsible for clinical coding; provides oversight to 2 Officer's, 1 Enlisted & 5 Civilians. Healthcare Administrator in primary's absence; leads 24 member Medical Control Center; Health Services Administrator Unit Type Code Team Chief; Medical Services Corps Readiness Skills Verification Plan Team Chief

10th Medical Support Squadron   **January 2008-October 2009**
United States Air Force Academy, CO

   Resource Management Flight Commander; commands 17-member Resource Management Flight. Chief Financial Officer; DRU-level $60M budget & 158 cost centers. Leads 750-billet manpower portfolio, develops 6-yr POM submission.

Executes $1.5M Third Party Collections, MAC and MSA programs; leads 12-mbr Medical Control Center Team in war/peacetime.

310th Mission Support Group   **June 2007-January 2008**
Schriever AFB, CO

Medical Support Flight Commander/Healthcare Administrator; managed 31 medical Reserve personnel. Hand-selected by 310th Space Group Commander to set-up brand new medical squadron for 310th Space Wing for Reserve weekends.

43rd Aeromedical Evacuation Squadron   **January 2006-June 2007**
Pope AFB, NC

Chief of Scheduling/Executive Officer; scheduled all ground training events for 165 squadron members. Managed flight schedules and mission-ready requirements for 37 flight nurses and 55 technicians.

355th Medical Group   **April 2004-January 2006**
Davis-Monthan AFB, AZ

Medical Readiness Flight Commander; managed medical readiness training for 298 personnel. Coordinated annual training 16 Unit Type Code teams, 12 medical-disaster teams and five homeland defense teams; oversaw all medical readiness training plans. Supervised team of two readiness technicians

355th Fighter Wing   **May 2003-April 2004**
Davis-Monthan AFB, AZ

Wing Protocol Officer; planned, coordinated and executed visits of distinguished guests to the 355th Fighter Wing. Provided protocol guidance to the Wing Commander, senior leadership, local government and civilian organizations. Supervised two protocol specialists.

355th Medical Group   **May 2002-May 2003**
Davis-Monthan AFB, AZ

Patient Administration Flight Commander; maintained functional liaison with 3 local military and 11 civilian hospitals. Obtained relevant information incidental to the admission, transfer and discharge of military members. Managed 55K-beneficiary record accountability. Supervised 36 staff.

EDUCATION

MS, HUMAN RESOURCE MANAGEMENT   **Dec 2002**
Wilmington College, Delaware
BS, MANAGEMENT INFORMATION SYSTEMS   **May 2000**
Wesley College, Delaware
AS, PARALEGALISM   **May 1998**
Central Texas College, Texas

PROFESSIONAL MEMBERSHIPS

Diplomate in Healthcare Administration, American Academy of Medical Administrators
Fellow in the American College of Contingency Planners
Program for Emerging Leaders, National Defense University
Certified Emergency Manager, International Agency of Emergency Management
Certified Medical Administrator, American Academy of Medical Administrators
Member of American College of Healthcare Executives

SPECIALIZED TRAINING

Contingency Wartime Planning Course	Sep 2010
The Warfighting Planning Course Online	Aug 2010
USAF FAM WBT Course	Jul 2010
USAF Global Medical Readiness Symposium	Apr 2010
Air Command and Staff College (Correspondence)	Apr 2009
USAF Global Medical Readiness Symposium	Jun 2008
CENTAF Air Mobility Division Aeromedical Evacuation Course	Aug 2006
Squadron Officer's School (Residence)	Jun 2006
Aeromedical Evacuation Contingency Operations Training	May 2006
Squadron Officer's School (Correspondence)	Dec 2005
Expeditionary Medical Operations Planners Symposium	Mar 2005
Medical Readiness Planners Course	Apr 2004
Health Services Administration Course	Aug 2002

AWARDS

2008 DRU Resource Manager OTY
2008 DRU Resource Management Team OTY
2007 AMSUS Company Grade Officer OTY assigned to a Non-Deployable Unit
2007 Brigadier General Peter C. Bellisario Young Healthcare Executive Officer OTY