

AN ABSTRACT OF THE THESIS OF

Andrea M Juhl for the degree of Master of Science in Movement Studies in Disability presented on February 15 2001. Title: The Relationship between Level of Physical Activity and Health Related Quality of Life in Women with Multiple Sclerosis.

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Multiple Sclerosis (MS) is a debilitating, degenerative, and chronic disease that affects over 350,000 individuals in the United States. Symptoms such as fatigue, spasticity, weakness, gait and visual disturbances, numbness and balance problems affect many with MS on a regular basis. There are literally an infinite number of combinations of symptoms that may be experienced by an individual with MS.

These destructive symptoms often lead to the reduction or lack of participation in leisure and physical activity. In fact, people with MS were previously told not to exercise at all in fear of exacerbation of symptoms due to excess fatigue. It is now known that exercise can provide important benefits to the MS populations.

However, a relationship between the level of physical activity performed and health related quality of life has not been firmly established. This investigation evaluated whether a relationship exists between activity levels and quality of life in individuals with MS. Approximately 180 women with clinically diagnosed multiple sclerosis were contacted and 160 women participated in this study. The average age of the women in this study was 50.1 +/- 11.1 years. Each participant

completed 2 questionnaires; The Multiple Sclerosis Health Related Quality of Life Scale (MSQOL-54), and an adapted Yale Physical Activity Survey for Older Adults. Information from the questionnaires was scored and analyzed using the Pearson Product Moment Correlation Coefficient. The women had been diagnosed for an average of 12 years and over half the women (55%) were diagnosed with relapsing-remitting MS. It was found that total physical activity was correlated to physical health score ($r = .446$), social function score ($r = .326$) and physical composite score ($r = .330$) at $p < .01$. Specifically, total physical activity was able to account for 20% of the variance in the physical health score according to an $r = .446$ and $r^2 = .199$. Light and moderate physical activity scores were significantly correlated to several quality of life scales as well, but total activity was the variable with the strongest relationships ($r = .446$ for total activity versus $r = .235$ and $r = .281$ for light and moderate). This study showed a relationship between levels of daily physical activity and several components of health-related quality of life. These results are valuable considering it had been shown that physical dimensions play a very large role in overall health-related quality of life.

The Relationship between Level of Physical Activity and Health Related Quality of
Life in Women with Multiple Sclerosis

by

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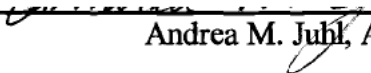
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I understand that my thesis will become part of the permanent collection of Oregon State University libraries. My signature below authorizes release of my thesis to any reader upon request.

 Andrea M. Juhl, Author

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Sincerely,

Andrea M. Juhl

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The Relationship between Level of Physical Activity and Health Related Quality of Life in Women with Multiple Sclerosis

Introduction

There are nearly 350,000 Americans diagnosed with multiple sclerosis (MS). This is probably a large underestimate considering many individuals live with the disease for years before being diagnosed. In fact, there have been reports that there may be over 2 million persons living with MS. Seventy-three percent of people with MS are female, 71% are no longer in the work force, and 95% are Caucasian. Seventy-five percent of those reported with MS are between the ages of 35-64, while the typical onset of the disease is between the ages of 20 and 40 years (Stuifbergen, 1997). The true number of people who have the disease is not really known. Many individuals may exhibit symptoms for years before the condition is appropriately diagnosed.

Multiple sclerosis is a progressive demyelinating disease that produces lesions in the white matter of the central nervous system (Ponichtera-Mulcare, 1993). Although reported symptoms of MS are similar, each individual experience is very unique. Primary symptoms include fatigue, dizziness, gait disturbances, weakness, numbness, ataxia, visual disturbances, bowel and bladder problems, pain, changes in sexual functioning, spasticity, and problems with cognitive functioning. There are almost infinite combinations of symptoms that can result from different patterns of demyelinating lesions (Stuifbergen, 1997). This extreme variability in disease appearance makes it very difficult to generalize treatment or therapy options. It

also makes it very difficult to prescribe or suggest physical activity and exercise for the MS population as a whole.

It was not too long ago when people with MS were told to “take it easy” or “do not push too hard,” due to fear of fatigue and resultant muscle weakness and other symptoms (Pitetti, 1993). This is still a concern considering over 85% of the MS population experiences fatigue as a primary symptom (Petajan & White, 1999). Individuals with MS are often thermosensitive and manifest an increase in symptoms during exercise. This sensitivity to heat often increases the occurrence and severity of fatigue. However, these circumstances can be avoided if precautions are taken (Petajan & White, 1999). Consequently, the fear of fatigue does not have to cause an avoidance of exercise.

The effects of prolonged inactivity are well documented for the general population: muscle weakness and atrophy, decreased flexibility, fatigue, cardiovascular deficits, depression, and trouble sleeping (Stuifbergen, 1997). Unfortunately, these problems are often attributed to the disease itself without considering inactivity. Since inactivity in the general population is inversely associated with morbidity and mortality, it may be even more significant with MS populations. One of the most common responses to symptoms of MS is to stop leisure time activity, which often leads to inactivity (Stuifbergen, 1997). Stuifbergen and Roberts (1997) reported that women with MS scored lower on measures of physical activity than a comparative healthy population. An exercise habit allows a person with MS to be proactive. Improved fitness will decrease

morbidity resulting from cardiovascular disease and other ailments associated with immobility (Petajan & White, 1999).

It has been reported that confidence in the ability to be active, perceived barriers to activity, and enjoyment of activity are strongly related to actual participation in physical activity (Stuifbergen, 1997). Most benefits of activity can be obtained outside of formal exercise, and the amount of activity is more important than specific manners in which the activity is performed.

Goodin (1999) randomly sampled 493 individuals with MS and found that exercise was one of the only factors associated with a lower score on the Expanded Disability Status Scale (EDSS) and less total disability. This correlation may help to strengthen the importance of exercise in the treatment of MS.

The subject area of quality of life (QOL) has not been actively pursued in the MS population. Quality of life measures can serve as alternative indicators of the impact of the disease (Nortvedt et al, 1999). The majority of research investigating quality of life measures and the MS population has used general QOL measures that may not properly represent this special population. It is important for health care providers to understand the impact of health status on quality of life of MS patients in order to properly intervene in a way that maintains or increases their quality of life (Gulick, 1997).

It is very important to consider the unique aspects of the MS population. Many domains found in QOL assessments would not be appropriate for the MS population. For example, the MS population will have a totally different type of

“physical domain” and “psychological domain.” Physical limitations and frequency of depression could make certain scales useless for measuring this type of population. It may be more appropriate to measure health-related QOL for individuals with MS.

Brunet and colleagues (1996) used a health-related quality of life measure and compared the scores to scores on the Kurtzke Expanded Disability Status Scale (EDSS) (Kurtzke, 1983). The authors’ point out that general quality of life is difficult to conceptualize due to the influence of so many confounding variables. The HRQOL is distinguished from regular QOL because it is based on health domains which can be measured and quantified (Brunet et al, 1996). The general conceptualizations in HRQOL include physical, social and role functioning dimensions as well as general health and mental health perceptions (Brunet et al, 1996).

Vickrey, Harooni, Myers, and Ellison (1995) developed a “self-report measure of HRQOL for MS that combines the strengths of generic and disease-targeted approaches to HRQOL measurement” (Vickrey et al, 1995, pp188). In order to accomplish this, they used the generic HRQOL measure, the RAND 36-Item Health Survey, and supplemented it with HRQOL items that are particularly relevant to individuals with MS. The use of the RAND-36 allowed for comparisons of HRQOL of people with MS to the general population. The 18 additional items included areas specific to MS: health distress, sexual function, satisfaction with sexual function, overall quality of life, cognitive function, energy,

pain, and social function. The end result of the project was the Multiple Sclerosis Quality of Life (MSQOL)-54 Instrument. The authors concluded “the MSQOL-54 comprehensively assesses HRQOL for individuals MS” (Vickrey et al, 1995 pp198). The authors offer “preliminary support for the reliability and construct validity of the MSQOL-54” and suggest the usefulness of this measure in assessing quality of life in persons with MS (Vickrey et al, 1995 pp199).

To date, there has not been any research dealing specifically with the relationship between HRQOL and levels of physical activity in persons with MS. The physical domain is obviously a major component of QOL, as is social functioning, energy, pain, and general wellbeing. Physical activity has been shown to impact many if not all of these variables. Yet, the relationship between HRQOL and levels of physical activity has not been explored in persons with MS. Therefore, the purpose of this study was to determine the relationship between level of physical activity and HRQOL in women with MS.

Methods

Subjects

Approximately 180 women with MS were recruited for this study with a target set for 150 participants. The number of participants was based on guidelines for sample size in survey research with a 95 percent confidence level (Salant & Dillman, 1994). One hundred sixty women agreed to participate in the study. Subjects were recruited from Oregon communities through various techniques. An advertisement asking for participants was run in an Oregon newspaper (see appendix A). Participants in former studies were contacted by former investigators and encouraged to participate (see appendix B). Presentations about the research topic were made at various MS self-help groups around the state of Oregon. Although two participants were from the state of Washington, and two from Idaho, the remainder of women resided in Oregon. Selection criteria included confirmed diagnosis of clinically definite MS and no active exacerbation of MS at the time of participation. Women at all levels of the disease and of all ages were contacted. Age was not an issue in this study due to the fact that most patients with MS are between the ages of 30 and 65 years of age. In fact, the average age of women in this study was 50.14 years +/- 11.13. The youngest participant was 21 while the oldest was 78. Sixty-five percent of the women were between the ages of 40 and 60. Over half of the women were diagnosed with relapsing-remitting MS, while chronic progressive and relapsing progressive diagnosis accounted for 15% each. This descriptive data can be seen in Table 1 and 2. The Oregon State University

Institutional Review Board for the Protection of Human Subjects approved this research (see appendix C). The full application for approval is included (see appendix D). All participants signed an informed consent form detailing their rights and responsibilities in the study (see appendix E).

Instruments

Two different scales were used in this study to measure the dependent and independent variables. One scale was used to measure quality of life and the other for the measurement of physical activity.

Quality of life was measured using the Multiple Sclerosis Quality of Life (MSQOL)-54 Instrument. The MSQOL-54 is a scale that combines the RAND 36-item Health Survey and 18 additional items particular to the MS population. The SF-36 serves as the generic basis for the important domains of HRQOL. This scale has been shown to be relevant to the MS population. It includes five general health perception items, four energy/fatigue items, two social function items, five emotional well-being items, three role limitation due to emotion items, ten physical function items, four role limitation due to physical problem items, and two pain items. There is also one item that examines health state change. Permission to use this portion of the survey was granted by the RAND Corporation (see appendix F).

The supplemental items were added in the areas of social function, pain, and energy/fatigue scales (one item per scale). Four items address health distress such as frustration, despair, and worry. Two items address overall quality of life. Five

items address sexual function, and four items address cognitive function. Overall, the scale includes 54 items measuring 12 dimensions of HRQOL (physical health, role limitations due to physical problems, role limitations due to emotional problems, pain, emotional well-being, energy, health perceptions, social function, cognitive function, health distress, sexual function, and overall quality of life), one item measuring health status change, and one item measuring satisfaction with sexual function. These scores all reflect an individual's "perception" of the particular dimension in their life over the past four weeks. A total score for physical function (physical composite) and social function (social composite) was also calculated (Vickrey et al, 1995).

The internal consistency reliability for the 12 multi-item scales has been shown to range from 0.75 to 0.96. The test-retest intraclass correlation coefficients ranged from 0.66 to 0.96. This scale has also been shown to have construct validity when associated with a variety of factors. Overall, this scale has demonstrated both validity and reliability in the MS population (Vickrey et al, 1995). Written permission to use the entire MSQOL-54 was granted by Dr. Vickrey and colleagues. A special scoring sheet was used to ensure proper weighing of scale values (see appendix G).

Physical activity levels were measured using an adapted form of the Yale Physical Activity Survey. The original survey, which is divided into two sections, was not used. The first section requires a personal interview, which could not be conducted for this study. The second section gathers information about the

duration and frequency of participation in vigorous activity, leisurely walking, moving, standing, and sitting (Dipietro et al, 1993). This second section, however, does not account for low or moderate intensity forms of activity other than leisurely walking. Many individuals with MS may not be able to perform activities on the Yale, but do perform alternative activities. The second section of the Yale would not be very accurate in obtaining information about the MS population.

Modifications were therefore made to include moderate-intensity and alternative forms of low-intensity physical activity. The modified survey includes questions concerning the weekly duration and frequency of recent participation in vigorous, moderate, and low intensity activities. The participants were asked to list their activity and provide a score for the frequency and duration per week of the particular activity. This score was obtained from a table on the survey. The frequency score was multiplied by the duration score. This score was then multiplied by a weighted factor to create a summary index. A total summary index was created by adding the three individual activity indices (vigorous, moderate, light). This final score was used to correlate with the MSQOL-54 values.

Procedures

Each participant in the study first received a personalized letter, including an informed consent. This letter described the purpose of the study and informed them that they would soon receive the questionnaires (see appendix H). One week later, or immediately following the return of the informed consent, the participants

were sent a packet in the mail containing a cover letter (see appendix I), an informed consent form, a basic information survey (see appendix J), a Multiple Sclerosis Quality of Life (MSQOL)-54 Instrument (see appendix K), and an adapted form of the Yale Physical Activity Survey for Older Adults (see appendix L). If the participant called directly and asked to participate, they were not mailed an advance letter, but immediately sent a full packet. Potential participants at the group meetings who agreed to participate were given a packet directly. Participants were asked to fill out each form in its entirety while providing their names only on the informed consent. If the subject had already completed an informed consent, they were not required to return a second one with the packet. Each packet also contained a pre-addressed, stamped envelope for returning the completed forms in hopes of increasing compliance. A postcard was sent to participants who had not returned the packet within two weeks in order to remind them of their participation. A new personalized cover letter and questionnaire packet was sent to those who had not responded after three weeks. This follow-up procedure is a common practice suggested for survey research and should yield a high response rate (Salant & Dillman, 1994). Only about five secondary packets had to be sent. The compliance rate was very high; about 85% of the women returned a completed packet.

Once the information was received, each packet was checked to ensure it was complete. All incomplete questionnaires were excluded. Each subject was coded with a number to ensure confidentiality. The surveys were scored and recorded.

Demographic information was also recorded. Once all the packets were received and scored, the data were analyzed. Each subject who responded was sent a postcard thanking her for her participation.

Statistical Analysis

Statistical analysis was done using SPSS 10.0 for Windows (SPSS, 1998). Basic descriptive statistics (mean, standard deviation, minimum/maximum) were computed for the self described demographic data; age, height, weight, time since first symptoms, time since diagnosis, and mobility level. Information concerning current medications was also gathered. These demographic data served to describe the sample being tested. Pearson Product Moment correlation coefficients were computed to determine the relationships between level of physical activity (light, moderate, vigorous, total) and quality of life as measured by the previously discussed scales.

Results

The compliance rate for this study was exceptionally high for survey research. Approximately 85% of the questionnaire packets were returned. Of the returned packets, only 3 were incomplete and could not be used. This left 160 completed questionnaire packets suitable for analyses.

Table 1.1 summarizes the basic demographic data including age, height, weight, BMI, time since first symptoms, and time since diagnosis. The average age of the participants was 50.1 years. As shown in table 1, the sample was normally distributed and a representative group by age for women with MS. The majority of persons with MS are between the ages of 30 and 60. According to the data, 65% of the individuals were between the ages of 40 and 60, while around 18% were below 40 and above 60. The average weight of the subjects was 157.4 pounds while the average height was 65.4 inches. The average body mass index of the participants was 25.9. According to the data, approximately 45% of the subjects would be considered overweight ($BMI > 25$). The average time since first symptoms was 16.8 years while the subjects were diagnosed an average of 12 years ago.

Table 1

Basic Descriptive Data for the Sample (N=160)

Variable	min	max	<u>M</u>	<u>SE</u>	<u>SD</u>
Age	21	78	50.1	.88	11.1
Height (in)	59	73	65.4	.20	2.6
Weight (lb)	100	371	157.4	3.1	39.7
BMI	17.2	58.4	25.9		6.26
Time Since First Symptoms (yrs)	1	50	16.8	.82	10.4
Time Since Diagnosis (yrs)	1	49	12.1	.71	9.0

Table 2 summarizes the occurrence of different types of MS within the given sample. The majority of subjects (55.6%) were diagnosed with relapsing-remitting MS while the next most common diagnosis were chronic progressive (15%) and relapsing-progressive (15%). Table 3 shows the rates of employment and marriage among the subjects. Only 37.5% of the women were employed and over half (58.1%) were married.

Table 2

Types of MS Reported by Participants (N=160)

MS Type	n	%N
Benign	7	4.4
Chronic Progressive	24	15
Progressive	10	6.3
Primary Progressive	1	.6
Relapsing Progressive	25	15.6
Relapsing Remitting	89	55.6
Secondary Progressive	4	2.5

Table 3

Employment and Marriage Rates (N=160)

Group	n	%N
Employed	60	37.5
Unemployed	100	62.5
Married	93	58.1
Unmarried	67	41.9

Mobility levels were broken down in Table 4. The majority of women were able to walk, however most had to use some sort of assisting device. Only around 2% of the women used a wheelchair for all ambulation. The ten most common medications used by the subjects are summarized in Table 5. Thirty percent of the women were taking Avonex at the time of the study. Avonex is a popular MS drug to treat overall MS symptoms. Thirty percent of the women were also taking some sort of antidepressant with Prozac being the most common.

Table 4

Mobility Levels Among Participants

Mobility Level	<u>n</u>	%N
6	56	35
5	40	25
4	41	25.6
3	11	6.9
2	9	5.6
1	3	1.9

Note. Mobility levels are based on the following scale:

6-No restrictions on activities of normal employment or domestic life

5-Able to walk on level surfaces w/no aids for short distances

4-Able to walk but must use aids (walls, furniture, cane, walker, etc)

3-Can walk a few steps but usually uses a wheelchair

2-Cannot walk, uses a wheelchair, but has the ability to transfer

1-Uses a wheelchair exclusively and cannot transfer

Table 5

Types of Medication Taken by Participants

Medication N	Treatment	
Avonex	Interferon – Overall treatment	48
Betaseron	Interferon – Overall treatment	7
Baclofen	Urinary symptoms	23
Amantadine	Fatigue symptoms	7
Copaxone	Imitation myelin	23
Premarin	Hormone replacement	7
Prozac	Antidepressant	25
Paxil	Antidepressant	9
Zoloft	Antidepressant	9
Wellbutron	Antidepressant	5

Pearson Correlation coefficients were calculated to determine the relationship between the individual scale scores and total scores of the MSQOL-54, and the

three physical activity scores. All significant values are summarized in Table 6. The explained variance as represented by r^2 is also reported. Significance is reported for $p < .05$. The highest correlation occurred between total activity and the physical health scale $r = .446$. This may also be stated that total activity scores can account for 19.9 % of the variance in the physical health scale. This relationship was also significant for light activity ($r = .235$) and moderate activity ($r = .281$) with physical health. Total activity was also correlated with social function ($r = .326$) and the physical composite score ($r = .330$). This relationship accounted for 10.6% of the variance in social function scores and 10.9% in the physical composite scores. Total activity was related to mobility ($r = .354$). This would indicate that the lower the mobility rating, the lower the total activity score. Total activity was also related to several other MSQOL-54 scores as shown in table 6. Both light activity and moderate activity scores are also significantly correlated with many MSQOL-54 scores. The magnitude of each significant relationship is reported in Table 6. Vigorous activity was not significantly related to any of the quality of life subscales, and is therefore not included in Table 6. It is also important to note that although all 12 subscales and 4 additional scores in the MSQOL-54 were analyzed, only the 8 scales/scores showing significance were reported.

Table 6

Correlations Between Physical Activity Levels and MSQOL-54 Scale Scores
(N=160)

Activity Level	Light		Moderate		Total	
	r	r ²	r	r ²	r	r ²
Physical Health	.235	.055	.281	.079	.446	.199
Role-Physical	.158	.025			.207	.043
Health Perception			.250	.063	.197	.039
Social Function	.198	.039	.183	.033	.326	.106
Satisfaction w/ sexual function					.163	.027
Physical Composite			.225	.051	.330	.109
Overall Quality of Life			.182	.033	.158	.025
Mobility	.207	.043	.183	.033	.354	.125

Note: All values are significant at $p < .05$

Discussion

This study showed that levels of daily physical activity are related to several dimensions of health-related quality of life in women with multiple sclerosis. Specifically, total physical activity levels were significantly related to the physical health, role-physical, health perception, social function, satisfaction with sexual function, physical composite, and overall quality of life scale scores on the MSQOL-54 instrument. Light activity scores were related to physical health, role-physical, and social function scores. Moderate activity scores were related to physical health, health perception, social function, physical composite, and overall quality of life scores. Vigorous physical activity was not significantly related to the quality of life variables. This is most likely due to the fact that only 16 women reported participating in a vigorous activity. All three physical activity scores were significantly related to mobility as well. Total physical activity had the strongest correlation with mobility ($r = .354$) meaning the lower the mobility score, the physical activity score. It may also be said that mobility accounted for 12.5% of the variance in total physical activity scores.

Although the highest correlation was only .446 (total activity and physical health ratings), this should still be considered practically significant. This would mean 19.9% of the variance in ratings of physical health can be explained by total physical activity levels. Almost 20% explained variance is quite significant when we consider the sample size, the vast variability in MS, and the many confounding

variables that may play a role in the lives of persons with MS. The sample size of 160 for this study is large when compared to some other similar studies dealing of women with MS. Total activity also accounted for 10.6% of the variance in social function scores, and 10.9% of the variance in physical composite scores. These are very significant figures when we consider the role physical health and social function play in overall quality of life. Previous studies that have not found significance have utilized much smaller sample sizes (Hudson, 1993). These relationships may be much stronger in a larger population of women, thus these current findings must be considered significant.

The results of this study may have been affected by confounding variables such as depression. Over 30% of the women in this study were taking antidepressants. Still, there may have been many more women in the study who have depression and were not taking medication. Obviously, depression will have a negative affect on quality of life ratings and physical activity levels. If a woman is depressed, she may be exercising on a regular basis, but due to depressed feelings, her quality of life ratings would still be low. This would obviously create problems with this type of research. Depression rates are high in the MS population (up to 54%) so it is difficult to determine the extent to which depression plays a role in activity levels and/or health-related quality of life. It would be beneficial to examine this relationship in healthy populations (without MS) and depressed populations (without MS) and determine what role depression may really play in this dynamic.

It is also important to note that almost half of the women in this study were overweight. Using BMI measurements, nearly one quarter could be considered obese by current standards (World Health Organization 1998). Obesity may play a large role in the fact that 18% of the women in this study reported absolutely no physical activity at all. Only 10% of the women reported participating in what could be considered vigorous physical activity. There was not a significant relationship between body mass index and physical activity levels. These results point to the need of encouraging any type of physical activity for the MS population, if not for quality of life, but for basic health benefits.

It should also be noted that many of the women who participated in this study were likely to be highly motivated and proactive individuals. This is due to the fact that the majority of women participated in self-help groups and several MS group activities. This type of sample may not be representative of all women with MS.

If we can establish that a relationship does exist between levels of physical activity and health-related quality of life, we can better prescribe and plan exercise programs for women with MS. Specific recommendations may be made for individuals that target quality of life improvements. It has already been shown that individuals with MS can and do obtain the same benefits from exercise as healthy populations (Tantucci et al, 1996). Petajan, et al. (1996) also found increases in VO_2 max, strength increases, lower body fat and cholesterol levels following training in individuals with MS. If a relationship does exist, it may then be possible to improve dimensions of quality of life through exercise.

It is extremely important to remember individuality when discussing exercise programs for individuals with MS. Petajan and White (1999) stressed the importance of individual consideration when recommending exercise to persons with MS. One mode of exercise will not be successful for every individual. As far as quality of life is concerned, programs may include not only aerobic components, but stress reduction/relaxation, flexibility, and strength training. An exercise or activity program developed for an individual specific needs and desires will probably be more successful and easier for the individual to adhere to.

This research has demonstrated that a relationship does exist between levels of daily physical activity and several dimensions of health-related quality of life in women with multiple sclerosis. However, it would also be interesting to further explore the direction of this relationship. We should examine the extent to which health-related quality of life influences exercise behavior. Perhaps we may increase exercise and activity levels in individuals with MS by specifically targeting health-related quality of life improvements. Future research should focus on the extent of these relationships and if it is possible to improve the quality of life perceptions through physical activity. Specifically, it would be helpful examine the effects of different training programs on these health-related quality of life dimensions. Exercise interventions could include aerobic components, strength training, flexibility, and yoga/relaxation techniques. We may also study specific types of MS to determine if differences exist between forms of the disease. Future research should also control for variables such as depression. All of this

information could be very helpful in furthering our understanding of the role of physical activity in the lives of individuals with multiple sclerosis.

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APPENDICES

APPENDIX A
NEWSPAPER ADVERTISEMENT

Women with MS can take part in survey research study

Women with multiple sclerosis are invited to participate in a study examining their physical activity levels and health related quality of life. Participation in the study will involve only the completion of three questionnaires requiring approximately 45 minutes to an hour. Participants will receive a packet by mail containing information about the study and the surveys. Self-addressed stamped envelopes will also be included for the return of the questionnaires. There is no cost to participants. Andrea Juhl, a graduate student at Oregon State University, is conducting the research. Contact Andrea Juhl for more information at 1-800-539-3786 code (00).

APPENDIX B
PARTICIPATION ENCOURAGEMENT LETTER

April 10, 2000

Dear ,

I would like to begin by thanking you for participating in the study "Physical Activity and Coronary Heart Disease Risk Factors in Women with Multiple Sclerosis." I am writing this letter because a colleague of mine, Andrea Juhl, is currently recruiting subjects for a survey research study. The study will explore the relationship between health-related quality of life and levels of physical activity in women with multiple sclerosis. Because quality of life is of utmost importance to individuals with MS, it is important to discover how exercise may influence different aspects of quality of life. It is hoped that the information gathered from the study will contribute to the design of exercise programs that may influence quality of life in women with MS.

Your participation in the study will involve the completion of three questionnaires. A packet will be sent to you through the mail. The packet will contain a personal letter, an informed consent, three questionnaires and a self-addressed stamped envelope. The surveys are completely confidential and will be coded with a number. Your name will not appear on any of the questionnaires. You will be asked to sign an informed consent, which ensures that your rights are protected. You will be asked to complete the questionnaires and informed consent and return them with the enclosed envelope. There is no cost to participants. Completion of the surveys should take approximately 45 minutes. The information from these surveys will help determine the extent to which levels of physical activity may influence quality of life in women with MS. Andrea will send you a description of the results of the study when it is completed.

I encourage you to participate in this study. If you are interested in participating, or would like further information, please contact

Andrea Juhl (graduate investigator)
(541)738-2599 or 1-800-539-3786 code (00)
juhla@ucs.orst.edu

Sincerely,

Jenny Slawta

APPENDIX C
INSTITUTIONAL REVIEW BOARD APPROVAL

RESEARCH OFFICE

March 30, 2000

Principal Investigator:

The following project has been approved for exemption under the guidelines of Oregon State University's Committee for the Protection of Human Subjects and the U.S. Department of Health and Human Services.



OREGON
STATE
UNIVERSITY

Kerr Administration Building
Corvallis, Oregon
97331-2140

Principal Investigator(s): Jeffrey A. McCubbin

Student's Name (if any): Andrea Juhl

Department: Exercise and Sport Science

Source of Funding:

Project Title: The Relationship between Level of Physical Activity and Health Related Quality of Life in Women with Multiple Sclerosis

Comments:

This approval is valid for one year from the date of this letter. A copy of this information will be provided to the Committee for the Protection of Human Subjects. If questions arise, you may be contacted further.

Sincerely,

Laura K. Lincoln
IRB Coordinator

cc: CPHS Chair

Telephone
541-737-8008
Fax
541-737-3093
INTERNET

APPENDIX D
INSTITUTIONAL REVIEW BOARD APPLICATION

The Relationship between Level of Physical Activity and Health Related Quality of Life in Women with Multiple Sclerosis

Application for Approval of the OSU Institutional Review Board (IRB) For the protection of Human Subjects

1. Significance of the Project

Multiple Sclerosis (MS) is a debilitating, degenerative, and chronic disease that affects over 350,000 individuals in the United States. Seventy-three percent of individuals with MS are women and 71% can no longer participate in the workforce. There is an infinite number of combinations of symptom that may be experienced by those with MS. The destructive symptoms often lead to the reduction or lack of participation in leisure and physical activity. Individuals with MS have also shown lower scores on several quality of life domains compared to healthy populations.

Although individuals with MS were previously told not to exercise at all in fear of exacerbation, it is now known that exercise can provide important benefits to the MS population. However, a relationship between the level of daily physical activity and health related quality of life has not been firmly established for this population. If there is a better understanding of the role of exercise in the lives of persons with MS, professionals may be able to better prescribe and suggest exercise for this population. Physical activity may then be used as a means of changing health related quality of life.

The primary aim of the proposed study is to determine if a relationship exists between level of physical activity and health related quality of life in women with MS.

2. Methods and Procedures

The proposed study is a correlational research project. The design used for this study is a one-group post-test only survey design. The survey method will be questionnaires. Participants will first receive a personalized letter and informed consent. Once the informed consent is returned, the participants will be sent a survey packet. Each participant will be mailed the questionnaires and asked to respond only once. Each survey packet will include a cover letter, complete instructions for the questionnaires, a basic demographic questionnaire, a physical activity survey, and a quality of life survey. The questionnaires will require approximately 45 minutes to complete. A stamped return envelope will also be provided for the participants.

The demographic data will be used to describe the sample. The data collected from the physical activity and quality of life questionnaires will be used to determine a relationship between activity levels and health related quality of life in women with MS.

Physical Activity Assessment

A modified version of the Yale Physical Activity Survey (YPAS) will be used to assess physical activity levels of the participants. (see appendix for copy) This survey will account for vigorous, moderate, and leisure/light activity levels. The participants will describe the type activities they have done over the past 30 days and the frequency and duration of the activities. This modified form of the YPAS will be used because the original survey does not account for moderate activity or leisure activity other than walking. This could misclassify many women with MS. The modified version will give a more accurate account of activity levels for this population.

Quality of Life Assessment

Health related quality of life will be assessed using the Multiple Sclerosis Quality of Life (MSQOL)-54 Instrument. (see appendix for copy) The MSQOL-54 is a scale which combines the RAND-36 item Health Survey and 18 additional items particular to the MS population. The SF-36 serves as the generic basis for the important domains of HRQOL. The overall scale has been shown to comprehensively assess HRQOL for individuals with MS. This scale is a valid and reliable tool for measuring HRQOL in persons with MS.

Demographic Survey

Basic demographic information will be gathered in order to describe the sample. Information will include age, height, weight, time since diagnosis, time since first symptoms, and most recent EDSS score. Participants will be asked to list their current medications and ambulation status (walks without assistance, walks with assistance, uses a wheelchair). (see appendix for copy)

Data Analysis

Canonical correlation analysis will be performed to determine the relationship between levels of physical activity and health related quality of life. Levels of physical activity can be correlated with all domains from the quality of life questionnaire. An overall relationship may be determined as well as possible relationships between individual domains of health-related quality of life and levels of physical activity.

3. Benefits and Risks.

Benefits

Subjects participating in the study will gain an increased awareness of their own activity levels. They may use this information to evaluate their own desires for physical activity. The subjects will also be increasing the knowledge base for the overall MS population.

Risks

There are no foreseeable risks or discomforts associated with participation in this study. There is no physical participation required other than reading and completing the questionnaires.

4. Subject Population.

Approximately 150 volunteers for the proposed study will be recruited from Oregon MS chapters and newspaper advertisements. (see appendix for ad) Women interested in participating in the proposed study will be given Andrea Juhl's phone number for further information regarding the study. Because MS affects almost three times as many women than men, subjects recruited for the proposed study will be exclusively women with clinically definite MS. There are no age or ethnic restrictions for participation in the proposed study.

5. Informed Consent Document.

A copy of the informed consent for the proposed study is attached.

6. Method by which subject confidentiality will be maintained.

Participant will be sent an initial letter asking them to read and sign an enclosed informed consent for the proposed study. Participants will be informed of their rights concerning the study. The investigator will answer any questions regarding the proposed study, procedures, or any other concerns.

7. Method by which subject confidentiality will be maintained.

Subject information will only be available to the researcher of the proposed study. Subject's identity will remain anonymous in the study by the use of identification numbers instead of names. The only place where names will be recorded is on informed consents, which will be kept by the principal investigator. The database of names and addresses will only be accessible to the investigator.

8. Questionnaires, surveys, and testing instruments.

The modified Yale Physical Activity Survey, the Multiple Sclerosis Quality of Life-54 Instrument, the demographic survey, and the possible newspaper advertisement are attached.

APPENDIX E
INFORMED CONSENT FORM

OREGON STATE UNIVERSITY

Informed Consent Form

A. Title of the Research Project

The Relationship between Level of Physical Activity and Health Related Quality of Life in Women with Multiple Sclerosis.

B. Investigators

Jeff McCubbin, Ph.D. (principal investigator), Andrea Juhl (investigator)

C. Purpose of the Research Project

It is now known that exercise can provide important benefits for persons with MS. It has also been reported that individuals with MS tend to demonstrate lower quality of life scores than healthy populations. However, a relationship between the level of physical activity performed and health related quality of life has not been firmly established.

We hope to determine the relationship between levels of physical activity and health related quality of life in women with multiple sclerosis. We hope that this information may better enable professionals to prescribe or suggest exercise for individuals with MS.

D. Procedures

Participation in this study will involve completing two questionnaires and supplying basic demographic information. The responses on the questionnaires will be used to determine the relationship between physical activity levels and health related quality of life. Participation should take approximately 45 minutes. A stamped return envelope will be included so there is no cost to the participant.

E. Risks and Discomforts

There are no foreseeable risks or discomforts associated with participation in this study. The only responsibility of the subjects is to fully complete and return the questionnaires. There is no physical participation required.

F. Benefits

Subjects participating in the study will gain an increased awareness of their physical activity levels. Further benefits include increased knowledge for the MS population.

G. Confidentiality

Subject information will only be available to the researcher of the proposed study. Subjects' identity will remain anonymous in the study by the use of identification

numbers instead of names in data entry and analysis. Confidentiality will be respected regarding the data received in the proposed study.

H. Voluntary Participation

Your participation in the study is completely voluntary and you may withdraw from the study at any time without prejudice.

I. Questions regarding the study

Questions regarding your participation in the study, questionnaires, or any other concerns will be answered by Jeffrey McCubbin, Ph.D. (principal investigator) (541-737-5921), or Andrea Juhl (investigator) (541-738-2599). Questions regarding your rights as a research subjects will be answered by the IRB Coordinator, OSU Research Office: 541-737-8008.

J. Understanding and Consent

Your signature below indicates that you have read and understand the foregoing and agree to participate in this study. You will receive a copy of this consent form.

Signature of Subject

Date Signed

Signature of Investigator

Date Signed

APPENDIX F
RAND CORPORATION PERMISSION LETTER

RAND

April 17, 2000

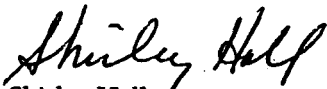
Andrea Juhl, B.S.
3930 Witham Hill Dr. #204
Corvallis, Or 97330

Dear Ms. Juhl:

RAND hereby grants permission to you to use the "RAND 36-Item Health Survey 1.0" in accordance with the following conditions which shall be assumed by all to have been agreed to as a consequence of accepting and using this document:

1. Changes to the Survey may be made without the written permission of RAND. However, all such changes shall be clearly identified as having been made by the recipient.
2. The user of the Survey accepts full responsibility, and agrees to indemnify and hold RAND harmless, for the accuracy of any translations of the Survey into another language and for any errors, omissions, misinterpretations, or consequences thereof.
3. The user of the Survey accepts full responsibility, and agrees to indemnify and hold RAND harmless, for any consequences resulting from the use of the Survey.
4. The user of the RAND 36 - Item Health Survey 1.0 will provide a credit line when printing and distributing this document acknowledging RAND as the copyright holder and stating that it was developed in conjunction with the Medical Outcomes Study.
5. No further written permission is needed for use of this Survey.

Sincerely,



Shirley Hall
Copyright Administrator
Office of Contract and Grant Services

Log#: 2000-070

1700 Main Street, PO Box 2138
Santa Monica, CA 90407-2138
TEL: 310.393.0411
FAX: 310.393.4818

APPENDIX G
MSQOL-54 SCORE SHEET

Table 2
Formula for calculating MSQOL-54 Physical Health Composite Score

MSQOL-54 Scale	Final Scale Score	x	Weight	=	Subtotal
Physical function	_____	x	.17	=	_____(a)
Health perceptions	_____	x	.17	=	_____(b)
Energy/fatigue	_____	x	.12	=	_____(c)
Role limitations - physical	_____	x	.12	=	_____(d)
Pain	_____	x	.11	=	_____(e)
Sexual function	_____	x	.08	=	_____(f)
Social function	_____	x	.12	=	_____(g)
Health distress	_____	x	.11	=	_____(h)
PHYSICAL HEALTH COMPOSITE: Sum subtotals (a) through (h) =					_____

Table 3
Formula for calculating MSQOL-54 Mental Health Composite Score

MSQOL-54 Scale	Final Scale Score	x	Weight	=	Subtotal
Health distress	_____	x	.14	=	_____(a)
Overall quality of life	_____	x	.18	=	_____(b)
Emotional well-being	_____	x	.29	=	_____(c)
Role limitations - emotional	_____	x	.24	=	_____(d)
Cognitive function	_____	x	.15	=	_____(e)
MENTAL HEALTH COMPOSITE: Sum subtotals (a) through (e) =					_____

APPENDIX H
PERSONALIZED LETTER

March 29, 2000

Mrs. X
1234 Street
Corvallis, Or 97330

Dear Mrs. X,

I would like to begin by thanking you for your interest in this research. This study will help further our understanding of the role of physical activity in the lives of individuals with multiple sclerosis.

Enclosed with this letter is an informed consent form. This document will inform you of your rights and responsibilities in this study. Please read the form carefully and sign it where indicated. Once you have signed the informed consent, you may send it back to us using the enclosed stamped envelope.

Within a few days of returning the consent form, you will receive the complete packet of questionnaires, a set of instructions, and a copy of your informed consent. We would greatly appreciate your taking the time to complete the enclosed informed consent and the future questionnaires.

Thank you in advance for your help!

Sincerely,

Andrea Juhl
Investigator

APPENDIX I
COVER LETTER

“The Relationship between Health Related Quality of Life and Level of Physical Activity in Women with Multiple Sclerosis”

Dear Participant,

I would like to begin by thanking you for your participation in this research! The information you provide will help us better understand the role of exercise in the lives of women with multiple sclerosis. I believe this research is very valuable and I am so excited that you are involved!

Enclosed in this packet are three surveys, an informed consent, and an envelope. If you have already returned an informed consent, please disregard the enclosed form. If you did not previously sign an informed consent, please be sure to read the form carefully, sign where indicated and return the form with the surveys. Remember that you only need to sign and return one informed consent and you will receive a copy of your signed form.

The first survey is a basic or general information questionnaire. The information from this survey will be used to provide a description of the population who is participating in the study. Your name will never be associated with any of the information on any of the surveys.

The second survey concerns your level of physical activity. Please read the questions carefully and answer as best you can. There are a total of three questions on this survey. Each question contains multiple parts. If a question does not apply to you, skip to the next question. If you feel extra comments are needed, feel free to write further explanations on the survey.

The third and final survey is the Multiple Sclerosis Quality of Life – 54 Instrument. This survey asks questions concerning your health and daily activities. There are 54 questions, which are broken into different sections. Please read each question carefully and answer as best you can.

I've included an envelope for the return of the surveys. If you have any questions at all, please feel free to call me. I sincerely appreciate you taking the time to complete these questionnaires. Your participation in this study is very important and I look forward to sending you the results!

Thank you so much for your help!

Sincerely,

Andrea Juhl
Student investigator – Oregon State University
1-800-539-3786 code (00)

APPENDIX J
BASIC INFORMATION SURVEY

GENERAL INFORMATION SURVEY

Age: _____ Are you currently employed? Yes No

Height: _____ Are you married? Yes No

Weight: _____

Date of/time of diagnosis:

Time since first symptoms:

Most recent EDSS score (if known):

Current Medications (if any): _____

Which type of MS best describes your condition? _____ Relapsing-
Remitting _____ Relapsing-Progressive _____ Chronic-Progressive _____
Progressive _____ Benign

PLEASE CHECK THE STATEMENT THAT BEST DESCRIBES YOUR LEVEL OF MOBILITY

_____ I have no restriction on activities of normal employment or domestic life, but I am not necessarily symptom free

_____ I am able to walk on level surfaces with no aids for short distances only before I must stop and rest.

_____ I am able to walk alone but must use aids (walls, furniture, cane, crutches, walker, or braces).

_____ I can walk a few steps but usually use a wheelchair.

_____ I use a wheelchair and cannot walk, but I have the ability to transfer.

_____ I use a wheelchair exclusively, and I cannot transfer.

_____ I must be in bed all or most of the time.

APPENDIX K
MULTIPLE SCLEROSIS QUALITY OF LIFE – 54 INSTRUMENT

Multiple Sclerosis Quality of Life (MSQOL)-54 Instrument

INSTRUCTIONS:

This survey asks about your health and daily activities.
Answer every question by circling the appropriate number
(1,2,3,...)

**If you are unsure about how to answer a question,
please give the best answer you can and write a
comment or explanation in the margin.**

Please feel free to ask someone to assist you if you need help reading or marking the form.

1. In general would you say your health is:

	(circle one number)
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. Compared to one year ago, how would you rate your health in general now?

	(circle one number)
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

3–12. The following questions are about activities you might do during a typical day. Does *your health* limit you in these activities? If so, how much?

(Circle 1, 2 or 3 on each line)

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3. <i>Vigorous activities</i> , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
4. <i>Moderate activities</i> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
5. Lifting or carrying groceries	1	2	3
6. Climbing <i>several</i> flights of stairs	1	2	3
7. Climbing <i>one</i> flight of stairs	1	2	3
8. Bending, kneeling or stooping	1	2	3
9. Walking <i>more than a mile</i>	1	2	3
10. Walking <i>several blocks</i>	1	2	3
11. Walking <i>one block</i>	1	2	3
12. Bathing and dressing yourself	1	2	3

13–16. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities as a *result of your physical health*?

(Circle one number on each line)

	YES	NO
13. Cut down on the <i>amount of time</i> you could spend on work or other activities	1	2
14. <i>Accomplished less</i> than you would like	1	2
15. Were limited in the <i>kind</i> of work or other activities	1	2
16. Had <i>difficulty</i> performing the work or other activities	1	2

17–19. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities as a *result of any emotional problems* (such as feeling depressed or anxious)?

(Circle one number on each line)

	YES	NO
17. Cut down on the <i>amount of time</i> you could spend on work or other activities	1	2
18. <i>Accomplished less</i> than you would like	1	2
19. Didn't do work or other activities as <i>carefully</i> as usual	1	2

20. During the *past 4 weeks*, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors or groups?

- (circle one number)
- Not at all 1
 Slightly 2
 Moderately 3
 Quite a bit 4
 Extremely 5

Pain

21. How much *bodily* pain have you had during the *past 4 weeks*?

- (circle one number)
- None 1
 Very mild 2
 Mild 3
 Moderate 4
 Severe 5
 Very severe 6

22. During the *past 4 weeks*, how much did *pain* interfere with your normal work (including both work outside the home and housework)?

- (circle one number)
- Not at all 1
 A little bit 2
 Moderately 3
 Quite a bit 4
 Extremely 5

23–32. These questions are about how you feel and how things have been with you *during the past 4 weeks*. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the *past 4 weeks* ...

(Circle one number on each line)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6
32. Did you feel rested on waking in the morning?	1	2	3	4	5	6

33. During the *past 4 weeks*, how much of the time has your *physical health or emotional problems* interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one number)

Not at all 1
 A little bit 2
 Moderately 3
 Quite a bit 4
 Extremely 5

Health in General

34-37. How TRUE or FALSE is each of the following statements for you.

(Circle one number on each line)

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
34. I seem to get sick a little easier than other people	1	2	3	4	5
35. I am as healthy as anybody I know	1	2	3	4	5
36. I expect my health to get worse	1	2	3	4	5
37. My health is excellent	1	2	3	4	5

Health Distress

How much of the time during the *past 4 weeks* ...

(Circle one number on each line)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
38. Were you discouraged by your health problems?	1	2	3	4	5	6
39. Were you frustrated about your health?	1	2	3	4	5	6
40. Was your health a worry in your life?	1	2	3	4	5	6
41. Did you feel weighed down by your health problems?	1	2	3	4	5	6

Cognitive function

How much of the time during the past 4 weeks ...

(Circle one number on each line)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
42. Have you had difficulty concentrating and thinking?	1	2	3	4	5	6
43. Did you have trouble keeping your attention on an activity for long?	1	2	3	4	5	6
44. Have you had trouble with your memory?	1	2	3	4	5	6
45. Have others, such as family members or friends, noticed that you have trouble with your memory or problems with your concentration?	1	2	3	4	5	6

Sexual function46-49. The next set of questions are about your sexual function and your satisfaction with your sexual function. Please answer as accurately as possible about your function *during the last 4 weeks only*.How much of a problem was each of the following for you *during the past 4 weeks?*

(Circle one number on each line)

Men	Not a problem	A little of a problem	Somewhat of a problem	Very much a problem
46. Lack of sexual interest	1	2	3	4
47. Difficulty getting or keeping an erection	1	2	3	4
48. Difficulty having orgasm	1	2	3	4
49. Ability to satisfy sexual partner	1	2	3	4

(Circle one number on each line)

Women	Not a problem	A little of a problem	Somewhat of a problem	Very much a problem
46. Lack of sexual interest	1	2	3	4
47. Inadequate lubrication	1	2	3	4
48. Difficulty having orgasm	1	2	3	4
49. Ability to satisfy sexual partner	1	2	3	4

50. Overall, how satisfied were you with your sexual function *during the past 4 weeks*?

- (circle one number)
- Very satisfied 1
 - Somewhat satisfied 2
 - Neither satisfied nor dissatisfied 3
 - Somewhat dissatisfied 4
 - Very dissatisfied 5

51. During the *past 4 weeks*, to what extent have problems with your bowel or bladder function interfered with your normal social activities with family, friends, neighbors or groups?

- (circle one number)
- Not at all 1
 - Slightly 2
 - Moderately 3
 - Quite a bit 4
 - Extremely 5

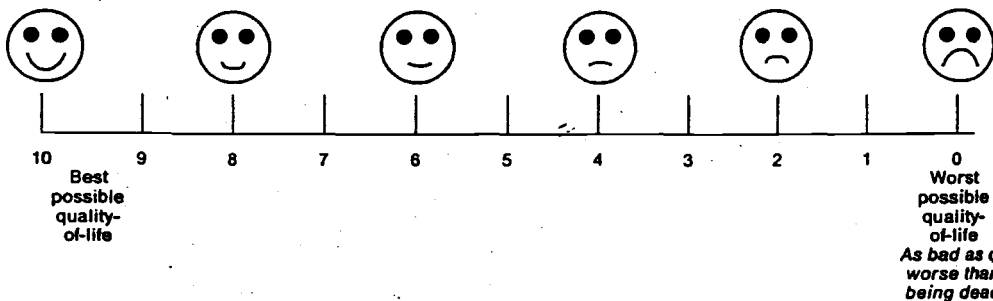
52. During the past 4 weeks, how much did *pain* interfere with your enjoyment of life?

- (circle one number)
- Not at all 1
 - Slightly 2
 - Moderately 3
 - Quite a bit 4
 - Extremely 5

QUALITY OF LIFE

53. Overall, how would you rate your own quality-of-life?

Circle one number on the scale below:



54. Which best describes how you feel about your life as a whole?

- (circle one number)
- Terrible 1
 - Unhappy 2
 - Mostly dissatisfied 3
 - Mixed – about equally satisfied and dissatisfied 4
 - Mostly satisfied 5
 - Pleased 6
 - Delighted 7

APPENDIX L
ADAPTED PHYSICAL ACTIVITY FORM

PHYSICAL ACTIVITY SURVEY

Vigorous Activity: Any activity similar to walking faster than 4.5 miles per hour (fast walking, jogging, swimming laps, exer-cycling somewhat strenuously)

1. According to the definition above, have you done any vigorous physical activity within the last 30 days?

1 NO (*Please skip to question number 2*)

2 YES

→ 1a. Please list, in the space below, all kinds of vigorous activity you have done in the past 30 days.

- 1b. From the list of vigorous activities you provided in 1a, please indicate which activity you have performed most often within the last 30 days.

- 1c. Thinking about your answer to 1b, approximately how many minutes, on average, do you spend doing this activity? (*Circle one number*)

- 1 LESS THAN 10 MINUTES
- 2 10 TO 20 MINUTES
- 3 21 TO 30 MINUTES
- 4 31 TO 45 MINUTES
- 5 46 TO 60 MINUTES
- 6 61 TO 90 MINUTES
- 7 91 TO 120 MINUTES
- 8 GREATER THAN 120 MINUTES

- 1d. On average, how many times per week is this same activity performed? (*Circle one number*)

- 1 1 TO 2 DAYS PER WEEK
- 2 3 TO 4 DAYS PER WEEK
- 3 5 TO 6 DAYS PER WEEK
- 4 7 DAYS PER WEEK

Moderate Activity: Any activity similar to walking briskly, about 3 – 4 miles per hour (brisk walking, water aerobics, easy to moderate exercising, swimming, etc.)

2. According to the definition above, have you done any moderate physical activity within the last 30 days?

1 NO (*Please skip to question number 3*)

2 YES

- 2a. Please list, in the space below, all kinds of moderate activity you have done in the past 30 days.

- 2b. From the list of moderate activities you provided in 2a, please indicate which activity you have performed most often within the last 30 days.

- 2c. Thinking about your answer to 2b, approximately how many minutes, on average, do you spend doing this activity? (*Circle one number*)

- 1 LESS THAN 10 MINUTES
- 2 10 TO 20 MINUTES
- 3 21 TO 30 MINUTES
- 4 31 TO 45 MINUTES
- 5 46 TO 60 MINUTES
- 6 61 TO 90 MINUTES
- 7 91 TO 120 MINUTES
- 8 GREATER THAN 120 MINUTES

- 2d. On average, how many times per week is this same activity performed? (*Circle one number*)

- 1 1 TO 2 DAYS PER WEEK
- 2 3 TO 4 DAYS PER WEEK
- 3 5 TO 6 DAYS PER WEEK
- 4 7 DAYS PER WEEK

Leisure Walking/Light Activity: Any activity similar to walking leisurely, about 2 miles per hour, (leisure walking, yoga, stretching, gardening, etc.)

3. According to the definition above, have you done any leisure physical activity within the last 30 days?

1 NO (*Please disregard the following questions*)

2 YES

→ 3a. Please list, in the space below, all kinds of leisure activity you have done in the past 30 days.

3b. From the list of leisure activities you provided in 3a, please indicate which activity you have performed most often within the last 30 days.

3c. Thinking about your answer to 3b, approximately how many minutes, on average, do you spend doing this activity? (*Circle one number*)

- 1 LESS THAN 10 MINUTES
- 2 10 TO 20 MINUTES
- 3 21 TO 30 MINUTES
- 4 31 TO 45 MINUTES
- 5 46 TO 60 MINUTES
- 6 61 TO 90 MINUTES
- 7 91 TO 120 MINUTES
- 8 GREATER THAN 120 MINUTES

3d. On average, how many times per week is this same activity performed? (*Circle one number*)

- 1 1 TO 2 DAYS PER WEEK
- 2 3 TO 4 DAYS PER WEEK
- 3 5 TO 6 DAYS PER WEEK
- 4 7 DAYS PER WEEK

APPENDIX M
LITERATURE REVIEW

Literature Review

Multiple Sclerosis – Epidemiology

There are an estimated 350,000 individuals diagnosed with multiple sclerosis (MS) in the United States. Approximately 8000 new cases are diagnosed each year (Petejan, 1999). The actual number of persons diagnosed with the disease is unknown and probably much higher than the estimated value. This is due to the fact that MS often goes undiagnosed for years before the symptoms are recognized and properly diagnosed.

Women are over twice as likely to develop MS than men. In fact, seventy-three percent of people with MS are female and 95% are Caucasian. Seventy-one percent of those with MS are no longer in the workforce, and 75% are between the ages of 35 and 64. The typical age of onset is between the ages of 20 and 40 years (Stuifbergen, 1997).

MS is a progressive demyelinating disease that produces lesions in the white matter of the central nervous system (Ponichtera-Mulcare, 1993). The body's immune system mistakenly attack and destroys its own myelin sheath, the protein membrane that insulates axons of neurons in the central nervous system (Rosner, 1992). The destruction of myelin makes it difficult or impossible for action potential to travel the length of the axon. Therefore, signals from the CNS cannot be properly propagated along an axon in which the myelin is destroyed (Rosner, 1992).

The symptoms of MS are often similar in individuals, but each person's experience with the disease is very unique. Primary symptoms include fatigue, dizziness, gait disturbances, weakness, numbness, ataxia, visual disturbances, bowel and bladder problems, pain, changes in sexual function, spasticity, and problems with cognitive functioning. There is practically an infinite combination of symptoms that can result from different patterns of demyelinating lesions (Stuifbergen, 1997). The extreme variability in symptoms makes MS very difficult to manage or provide generalized treatment. MS may be diagnosed as different forms. MS is often referred to as relapsing/remitting, chronic progressive, relapsing progressive, and benign. Approximately 75% of individuals with MS live at least 25 years after their diagnosis. Sixty-six percent of those individuals continue to be ambulatory throughout their lives (Petajan, 1999).

Physical Activity and Multiple Sclerosis

Less than 10 years ago, individuals with MS were told not to exercise and to "take it easy." These instructions were based on the fear of fatigue and resultant muscle weakness and exacerbation of other symptoms (Pitetti, 1993). This is a valid concern considering over 85% of the MS population experiences fatigue as a primary symptom (Petajan & White, 1999). Individuals with MS are often thermosensitive and manifest an increase in symptoms during exercise. This sensitivity to heat often increases the occurrence and severity of fatigue. However, these circumstances can be avoided if precautions are taken (Petajan & White, 1999). In fact, a recent study by White (2000) demonstrated a decrease of MS

symptoms with exercise when exercise is preceded by a period of lower body cooling.

Perceived barriers to activity, including fatigue, mobility, transportation, fear, and overheating are common to persons with MS and often limit the extent to which individuals with MS participate in physical activities. The diagnosis of MS itself is suggested to be responsible for low activity levels in persons with MS (Stuifbergen, 1997). Unfortunately, many problems associated with prolonged inactivity such as muscle weakness and atrophy, decreased flexibility, fatigue, cardiovascular deficits, depression, and trouble sleeping, are often attributed to MS without considering inactivity. Since inactivity in the general population is inversely associated with morbidity and mortality, it may be even more significant with MS populations. One of the most common responses to symptoms of MS is to stop leisure time activity, which often leads to inactivity (Stuifbergen, 1997).

Stuifbergen and Roberts (1997) reported that women with MS scored lower on measures of physical activity than a comparative healthy population. An exercise habit allows a person with MS to be proactive. Improved fitness will decrease morbidity resulting from cardiovascular disease and other ailments associated with immobility (Pejajan & White, 1999).

Gehlsen (1984) demonstrated that persons with MS are capable of improving muscle performance through training. Gehlsen tested the effects of an aquatic exercise program on muscular strength, endurance, work, and power on individuals with MS. Significant increases in power, strength, and work was observed.

Svensson and colleagues (1994) followed five persons with during an endurance training program. Individuals trained for 4 to 6 weeks using an endurance program designed for the lower extremities. The perception of peripheral fatigue changed positively following training. Three individuals improved peak force values as well. Tantucci et al (1996) examined the energy cost of exercise for individuals with MS. Maximal oxygen consumption and maximal workload was slightly lower in the MS group. This was associated with a higher heart rate at the same workloads. However, they found that there is not in increase in metabolic cost of exercise for persons with mild MS, and determined decreased exertional capacity was probably due to lack of training.

Individuals with MS have been shown to have lower aerobic capacities and less muscular strength, power, and endurance relative to sedentary, otherwise healthy controls (Ponichtera-Mulcare, 1993). It has been shown that individuals with mild to moderate MS had normal responses to maximal exercise in both land and aquatic environments, however their aerobic capacities were still lower than sedentary counterparts (Ponichtera-Mulcare, 1993).

Stuifbergen (1997) examined the relationship between physical activity and perceived health status in persons with MS. Using the Human Activity Profile (HAP), the scope of an individual's physical activities was measured. As a group, the people with MS had lower scores on the HAP than the normal population. The average or usual level of activity was much less than the level expected of a healthy population. It was determined that the physical activity scores significantly

correlated with general health and physical functioning subscales. Persons with MS who exercised regularly had significantly higher physical functioning scores than non-exercisers.

Petajan (1996) investigated the impact of aerobic training on fitness and quality of life variables in persons with MS. Following 15 weeks of training, the MS exercise group demonstrated significant increases in VO₂ max, upper and lower extremity strength, and significant decreases in skinfolds, triglycerides, and very low density lipoprotein. They also found a decrease in depression and anger scores for the exercise group. Overall, exercise resulted in improved fitness and improvement of factors related to quality of life (Petajan et al, 1996).

Petajan and White (1999) reviewed the role of exercise for individuals with MS. They concluded that a variety of exercise programs are helpful for persons with MS, but stress the importance of individual consideration when designing a program. Exacerbations of MS were not increased by a 15 week exercise program, but should one occur, exercise should cease. It is important to emphasize physical activity for pleasure purposes in this population. Such activity could include social interaction which is also very beneficial (Petajan & White, 1999).

Health-Related Quality of Life, Physical Activity, and MS

Quality of Life is an issue of profound importance for persons with disabilities and chronic illnesses. It is a multidimensional concept that is commonly referred to as one's satisfaction with life or sense of well-being (Gulick, 1997). The exact definition of quality of life has never been agreed upon. However, Andrews and

Withey (1976) and Campbell (1981) define well-being as “the subjective evaluation of one’s experiences across a number of life domains” (Gulick, 1997 pg 305). These life domains include places, activities, people, things, and roles across a lifetime. The evaluation of these domains depends on individual goals, aspirations, values, and standards. The National Quality of Life Project concluded that these domains are the same for individuals with disabilities (Gulick, 1997).

Among individuals with chronic illness, correlates of quality of life have included marriage, education, work, income, social interaction, health alterations, symptoms, and role functions (Gulick, 1997). However, the examination of quality of life and individuals with MS is fairly new. There is not much literature related to the subject. Even when the concept of quality life is defined, the issue of proper assessment still remains. When dealing with the MS population quality of life has been further broken down to health-related quality of life. Health-related quality of life (HRQOL) includes physical, mental, and social health (Vickrey et al, 1995). It may also be referred to as someone’s health concepts that are relevant to functional status and well-being (Nortvedt et al, 1999).

The most common measures of disability in MS are the Expanded Disability Status Scale (EDSS) and the Minimal Record of Disability. Generic HRQOL measures have been used with the MS population. These generic measures examine multiple domains of functioning and well-being that are applicable to a spectrum of conditions. The most commonly used HRQOL measure is the SF-36 Health Survey from the RAND Corporation.

Health-related quality of life has also been tested in other populations.

Kessenich et al (1998) used a HRQOL scale designed specifically for Osteoporotic populations. They founds HRQOL to be a very valuable tool for developing new therapies for the chronic disease.

Manns & Chad (1999) determined the relationship between quality of life, handicap, fitness, and physical activity for persons with spinal cord injuries. The authors used The Quality of Life Profile: Physical and Sensory Disabilities Version. They did not find a relationship between quality of life and physical activity for the tested population.

Rudick et al (1992) examined quality of life in MS in comparison to inflammatory bowel disease and rheumatoid arthritis. The quality of life scale used was general and not specifically targeted toward health. Results suggested that QOL was best of inflammatory bowel disease and worst for the MS group. It was concluded that QOL scores are a “meaningful addition to impairment scales, such as Kurtzke’s Expanded Disability Status Scale” (Rudick et al 1992). Quality of life assessment is valuable in measuring the impact of chronic disease and effects of interventions (Rudick et al 1992).

Petajan et al (1996), Brunet et al (1996), and Nortvedt et al (1999) all used the SF-36 tool to measure HRQOL in their research. Nortvedt et al (1999) concluded that the SF-36 “captures the broad effects of MS.” The authors also found that bodily pain and low vitality often bother patients. These factors are not reflected in

the EDSS or the SF-36 and should be addressed when working with the MS population.

Brunet et al (1996) concluded the SF-36 gives a broad measure of HRQOL that captures the disease burden better than the EDSS alone. Vickrey et al (1995) created a HRQOL measure that went beyond the generic SF-36 and included dimensions specific to the MS population. The tool is called the Multiple Sclerosis Quality of Life – 54 (MSQOL-54) Instrument. The SF-36 serves as a generic core, while 18 more disease specific items are added to better allow for comparisons with the MS population. The scale includes a pain scale and energy/vitality scale that are not included in the SF-36. It is hoped this tool will provide a clearer picture of the health-related quality of life in individuals with MS.

The Multiple Sclerosis Quality of Life - 54 (MSQOL-54) measure was developed by B. G. Vickrey, R. D. Hays, R. Harooni, L. W. Myers, and G. W. Ellison in 1993. Dr. Vickrey, the principal author, is a neurologist at UCLA. The instrument consists of questions found on the RAND 36 Item Health Survey (SF-36) and 18 supplemented items. The SF-36 is a generic self-report health related quality of life (HRQOL) measure designed in 1992 by R. D. Hays and colleagues. The SF-36 has been the tool commonly used in research with individuals with MS (Brunet et al, 1996).

The MSQOL-54 contains 52 items are distributed into 12 scales, and two single items. The SF-36 serves as a generic core measure. This allows comparisons of HRQOL of the general population and individuals with MS. Eighteen additional

items were supplemented in order to address problems specific to MS. The 12 scales include physical health, role limitations due to physical problems, role limitations due to emotional problems, pain, emotional well being, energy, health perceptions, social function, cognitive function, health distress, sexual function, and overall quality of life. The two single items are change in health and satisfaction with sexual function. Each question asks for information regarding the previous four weeks. The goal of this measure is to combine the strengths of generic and disease-specific approaches in a valid and reliable self-report HRQOL instrument. Health-related quality of life is a multidimensional construct that includes social, mental, and physical health. It is seen as a very important outcome of treatment trials and health policy studies (Vickrey et al, 1995). This measure allows for the comparison of HRQOL in the MS population with other disease populations or the general population. This measure provides an MS specific approach to quality of life. Multiple sclerosis affects each individual differently, but there are many common themes. Themes that are specific to MS and are not generally dealt with in generic quality of life measures. Most measures of disability in MS center on levels of neurological impairment and physical limitations (Nortvedt et al, 1999). It is hoped this instrument will provide valuable insight into the specific aspects of HRQOL in individuals with MS. This insight may help in treatment diagnosis, exercise prescription, and health promotion suggestions. This instrument may be used by researchers, physicians, and other health related caregivers.

It has been suggested that participation in certain low to moderate intensity exercises may have quality of life benefits even if such levels are insufficient to achieve cardiovascular benefits (Stewart et al 1991). Different exercise programs may influence different aspects of quality of life. Given this, it would make sense to design studies that assess both the acute and chronic effects of physical activity to better determine influences on quality of life (Stewart et al. 1991).

It is also suggested that exercise training enhances mood state. Specifically, exercise may lead to reduced anxiety, reduced depression, and increased well-being. Cramer et al (1991) found that exercise did indeed have a positive general effect on psychological well-being.

Sadovnick et al (1996) examined the prevalence of depression in the MS population. A link between depression and MS has been suggested for years. Studies suggest it may be due to a reaction to the stress of the disease and an increase in CNS involvement. However, few studies in MS have differentiated between “depressive symptoms” and “major depressive illness” (Sadovnick et al, 1996). It has been reported in a Canadian study that the suicide rate for MS patients was 7.5 times that of the general population. Sadovnick et al (1996) examined 221 individuals with MS and found a high rate of depression (50.3%) by age 59. Joffe et al (1987) had previously looked at 100 persons with MS and found 42% had a lifetime history of depression. Thirteen percent of the individuals were manic-depressive, and only 28% had no psychiatric diagnosis. It can be concluded that there is a high prevalence of mood disorders in the MS population.