

**FOCUSING-ORIENTED ART THERAPY IN MULTIPLE SCLEROSIS:
A RANDOMIZED CONTROLLED TRIAL TO ENHANCE
QUALITY OF LIFE**

A Grant Proposal
Submitted in Partial Fulfillment
Of the Requirements
For the Degree of
Master of Arts in Marriage and Family Therapy
Notre Dame de Namur University

Submitted by:
Marise Larivière
December 2011

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Signature Page

I certify that I have read this thesis and that, in my opinion, it meets the thesis requirement for the Master of Arts in Marriage and Family Therapy degree

Richard Carolan, Ed.D., ATR-BC, Licensed Psychologist
Professor & Chair
Thesis Director

I certify that I have read this thesis and that, in my opinion, it meets the thesis requirement for the Master of Arts in Marriage and Family Therapy degree

Laury Rappaport, Ph.D., ATR-BC, LMFT
Art Therapy Psychology Faculty
Second Reader

Approved for submission to the College of Arts and Sciences at Notre Dame de Namur University

John Lemmon, Ph.D.
Interim Dean, College of Arts and Sciences

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Table of Contents

Title Page.....	i
Copyrights	ii
Signature Page	iii
Acknowledgements	iv
Table of Contents.....	v, vi, vii
List of Figures.....	viii
List of Tables	ix
Abstract.....	x
Authorization Letter	xi
Sponsoring Letter	xii
Introduction of Sponsoring Agency	xiii
Problem Statement.....	1
Multiple Sclerosis	1
Psychotherapeutic Approaches.....	3
Cognitive Behavioral Therapy.....	3
Group Therapy.....	5
Mindfulness-Based Therapy	6
Mindfulness-Based Art Therapy	9
Focusing-Oriented Art Therapy.....	10
General Objectives	12
Primary Goal	12
Secondary Goal	12
Methodology.....	13
I. Hypothesis.....	13
II. Trial Design	13
III. Study Participants.....	14

i. Sample Size and Participant Assignment	14
ii. Participant Criteria	15
iii Participant Recruitment.....	16
IV. Location.....	17
V. Instruments	17
VI. Procedure.....	18
VII. Data Collection	21
VIII. Risks	26
IX. Potential Benefices.....	26
X. Confidentiality.....	27
XI. Protection of Human Participants	28
Evaluation.....	29
Future Funding	31
Budget.....	32
References	35
Appendices	48
Appendix A. Literature Review	48
Appendix B. Letters of Support.....	74
Appendix C. Consent Forms	75
. Informed Consent to Participate in a Research Study	76
. Permission to Use Art Work.....	81
Appendix D. Evaluation Forms	82
. Multiple Sclerosis Quality of Life Inventory (MSQLI)	83
. Life Event List (LEL).....	84
. Perceived Stress Scale (PSS).....	85
. Beck Depression Inventory II (BDI-II).....	86
Appendix E. Debriefing Form.....	87
Appendix F Clearing A Space Protocol	88

Appendix G. Resume.....	89
Appendix H. Funding Source Identification	90
Appendix I. RFP from Funding Source.....	92
Appendix J. Copy of Proposal Forwarding to Funding Source.....	94

List of Figures

Figure 1 – FOAT & Measurement Protocol	15
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List of Tables

Table 1 – Summary of Budget Request.....	32
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Abstract

Background: Multiple Sclerosis (MS) is a chronic disabling disease in which the immune system attacks the brain and the spinal cord. Stress has been identified as one of the many factors that can precipitate such attacks. Health-related quality of life (HRQoL) is often much reduced among individuals with MS, and incidence of depression, fatigue, and anxiety is high. The purpose of this grant is to request funding for a research trial on MS patients that will examine the effects of a mindfulness-based art therapy approach, Focusing-Oriented Art Therapy (FOAT). FOAT is an experiential therapy in which Focusing provides the inner direction while art therapy offers the outer expression to generate a healing response.

Research hypothesis: The study hypothesizes that FOAT will reduce stress therefore increasing quality of life in patients suffering from MS.

Research Method and Design: This is a 6-month prospective, randomized, controlled trial investigating the efficacy of seven FOAT intervention sessions administered every 2 weeks over 3 months using validated repeated measures of quality of life questionnaires on 30 MS participants (15 treated and 15 control MS participants) recruited from the Yale University Multiple Sclerosis Center.

...Letter asking for organization's authorization to support the research...

...not included to preserve confidentiality...

...Sponsoring letter from the organization confirming the support of the research...

... not included to preserve identity...

Introduction of Sponsoring Agency

... not included to preserve identity...

Problem Statement

Multiple Sclerosis

Multiple Sclerosis (MS) is an incurable, chronic, and disabling disease in which the immune system is believed to attack the central nervous system (Noseworthy, Lucchinetti, Rodriguez, & Weinshenker, 2000). The disease is characterized by the destruction of the myelin sheath, which surrounds the nerves, resulting in the formation of scars or ‘plaques’. These plaques disrupt the transmission of nerve impulses leading to the symptoms of the illness, which include but are not limited to, blurred vision, blindness, loss of balance, poor coordination, slurred speech, tremors, numbness, extreme fatigue, problems with memory and concentration, paralysis, loss of cognitive functioning, and psychological disturbances, which are most frequently characterized by depression (Mohr & Cox, 2001; Noseworthy et al., 2000). These problems may be permanent or transient. MS is not considered a fatal disease, as the vast majority of patients live a normal life span. However, they struggle to live as productively as they desire, often facing increasing personal and social limitations.

Approximately 400,000 Americans have MS and every week about 200 people are diagnosed. MS affects more than 2.5 million people worldwide. Most people are diagnosed between the ages of 20 and 50. MS is more common in females than males (3F:1M). It is among the most disabling diseases in young adults in the United States, with 81% of all patients not contributing to the labor force. The impact of the illness on

people's lives can be profound. Disability in diseases, such as MS, clearly stems from the impact of symptoms and neurologic signs. Approximately 85% of patients initially experience an attack of symptoms (as previously mentioned) followed by recurrent relapses with or without complete recovery. This clinical pattern is known as relapsing-remitting (RR) MS. Within 10-15 years, approximately 50% of patients with RR MS experience gradual progression of disability, and the need to use a cane in periods between relapses (*Lublin & Reingold, 1996*). This clinical pattern is called secondary progressive (SP) MS. The cause of the illness is largely unknown and there is currently no cure. Presently, FDA-approved treatments mostly focus on reducing the number of relapses (attacks) and modestly prevent disability progression.

Individuals who have MS are faced with uncertainties about the future, unpleasant and unpredictable symptoms, injectable treatment regimes and drug side effects. MS can have profound consequences, including disruptions of life goals, employment, income, relationships, social and leisure activities, and activities of daily living. Therefore, it is not surprising that MS poses multiple challenges for psychological adjustments. The neuropsychiatric symptoms of MS are broad and include depression, cognitive deficits, anxiety, obsession and others (*Brassington & Marsh, 1998*). A large body of empirical literature attests to poor adjustment outcomes in MS, including the following: elevated rates of depressive symptomatology or distress (*Hakim et al., 2005*), increased anxiety, and lowered health related quality of life (HRQoL) (*Janssens, van Dorn, de Boer, Meche, Passchier, & Hintzen, 2003*). As a matter of fact, HRQoL among people

with MS is lower than HRQoL among people with other chronic illnesses (*Hermann, Vickery, & Hays, 1996*). HRQoL psychosocial impairment shows great variations among patients with MS and is, to an important degree, independent of extent of disease (*Koch, Uyttenboogaart, Harten, Heerings, & De Keyser, 2008; Ford, Gerry, Johnson, & Tennant, 2001*). Additionally, many FDA-approved disease-modifying drug regimens appear to produce modest or no improvements in HRQoL (*Putzki, Fisher, & Gottwald, 2009; Zivadinov, Zorzon, & Tommasi, 2003; Rudick, Miller, & Hass, 2007*) or even negative changes (*Simone, Ceccarelli, & Tortorella, 2006*). Consequently, complementary treatments that may improve HRQoL such as psychotherapeutic approaches are highly relevant to overall efficacy of MS clinical care.

Psychotherapeutic Approach

Cognitive Behavioral Therapy

Anxiety and depression commonly occur following MS diagnosis and immediately after MS treatment has started. This distress may be a reaction to the unique challenges of MS or may be influenced by underlying vulnerability to anxiety and depressive disorders. The most widely studied psychological treatments in MS have been on Cognitive Behavioral Therapy (CBT) interventions. Controlled trials based on behavioral group interventions, targeted depression, fatigue, or anxiety in patients selected for high symptom severity (*Mohr, Boudewyn, Goodkin, Bostrom, & Epstein, 2001; Crawford & McIvor, 1985; Tesar, Baumhackl, Kopp, & Gunther, 2003*). Other research studies have also shown

benefits of individual treatment of depression, fatigue, or anxiety in patients with MS

(Mohr, Hart, & Vella, 2007; Van Kessel, Moss-Morris, Willoughby, Chalder, Johnson, & Robinson, 2008).

Moreover, coping strategies play an important role in predicting the HRQoL of people with MS. Coping is a central mediator in the process of adjusting to a chronic illness. People with chronic illnesses utilize a number of processes (i.e. cognitive appraisal, coping strategies, coping resources) in adjusting to circumstances. Likewise, focusing on the positive and adopting a positive view of one's illness is likely to impact most aspect of psychological well-being or HRQoL *(McCabe, 2006)*. CBT has been found to be an effective treatment for learning coping mechanisms aiming at reducing stress, therefore improving quality of life. CBT stress-related interventions even demonstrated evidence of an effect on structural changes in the brains of MS patients undergoing treatment. MRI scans of patients undergoing CBT interventions showed a significant reduction of white matter lesions compared to a control group with no intervention *(Mohr, 2011, Under review)*.

Improvement in HRQoL as primary outcomes in broadly representative samples of patients with MS have been neglected, although HRQoL has gained increasing status as a metric of treatment effectiveness *(Zivadinov, Zorzon, & Tommasi, 2003; Rudick, Miller, & Hass, 2007)*. However, studies based on CBT have often used individual therapy, and findings have mainly focused on single dimension such as depression, stress, or anxiety. Additionally, cognitive behavioral treatments indicate reducing stress for patients during the course of treatments but do not demonstrate long lasting effects after six

months. Therefore, it is necessary to provide evidence of benefits related to quality of life, achievable by means of a cost-effective and relatively brief group intervention that will evaluate progress of different variables at the same time assessed via standardized HRQoL testing.

Group Therapy

Many psychotherapy groups have shown positive impacts on the healing experience of chronically ill population such as cancer and MS patients (*Cameron, Booth, Schlatter, Ziginas, & Harman, 2007; Manos, Sebastián, Mateos, & Bueno, 2009; Crawford & McIvor, 1985*). MacKenzie (1997) points out that the primal therapeutic factor in a psychotherapeutic group is self-disclosure. According to Yalom (1980), group self-disclosure is an interpersonal act where consciously disclosing personal significant information to other people starts the process of searching for answers and facilitates faster progress toward solutions. Self-disclosure also helps create cohesiveness in groups. Group cohesiveness is the attractiveness of a group to its members and the attractiveness of group members to each other (*Yalom, 1980*). Group cohesiveness provides a beneficial environment to achieve a successful healing experience. Group interventions have been used to facilitate adjustment to chronically ill patients for about half a century (*Lewis & Bloom, 1978*). Thereafter, many psychosocial group interventions have been studied with chronically ill patients and have shown greater increase in emotional wellbeing and coping efficacy (*Cameron & al., 2007*) as well as improving quality of life (*Manos et al., 2009*).

Additionally, research done specifically with MS population support the benefit of group psychotherapy and show long-term improvements in depressive stress coping style (Tesar et al., 2003). Historically, therapies used for chronically ill population have been a form of cognitive behavioral therapy (CBT) or supportive-expressive group therapy (SEGT) (Leszcz & Goodwin, 1998; Tesar et al., 2003). The underlying theories of the effectiveness of change through group therapy for chronically ill patients involve the mind-body connection. Both, CBT and group psychotherapy focus on the connection between the physical self and the psychological self (Leszcz & Goodwin, 1998). Cameron et al. (2007) demonstrate that affirmation in their cancer study. For several years, successful research studies have been conducted measuring the efficacy of CBT, group therapy, and a combination of CBT and group therapy treatments aiming at reducing stress for women diagnosed with threatening illness such as cancer and multiple sclerosis.

Mindfulness-Based Therapy

Since multiple sclerosis patients often suffer from depression and show improvement in HRQoL following stress reduction, mindfulness-based therapy (MBT), a new approach targeting depression and stress, was studied with that population. MBT interventions based on training in mindfulness skills are becoming increasingly popular. Mindfulness involves intentionally bringing one's attention to the internal and external experiences occurring in the present moment, and is often taught through a variety of meditation exercises. Mindfulness-based therapy has shown beneficial results as a

coping strategy to reduce stress and depression (Foley, Baillie, Huxter, Price, & Sinclair, 2010).

More specifically, mindfulness based cognitive therapy (MBCT) is a psychological therapy which blends cognitive therapy features to mindfulness techniques. Teasdale, Segal, and Williams (1995) proposed that the skills of attentional control taught in mindfulness meditation could be helpful in preventing relapse of major depressive episodes. It incorporates elements of cognitive therapy that facilitate a detached or decentered view of one's thoughts, including statements such as "thoughts are not facts" and "I am not my thoughts." This decentered approach also is applied to emotions and bodily sensations. MBCT is designed to prevent depressive relapse by teaching formerly depressed individuals to observe their thoughts and feelings nonjudgmentally, and to view them simply as mental events that come and go, rather than as aspects of themselves, or as necessarily accurate reflections of reality. This attitude toward depression related cognitions is believed to prevent the escalation of negative thoughts into ruminative patterns (Teasdale et al., 1995). Foley et al. (2010) conducted an MBCT controlled trial that demonstrated clinically significant improvements in depression, anxiety, and distress and a trend for improved quality of life in the cancer patients' treatment group compared to a wait-list control group. Results indicated that treatment gains were maintained up to three months post therapy. Grossman, Kappos, Gensicke, D'Souza, Mohr, Penner, & Steiner's (2010) randomized trial provides evidence that mindfulness based interventions improve HRQoL and other measures related to quality of life for at least eight months in mild to moderately severe

impaired patients with MS. Success in maintaining long-term psychosocial improvement may help to evaluate whether quality of life meaningfully contributes to disease-related physiologic processes (e.g., immune function) in MS and other diseases involving immunologic dysfunction (*Kern & Ziemssen, 2008*).

However, the most frequently cited method of mindfulness training is the mindfulness-based stress reduction (MBSR) program, formerly known as the stress reduction and relaxation program (*SR-RP; Kabat-Zinn, 1982, 1990*). It has been described as “paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally” (*Kabat-Zinn, 1994, p. 4*). This involves accepting thoughts and feelings without judgment rather than trying to push them out of consciousness, with a goal of correcting cognitive distortions. The therapy enhances awareness so clients are able to respond to things instead of reacting to them. It was developed in a behavioral medicine setting for populations with a wide range of chronic pain and stress-related disorders. Clinical trials have supported the use of Kabat-Zinn’s mindfulness-based stress reduction (MBSR) (*Kabat-Zinn, Massion, Kristeller, & Peterson, 1990*) in cancer patients (*Carlson & Garland, 2005; Carlson, Speca, Patel, & Goodey, 2003, 2004; Shapiro, Bootzin, Figueredo, Lopez, & Schwartz, 2003; Speca, Carlson, & Goodey, 2000*).

In addition to evidence of improved HRQoL and well-being, these findings demonstrate broad feasibility and acceptance, as well as satisfaction and adherence, in a program of mindfulness training for chronically ill patients. Notably, although many patients traveled substantial distances to attend sessions in Grossman’s study (2010), and mobility problems frequently made travel difficult, only four of 76 patients dropped out

of the MBI course and did not complete post-intervention inventories (5%). Therefore, there is an apparent need to develop innovative group formats that could potentially accommodate a broad range of patients and provide alternative modes of information processing.

Mindfulness-Based Art Therapy

Mindfulness Based Art Therapy (MBAT) was developed and intended to provide opportunities for both verbal and non-verbal expression, enhanced support, and expanded coping strategies therefore providing a substitute way of expression and information processing. MBAT incorporates Mindfulness Based Stress Reduction (MBSR) and Art Therapy. Although MBAT has never been tested with MS patients, the Mindfulness-Based Stress Reduction intervention has demonstrated a statistically significantly greater decrease in symptoms of distress and better HRQoL among cancer patients (*Monti, Peterson, Kunkel, Hauck, Pequignot, & Rhodes, 2006*). In addition, Focusing developed by Eugene Gendlin (1981; 1996), a mindfulness-based approach that has also demonstrated beneficial results when combined with expressive arts therapy in reducing stress among cancer patients (*Klagsbrun et al., 2006*). In connection to those findings, Dr. Rappaport (2009) has developed a new approach joining Focusing and art therapy together for a greater result than focusing alone. This intervention might have particular potential because it is not aimed at a single disease or specific dimensions of HRQoL, but the whole body-mind process.

Focusing-Oriented Art Therapy

FOAT was developed as a theoretical and methodological approach that synthesizes Gendlin's Focusing method, the principles of Focusing-Oriented Therapy, and Art Therapy theory and practice (Rappaport, 2009). The creative synthesis of integrating Focusing with art therapy is a perfect balance for accessing the inner felt sense while unfolding its wisdom through creative expression (Rappaport, 2008, p.139). Similarly to MBAT, in Focusing the felt sense is accessed by bringing mindful attention along with a welcoming, friendly, and accepting open mind. However, from a Focusing-Oriented point of view, the felt sense is described as an integrated whole of mind, body, and spirit and can identify its own steps toward healing and change (Rappaport, 2009, p.33). Although the application of combining Focusing with art therapy has been explored by Focusing therapists with different clientele and media (Ikemi, Yano, Miyake, & Matsuoka, 2007; Leijssen, 1992; Merkur, 1997; Murayama, 1988; Neagu, 1988; and Tsuchie, 2003), to my knowledge no quantitative research executed in a medical setting has been published from a FOAT perspective. Moreover, there is no published literature on the effects of group treatments and FOAT for MS population. Most importantly, although there are numerous published cases and qualitative studies from the field of psychotherapy and art therapy, including the widely reported and beneficial use of art therapy with cancer populations in both individuals and group formats (Berardi 1997; Malchiodi, 1999; Luzzatto, & Gabriel, 2000; Borgmann, 2002; Klagsbrun, Rappaport, & Speiser, 2005; Collie, Bottorff, & Long, 2006), few controlled studies exist.

Patients with MS need support in addition to medication because they must endure an unpredictability of disease impairment throughout their lives, in terms of exacerbations or worsening of symptoms, and of emotional, social, professional, recreational, and physical costs of the disease. A high rate of attendance during the course of Grossman et al's (2010) research using Mindfulness-Based approach may suggest a desire among MS patients for complementary treatment that enhances their ability to cope with consequences of MS and medical management.

The field of art therapy needs increased research to advance the understanding of how visual art functions in the treatment and well-being of people. Appropriate trial design using psychotherapy such as FOAT in group settings is necessary to provide scientific validation. This pilot randomized-controlled study will enhance interest in the field and prepare the basic foundation for larger studies. Moreover, this study will develop a new approach aiming at helping MS patient, a population in high need for alternative psychotherapy, specifically related to their HRQoL. Therefore, this study hypothesizes that Focusing-Oriented Art Therapy in a group setting will reduce stress therefore impacting quality of life in patients suffering from MS. This study further hypothesizes that improvement would be sustained at a six-month from baseline assessment.

Objectives

The present study is designed to assess the effectiveness of Focusing-Oriented Art Therapy (FOAT) for MS patients. The researcher hypothesizes that FOAT (*Rappaport, 2009*), a mindfulness-based approach, will significantly improve overall quality of life as measured by score on the Multiple Sclerosis Quality of Life Inventory for individuals with a neurodegenerative disease such as MS. This research represents the first randomized controlled trial of FOAT in MS.

Primary Goal

1. To determine the efficacy of 7 FOAT sessions over 3 months, compared to one FOAT session, in improving overall quality of life measured by validated MS questionnaires in randomized participants diagnosed with MS. It is hypothesized that FOAT treated participants will demonstrate significant improvement in quality of life, while control participants will show either no improvement or decline.

Secondary Goal

1. To explore the sustained efficacy following 7 FOAT sessions, compared to one FOAT session, in improving overall quality of life between month-3 to month-6. It is specifically hypothesized that participants receiving multiple FOAT sessions will maintain their improvement, whereas control participants receiving only one FOAT session will continue to either show further decline or no improvement.

2. To evaluate the efficacy of 7 FOAT sessions over 3 months on stress in improving validated measures of stressful life events (Life Event List) and perceived stress (Perceived Stress Scale) and depressive symptoms (as measured by the Beck Depression Inventory II), compared to control participants receiving one FOAT session.

Methodology

I. Hypothesis

This grant proposes that Focusing Oriented Art Therapy offered in a group setting will increase overall quality of life, as measured by the MSQLI questionnaire, in patients suffering from MS. The study further hypothesizes that improvement would be sustained at a six-month follow-up assessment from baseline.

II. Trial Design

The study is a prospective, randomized, controlled, single-center, two-arm therapeutic clinical pilot trial looking at the effectiveness of Focusing Oriented Art Therapy using quantitative and qualitative assessments of quality of life in participants with multiple sclerosis.

III. Study Participants

i. Sample size and participant assignment

This research protocol calls to enroll approximately 30 randomized patients; 15 of them being in a control group receiving only one art therapy (FOAT) group session. The other group will receive seven 2-hour art therapy (FOAT) group sessions every other week for 3 months (see figure 1 below). Each group session will contain a maximum of 5 participants.

No sample size or formal power calculation was performed to justify the number of participants. The study is intended to gather pilot data only and to look at feasibility of a randomized trial using FOAT. However, a robust treatment effect size between the two arms could still be detected. As such, statistical data analysis will be performed once all time points have been collected.

Participants will be assigned using a 1:1 ratio to either treatment arm randomly via a computer-based algorithm that keeps track of number of enrolled participants and previous assignments.

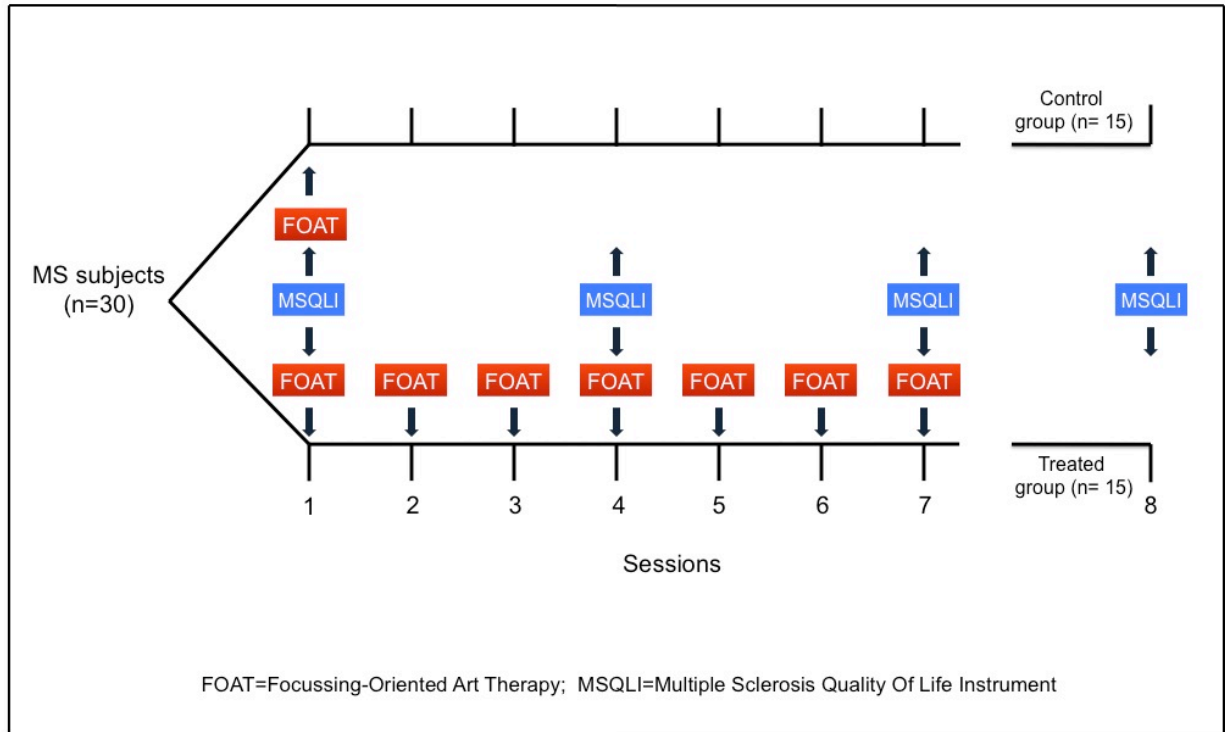


Figure 1

ii. Participant Criteria

Inclusion:

- Any participants carrying a diagnosis of RR or SP MS based on McDonald criteria revised by Polman, Reingold, Edan, Filippi, Hartung, Kappos, & Wolinsky, (2005).
- Entry age greater than or equal to 18 years old.
- Males and females.
- EDSS between 0 and 7.0 (5 yards with a walker).
- Minimal impairment of upper limbs.

Exclusion:

- History of substance abuse.
- Oral or i.v. glucocorticosteroid exposure 4 weeks prior to a baseline session.
- Meet criteria for dementia according to DMSR-IV. Patients with this level of cognitive impairment would be unlikely to benefit from a psychosocial intervention. Furthermore, the validity and reliability of their self-reports would be questionable.
- Participants with suicidal ideation.
- Pregnant or nursing patients.
- Patients participating in other ongoing MS clinical trials involving experimental non-approved drugs.
- History of systemic illness that would limit the likelihood of completing the study.
- Automatic exclusionary conditions will include uncontrolled hypertension, epilepsy, insulin dependent diabetes, known malignancy other than skin cancer, and symptomatic cardiac disease.
- Patient's physician recommends against patient's participation.

iii. Participant Recruitment

Consecutive clinical patients seen at the Yale MS Center who meet criteria defined above will be invited to participate by Dr. Pelletier, Director of the Multiple Sclerosis Center and Professor of Neurology and Radiology at Yale University, and his research coordinators. Informed consent will be obtained from all participants and approved by local Internal Review Board Committee (Appendix C). No financial incentive will be offered to participants throughout the study.

The names and phone numbers of interested participants will be gathered and given to the researcher. Participants will be informed that the art therapist will contact

them within one week. Potential participants will be screened over the phone to assure that they meet the specific criteria for participation in this study. Once the participant clears the initial screening, they will be scheduled for the first session.

IV. Location

All therapeutic sessions will be held in a comfortable conference room located at the Yale MS Center (40 Temple Street, New Haven, CT), where handicapped participants with physical disabilities will have easy access to elevator and enough space for wheelchair. One large table will be set up to provide adequate space for cutting and making collage. Another table will be set up on the side of the room providing a space for spreading images and magazines. One smaller table will be set up offering snacks and beverages. Free parking will be provided.

V. Instruments

Primary Endpoint – change in MSQLI scores

HRQoL will be measured using the Multiple Sclerosis Quality of Life Inventory (MSQLI) (Fisher, 1999) developed by the Consortium of MS Centers (Appendix D). The MSQLI is a validated questionnaire that uses the SF-36 (overall health, vitality, and daily activities) as its core, which permits comparisons across diseases, but supplements the core with established scales to assess MS specific symptoms including fatigue, pain, sexual, bladder, bowel, visual impairment, and social support survey. The SF-36 takes

20 minutes to administer and individual scores ranging from 0 (worst health status) to 100 (best health status). Supplements MSQLI subscales (higher scores indicate better health status) take 10 additional minutes. Reproducibility ranges from .67 to .94 for the SF-36 scales and from .78 to .97 for MSQLI added scales. The MSQLI will be administered at baseline, session 4 (month-1.5), session 7 (month-3), and 3 months after the completion of the last therapeutic session (month-6).

Change in MSQLI scores from baseline to month-3 will be the primary outcome of the study. A sustained treatment effect, measured by change in MSQLI scores from month-3 to month-6, will be analyzed at month-6. All other measures will be secondary.

Secondary Endpoints

- *Life Events List (LEL)*, a checklist of stressful life events (24 items), will be administered at baseline, month-3, and month-6 (Cohen, 1991). (Appendix D)
- *Perceived Stress Scale (PSS)*, a validated 10-item measure of global perception of stress with strong internal consistency ($\alpha=.88$) (Cohen, 1991:1988:1983), will be administered at baseline, month-3, month-6. (Appendix D)
- *Beck Depression Inventory-II (BDI-II)*, to assess dysphoria and depressive symptoms (Beck, 1996), will be administered at baseline, month-3, month-6. The inventory measures the intensity of 21 depressive symptoms (higher scores are reflective of higher levels of depression). (Appendix D)
- Qualitative interview with the principal investigator will take place at baseline and month-6.

VI. Procedure

Dr. Pelletier, Director of the Multiple Sclerosis Center and Professor of Neurology and Radiology at Yale University, and his research coordinators, will recruit participants who meet criteria defined above at the Yale MS Center. Informed consent will be obtained from all participants and approved by local Internal Review Board Committee (Appendix C). No financial incentive will be offered to participants throughout the study. The names and phone numbers of interested participants will be gathered and given to the researcher. Participants will be informed that the art therapist will contact them within one week. Then, once all the volunteers will be recruited (30), the participants will be scheduled for their first session.

The treated participants will be asked to participate in 8 sessions of approximately 2 hours. In addition, participants will be asked to meet individually two times with the investigator prior to the first session and shortly after the last session to complete a qualitative interview. On the first session, treated group participants will be asked to complete the Multiple Sclerosis Quality of Life Inventory, the Life Events List, Beck Depression Inventory-II, and the Perceived Stress Scale questionnaires. In addition, participants will be asked to take part in a FOAT directive designed to further investigation the impact of FOAT on participants' quality of life. On the second and third session, participants will engage in FOAT directive only. On the fourth session, participants will be ask to complete the Multiple Sclerosis Quality of Life Inventory, the Life Events List, Beck Depression Inventory-II, and the Perceived Stress Scale

questionnaires followed by a FOAT directive. On the fifth and sixth session, participants will engage in FOAT directive only. On the seventh session, participants will be asked to complete the Multiple Sclerosis Quality of Life Inventory, the Life Events List, Beck Depression Inventory-II, and the Perceived Stress Scale questionnaires followed by the last FOAT directive. Participants will be asked to meet again 3 month later to complete for the last time the Multiple Sclerosis Quality of Life Inventory, the Life Events List, Beck Depression Inventory-II, and the Perceived Stress Scale questionnaires (see Figure 1 above). A final individual meeting will be schedule for the qualitative interview and provide the participants with a Debriefing Statement (Appendix E).

The control participants will be asked to participate in 4 sessions. Prior to the first session, each participant will be asked to meet individually to participate in a qualitative interview. On the first session, participants will be asked to complete the Multiple Sclerosis Quality of Life Inventory, the Life Events List, the Beck Depression Inventory-II, and the Perceived Stress Scale questionnaires. After completion of the questionnaires, participants will engage in a FOAT directive. On the second, third, and fourth session, participants will be asked to complete the Multiple Sclerosis Quality of Life Inventory, the Life Events List, Beck Depression Inventory-II, and the Perceived Stress Scale questionnaires only. A final individual meeting with the principal investigator will be schedule for the qualitative interview and provide the participants with a Debriefing Statement (Appendix E).

VII. Data Collection

Participants will be asked to read and sign two informed consent forms prior to the first therapeutic session (Appendix C). Informed consent form explaining the purpose, methods, benefits, and risks of the research study; informed consent form for Artwork form for educational and research purposes, with names remaining confidential. Participants will be asked to participate in two qualitative interviews prior to the beginning of the project research and shortly after completion of the research project. Treated participants will be asked to take part in a seven sessions art based research (FOAT). Throughout the project research, treated participants will be ask to complete 4 times the MSQLI, the LEL, the BDI-II and the PSS questionnaires (session 1, 4, 7, and at final meeting).

Each FOAT session will be as follows:

1. A group of five participants will meet in a comfortable room filled with clips of pictures, different magazines, and other art materials.
2. Facilitator will check in with participants.
3. Participants will be guided through a Focusing-Oriented Art directive (*Rappaport, 2009*).
 - a. The first step “Clearing a Space” will start the focusing directive to help the participants gain distance from stressors in the body and access a place inside that is quiet and “all fine” (See protocol in Appendix F).
 - b. Once the participants have accessed the “all fine” place they will be guided to the next step “Choosing a Theme and Felt Sense” which will explore a different theme each week. Those themes have been chosen to serve MS population’s needs.

Themes will be as follows:

- i. Session One – Finding a Safe Place

Become aware of a peaceful place where you feel safe. It may be a place that you know or one that you make up in your imagination. Sense how it feels in your body. Be friendly to what you find. See if there is an image or a word that matches your inner felt sense. If it's not right, let it go and invite a new word or image to come. When you have a sense of it slowly open your eyes. Create an image of the felt sense of your safe place (Rappaport, 2009, p.141).

ii. Session Two – Identifying Pain

Become aware of a place in your body where you feel pain, discomfort, or numbness. Sense the feel of it in your body. Notice the quality of it. See if you can be friendly to whatever comes up. Now imagine sitting down next to it and ask: "What does it need?" See if there is an image or a word that matches your inner felt sense. If it's not right, let it go and invite a new word or image to come. When you have a sense of it slowly open your eyes. Create an artistic expression that matches the felt sense of your pain and what it needs (Rappaport, 2009, p.182).

iii. Session Three – Understand Loss / Gain

Become aware of something or someone you lost as a result of your illness. It can be a physical loss, the loss of a relationship or work related. Sense the feel of it in your body. See if you can be friendly to whatever comes up. Breathe that out. Now I invite you to become aware of something positive in your life. Feel the connection between the loss and the gain in your body. See if there is an image or a word that matches your inner felt sense. If it's not right, let it go and invite a new word or image to come. When you have a sense of

it, slowly open your eyes. Create an artistic expression that represents the felt sense of your loss and gain.

iv. Session Four – Listening to What my Body Needs

Become aware of your body... your legs, your arms, your stomach. Sense each part of your body, one at a time, then as a whole. What is the whole feel of your body? See if you can be friendly to whatever comes up. Now imagine sitting down next to it and ask: “What does it need?” See if there is an image or a word that matches the inner felt sense of your body. If it’s not right, let it go and invite a new word or image to come. When you have a sense of it, slowly open your eyes. Create an artistic expression that represents the felt sense of what your body needs.

v. Session Five – Point Out Support System

Become aware of the people, groups, and/or pets that are meaningful to you. They can be people living or people that passed away. As each person, group, or pet comes, sense him or her in your body, one at a time. What is the whole feel of that person, group, or pet? See if there is an image or a word that matches your inner felt sense. If it’s not right, let it go and invite a new word or image to come. When you have a sense of it slowly open your eyes. Create an image or your felt sense experience (Rappaport, 2009, p.223).

vi. Session Six – Source of Strength

Become aware of something in your life that has been a source of strength. It may be a person, something from nature, a spiritual source, or something else. Describe this source of strength to

yourself. Turn your attention inside to your body and notice how it feels inside as you focus on this source of strength. See if there's an image that matches for the inner felt sense. Check it against your body for a sense of rightness. If it's not right, let it go and invite a new image to come. When you are ready, bring your attention to being in this room and gently open your eyes. Create the image of your source of strength (Rappaport, 2009, p.174).

vii. Session Seven – Vision of the Future / Health and Wellness

Become aware of your health. How it is right now and how you would like it to be. Turn your attention inside as if it were a searchlight. Ask in a friendly way, "So how is my health right now? Just wait... sense your energy level, areas of tension and bodily stress, places of discomfort or pain, places of ease, vitality, whatever is there. See if there is an image or a word that matches your inner felt sense. If it's not right, let it go and invite a new word or image to come. Wait until it feels right. Now breathe that out. Take in a new breathe, new life. Imagine what it would look like and feel like in your body for your health to be as you wish it to be. Visualize and bodily feel yourself with the vitality, energy, state of ease, and whatever else you would like for your health, as if you had it right now. See if there is an image or color for the inner felt sense of your health now. Check inside the body to see whether it matches the felt sense. If it's not right, let it go and invite a new image or color to come from the body's felt sense. When you have it, ask in a friendly way, "So what's between these two felt images... my health now and the way I'd like it to be?" Give time for the answer to form. Ask inside, "What'd needed to get from the first felt image to the second?"

You might want to ask another question: “What’s a good small step in the right direction?” Just listen for an answer. When you’re ready, bring your attention back here to the room and gently open your eyes. Create the two images with what’s needed to get from one to the other, including the step (Rappaport, 2009, p. 225).

4. Participants will create a collage inspired by the Focusing experience. Participants will be asked to look for images that attract them or resonate with them. After, they will be asked to create collage on 5 inches by 8 inches card from chosen images. Collage might be done on a larger format of paper but will be photocopied and reduced on a 5 by 8 inches size allowing the client to easily bring home their pieces of art.
5. Later during the session, participants will be asked to engage in a dialogue with the art. Participants will describe parts or the whole of the image by speaking at loud “I am one who” as they describe the art on the first person. While, participants are free to talk or not, this method expands the client’s creativity and provides access to greater meaning and insight.
6. Participants will be asked to reflect on the artwork and process, and to check inside to see what they would like to carry into the week. The art will be taken home and placed in a strategic location as a visual reminder and affirmation homework.

After completion of the 7th session, participants will be asked to meet individually to complete the MSQLI, the LEL, the BDI-II and the PSS questionnaires and participate in a qualitative interview. In addition, each participant will be given a debriefing statement (appendix E), which specifies the purpose of the research and includes the researcher’s contact information for any follow-up questions or concerns.

VIII. Risks

Art interventions are intended to be enjoyable and participants' comfort and safety are important. While some patients may benefit from FOAT sessions, this may not be the adequate approach for some. Direct physical risks are not typical with psychotherapeutic therapy (directions will be given on how to use scissors). However, potential risks that may occur from participating in this art therapy group include the possibility of emotional reactions that may surface in response to topics discussed in sessions. Art therapy directives are designed to minimize risks and to provide a safe environment for emotional reactions. The researcher will check in with each participant before the end of each session to ensure comfort and emotional safety. Accordingly, participants have the freedom to withdraw from the group and the study at any time. If there is any concern stemming from participation in this study, please contact the MS Center of Yale University at (203) 785-4085.

IX. Potential Benefits

It is not known whether FOAT therapy will provide benefit to participants. However, the treatment offers a group dynamic approach, including a strong therapeutic alliance, focus on distinct goals, stress reduction, here-and-now focus, cognitive reappraisal, self-disclosure, and client collaboration. It encourages pleasant activities scheduling, identifying and reviewing success experiences, mood monitoring, relaxation training, and problem solving. FOAT can provide the opportunities to move beyond

removing negative affect, consequently moving the client towards positive affect, influencing quality of life. Lastly, the use of FOAT could reduce stress and enhance overall well-being including the following: capitalizing on strengths, instilling hope, flow (being absorbed in the moment while engaged in an art directive), mindfulness (being fully present), finding positive outcome, and addressing unsolvable problems.

X. Confidentiality

All questionnaires, tests, and artwork will be collected and stored in a locked cabinet located in the clinical research unit of the Yale MS Center to insure participant confidentiality after each session. The records from this study will be kept confidential. No individuals will be identified in any reports or publications resulting from the study. All artwork, tests, questionnaires, and transcribed material will be coded with a number that matches the corresponding consent and permission to use artwork forms. All forms will be stored separately from all artwork, tests, questionnaires, and transcribed material and will be accessible only to the primary researcher. After the study will be completed and all data transcribed, all forms will be held for three years (7 years if published) and then destroyed.

XI. Protection of Human Participants

Prior to implementation of this research study, approval will be obtained from the Institutional Review Boards at Yale University, New Haven, CT and Notre Dame de Namur University (NDNU), Belmont, CA, regarding all aspects of the proposed study. The research adhered to the general guidelines of the American Psychological Association (APA), the Art Therapy Credentials Board (ATCB), and Notre Dame de Namur University (NDNU) with respect to ethical guidelines for the protection of human subjects in research.

Evaluation

A Data Safety & Monitoring Board (DSMB) Committee will be formed prior to enrollment of any study participants. The DSMB will include the principal investigator, Dr. Pelletier from Yale University, experienced neuro-psychologists and psychotherapists (TBN) to oversee enrollment deadlines, safety issues and adverse events, and overall conduct of the study.

The study calls for 30 MS participants. It is expected that recruitment of all participants will take 6 to 12 months. The DSMB committee will be empowered to stop recruitment after one year of effort. However, alternative solutions such as including additional MS centers in the New England Area will be evaluated and taken into consideration.

Annual progress reports will be generated and submitted to the funding agency. The report will specifically include the number of patients screened, the number of enrolled and randomized participants, number of visits and FOAT sessions administered, number of drop outs (5-10% of drop outs per year is expected), the number and severity of adverse events, the overall recommendation of the DSMB.

Statistical analysis of the MSQLI and all secondary endpoints will be performed under the guidance of a biostatistician using the following assumptions; the use of intent-to-treat (ITT) analyses and statistical methods that can account for repeated measures and missing values.

For the primary endpoint analysis, we estimated the need to enroll 30 participants with 80% power to detect an effect with an alpha error of 0.05 for a treatment effect size of 60% (large effect size) separating MSQLI repeated scores between the two arms, favoring the group of subjects receiving 7 FOAT sessions compared to subjects only receiving one session at baseline. Outcome analyses between the two arms will be compared using ANOVA, a statistical method suited for repeated measures (MSQLI scores from baseline to month-3 and from month-3 to month-6). A *p*-value of less or equal to 0.05 will be interpreted as statistically significant.

Similarly, secondary endpoint analyses will use a mixed-effects repeated measures model with random subject-specific intercepts to detect treatment effects between the two arms on *Life Events Scale*, *Brief Inventory of Perceived Stress*, and *Beck Depression Inventory II* scores. Again, a *p*-value of less or equal to 0.05 will be interpreted as statistically significant.

Future Funding

If Focusing Oriented Group Art Therapy is found helpful for multiple sclerosis patients in reducing stress as well as improving quality of life, it would be of extreme importance to have future funding in continuing this art therapy group format approach. The researcher will seek additional funding by directly collaborating with the U.S. National MS Society dedicated specifically in counseling and emotional support services. Additionally, an MS Art Show might be an option to promote and raise fund to support a continuing art therapy program among the MS population along with family members involved.

Budget

Summary of Budget Request for a One Year Pilot Project	
Budget Category	Year 1
Personnel (see below for specifications)	37,900
Participants Costs	-
Permanent Equipment	-
Supplies (see below for specifications)	775.00\$
Travel	1,325.00\$
Other Expenses	-
Total DIRECT cost:	40,000
Indirect Cost (10%):	4,000
Total Annual Request:	44,000
Total request for one YEAR OF SUPPORT:	\$44,000

Table 1

Justification of budget requests:

PERSONNEL

Principal Investigator, Graduate Student in Art Therapy Program (20% for one year), will be responsible for the overall study design, implementation, conduct of the study, budget appropriation, personnel administration, data collection and data analysis. Salary+fringe: \$15k/y.

Research Coordinator (TBN) (30% effort), is a clinical research coordinator with several years of experience in managing MS research studies. The Coordinator will be the contact person between participants, the PI and the study biostatistician. The

Coordinator will be responsible to enter individual scores in the computerized database and help maintaining research documents and consent forms, collect artworks after each visit. Salary+fringe: \$15k/y.

Biostatistician, PhD, Consultant (TBN), is an experienced statistician with years of experience in clinical trial analysis and modeling of repeated measures. He/she will perform all blinded statistical analyses at the end of the study, work with the research coordinator to maintain database integrity, and provide the algorithm to the research coordinator to generate randomized treatment assignment numbers. Salary+fringe: \$6,500/yr.

Physician at MS Clinic, Consultant (5% effort, no salary support), is the MS specialist and will be responsible for identifying eligible participants, assuring availability of space needed to conduct the study, and data analysis.

Supervisor, ATR-BC and/or MFT (700\$) The supervisor (TBN) will be an experienced psychotherapist who will meet with the principal investigator once a week for 50 minutes. (100\$/hour X 7 sessions)

Supervisor, FOAT certified (700\$) The supervisor (TBN) will be an experienced Focusing Oriented Art Therapist who will meet with the principal investigator once a week for 50 minutes. (100\$/hour X 7 sessions)

SUPPLIES

6 scissors 8" straight handle @ 5.00\$ each for a total cost of	30.00\$
2 pack of 12 Elmer's Glue sticks @ 7.80\$/pack for total cost of	15.60\$
5 pack of 50 poster board (14x22) @ 58\$/pack for a total cost of	290.00\$
5 pack of 75 mat board (5x8) @ 40\$/pack for a total cost of	200.00\$
15 notebooks @ 3.50\$ each for a total of	52.50\$
1 pack of 6 Black Ink pens @ 7.30\$/pack for a total of	7.30\$
6 pack of 8 crayola markers @ 3.65\$/pack for a total of	21.90\$
6 pack of 12 watercolor pencils @ 3\$/pack for a total of	18.00\$
4 pack of magazines images @ 32\$/pack for a total cost of	128.00\$
1 pack of 6 pencils @ 1.70\$/pack for a total of	1.70\$
5 erasers @ 2\$/each for a total of	10.00\$
Grand Total:	775.00\$

OTHER EXPENSES

There will be no cost request for office space rent and no permanent equipment will be purchased.

TRAVEL

Travel costs of \$1,325 are requested. This cost is for travel, lodging, and registration for investigator to travel to one conference per year to present data.

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APPENDIX A

Literature Review

This section describes the clinical manifestations of MS as well as its psychological effects. I will review the empirical literature on the psychotherapeutic treatments of chronic illnesses notably in MS. I will also discuss MS psychosocial interventions in the context of CBT intervention and Group Therapy, discuss the potential role of Stress Reduction Methods such as Mindfulness-Based Therapy and Mindfulness-Based Art Therapy, and finally introduce Focusing Oriented Art Therapy.

Clinical Manifestations of Multiple Sclerosis

Multiple sclerosis is an autoimmune disease that affects the brain and the spinal cord also identified as the Central Nervous System (*Noseworthy, Lucchinetti, Rodriguez, & Weinshenker, 2000*). The disorder is most commonly diagnosed between ages 20 and 50, but can be seen at any age. MS affects approximately 400,000 people in the United States (*Anderson et al., 1992*) and more that 2.5 million people worldwide. MS is more common in females than males. It is among the most disabling diseases, with 81% of all patients out of the workforce [*U.S. Bureau of the Census: 1980 Census of Population, Alphabetical Index of Industries and Occupations. Washington D.C., 1982.*].

MS injury is caused by damage of the myelin sheath, the protective covering that surrounds nerve cells. When this nerve covering is damaged, nerve impulses are

slowed down or stopped. The nerve damage is caused by inflammation. Inflammation occurs when the body's own immune cells attack the nervous system. Repeated episodes of inflammation can occur along any area of the brain, optic nerve, and spinal cord.

Symptoms vary, because the location and severity of each attack can be different. Episodes can last for days, weeks, or months. These episodes alternate with periods of reduced or no symptoms (remissions). Most frequent symptoms of MS includes blurred vision, blindness, loss of balance, poor coordination, slurred speech, tremors, numbness, extreme fatigue, pain, problems with memory and concentration, paralysis and loss of cognitive functioning. Psychological disturbances such as depression and anxiety are also common in this illness. *(Mohr & Cox, 2001; Noseworthy et al., 2000).*

Individuals who have MS are faced with uncertainties about the future, unpleasant and unpredictable symptoms, injectable treatment regimes and drug side effects. MS can have profound consequences, including disruptions of life goals, employment, income, relationships, social and leisure activities, and activities of daily living. Because MS causes impairment in multiple domains of functioning, it is not surprising that MS poses several challenges for psychological adjustment and can have a profound impact on a patient's quality of life. Moreover, HRQoL among people with MS is lower than HRQoL among people with other chronic illnesses *(Hermann, Vickery, & Hays, 1996).*

A large body of empirical literature attests to poor adjustment outcomes in MS which all relates to HRQoL, including the following: elevated rates of depressive

symptomology or distress (*Hakim, Bakheit, Bryant, Roberts, McIntosh-Michaelis, Hart, ... & Mohr, 2005*), increased anxiety, and lowered health related quality of life (HRQoL). HRQoL psychosocial impairment shows great variations among patients with MS and is, to an important degree, independent of extent of disease (*Koch, Uyttenboogaart, Harten, Heerings, De Keyser, 2008; Ford, Gerry, Johnson, Tennant, 2001*). Additionally, many FDA-approved disease-modifying drug regimens appear to produce modest or no improvements in HRQoL (*Putzki, Fisher, Gottwald, 2009; Zivadinov, Zorzon, Tommasi, 2003; Rudick, Miller, Hass, 2007*) or even negative changes (*Simone, Ceccarelli, Tortorella, 2006*). Furthermore, many MS patients believe that stressful life events and emotional distress can make their disease worse, primarily by causing exacerbations. More than two decades of research has supported this belief, finding a relationship between stressful life events, in particular chronic family and work stressors, and subsequent clinical exacerbation (*Mohr et al., 2000*) and progression of disability (*Nortvedt MW, Riise T, Myhr K-M, Nyland HI, 2000*).

Psychosocial factors, which include changes in life such as loss of loved one, interpersonal conflict, mental stress, anxiety and depression, and lack of social support seem to play an important role in the development of MS. Because psychosocial factors are closely related to symptoms of MS, researchers believe that they may have an impact in the development of the disease as well as in the outcome of the disease. As a result, psychological factors can deteriorate or ameliorate the symptoms of MS. Furthermore, new theories are stipulating that psychosocial factors may even be a predictor for the onset of MS (*Liu, Ye, Li, Dai, Chen, & Jin, 2008*). Consequently,

complementary treatments that may help coping with stress and improve factors that affect HRQoL are highly relevant to overall efficacy of MS care. To better understand the intention of this study, some of the most important psychosocial factors previously mentioned will be presented next.

Depression in MS

Depression may be “reactive” and the result of difficult life situations or stresses (*Patten, Beck, Williams, Barbui, & Metz, 2003*). It is easy to understand how a diagnosis of multiple sclerosis, a chronic condition with the potential for progressing to permanent disability, can bring on depression. Depression in MS may also be associated with MS-related changes that occur in the immune and/or neuroendocrine systems. For example, there is some evidence that in persons with MS, changes in mood are accompanied by changes in certain immune cytokine-producing cells. Also, neuroimmunological studies have found that the lymphocytes and cytokines of patients with MS will change under different stresses, and these changes may have a clinical significance (*Streng, 2001*). One study found that the risk of suicide was 7.5 times higher among persons with MS than the general population (*Turner, Williams, Bowen, Kivlahan, & Haselkorn, 2006*). Severe depression can be a life-threatening condition because it may include suicidal feelings. Among the psychological symptoms, depression is of great concern, and it has a high correlation with quality of life and their vocational ability (*Zorzon et al, 2001; Golden et al. 2005*).

Furthermore, treating depression is related to a better quality of life in MS patients

independent of their level of neurological impairment and no particular treatment seem to be superior in improving HRQoL (*Hart, 2004*).

In addition, depression may affect MS indirectly by decreasing adherence to MS disease modifying FDA-approved medications (*Mohr, Goodkin, Likosky, & Gatto, 1997*) and more directly, by aggravating MS-related immune dysregulation (*Foley, Traugott, LaRocca, & Smith, 1992; Mohr, Goodkin, Islar, Hauser, & Genain, 2001*). The prevalence of both anxiety and depressive disorders is often higher among people with chronic medical conditions (*Scott et al., 2007*). This is particularly true of people with MS in which the lifetime prevalence of anxiety disorders is 36% (*Korostil & Feinstein, 2007*). Chwastiak, Ehde, Gibbons, Sullivan, Bowen, & Kraft (2002) reported a significant association between severity of illness and depressive symptoms in persons with MS. Similarly, Pakenham (1999) reported a correlation between social support and depression in MS patients, whereas Gold-Spink, Sher, & Theodos (2000) found that higher support was associated with lower levels of depression. Such results demonstrate that elevated depressive symptoms are not only products of adjustment mechanisms and the stresses and challenges that come with prolonged illness, but also these reflect a psychosocial aspect.

Stress in MS

Stress represents another important psychosocial factor closely associated with MS. A number of studies have adopted different methods to understand the effects of psychological stresses on the progress of MS. Chronic psychosocial stresses, such as

interpersonal conflicts, loss of loved ones, lack of social support, anxiety and depression were identified as risk factors to aggravate the symptoms of patients with MS. In addition, Brown et al. (2005, 2006) studies have shown that psychosocial factors are closely related to MS relapses, among which stress is a key factor. They concluded that the number rather than the severity of individual stressors was the most important risk factor to predict MS relapses, and recommended that MS patients should try to avoid situations that are likely to generate multiple stressors or which provide few avenues for social support. In addition, many kinds of negative emotions correlated negatively with the utilization of social support in the MS group, suggesting that MS patients lacked the ability to use social support when they were under stress and lacked external resources that could reduce stress (*Liu et al. 2009*). As a result, the risk of incidence could increase when an individual is under stress without social support. Another study also speculates that the susceptible population, which lacks social support or has low utilization of social support, suffered intense psychological stress, which resulted in immune responses that might lead to MS (*Strenge, 2001*).

Moreover, a meta-analysis of 14 studies examining the effects of stressful life events on MS patients found a significantly association with increased risk of exacerbation (or attack). These findings are consistent with epidemiological studies showing that stressful life events increase the risk of MS exacerbation (*Mohr, Goodkin, & Bacchetti, 2000*). More objectively, new brain white matter lesions detected with MRI technology were also associated with stressful life events (*Mohr & Pelletier, 2006*). Gilchrist

and Creed (1994) reported that a group of individuals with MS suffering from depression had higher stress than a non-depressed MS group. A high number and intensity of stressful events has been shown to precede the onset of first MS symptoms (Arnett, Higginson, Voss, Randolph, & Grandey, 2002). Additionally, patients experiencing more distressing events are more likely to have an exacerbation of the disease than patients not experiencing such events (Arnett *et al.*, 2002).

Because of the possible impact of psychological stress or stressful events on MS disease onset and exacerbation, understanding factors that mitigate or exacerbate stress in MS, such as coping strategies, appears critical. Patients who cope better with stress may experience less disease activity, whereas those who employ less effective strategies may show more activity. Additionally, better coping in response to stress would seem to result in better quality of life in MS patients.

Quality of Life in MS

In the management of MS, as well as other chronic diseases for which a cure is not possible, the main goal of health care is often the optimization of the patient's health related quality of life. A poorer quality of life may, in turn, further promote emotional and mental problems. Although there is no generally accepted definition of HRQoL, there seems to be a consensus that aspects of physical, functional, social, and psychological health should be included in HRQoL assessments. These elements are all captured in a validated self-estimated scale, the Multiple Sclerosis Quality of Life

Instrument (MSQLI) (Cella, Dineen, & Arnason, 1996). The MSQLI includes a questionnaire on the following domains: sense of physical and social well-being, thinking, fatigue, and pain (Appendix D). Patients consider measures of HRQoL, which are the subjective perception of their overall status as more important than impaired physical function (Rothwell, McDowel, Wong, Dorman, 1997). In agreement, measures of HRQoL are considered more comprehensive in capturing the overall impact of MS (Nortvedt, Riise, Myhr, & Nyland, 1999) than physical disability scales, such as the commonly used Expanded Disability Status Scale (EDSS). More recently, MS scientists were able to demonstrate that a reduced HRQoL may be related to neurodegeneration in MS (Mohr & Pelletier, 2006). Neurodegeneration was detected by high-resolution resonance imaging techniques (MRI) showing evidence of cortical grey matter tissue loss. Another study showed that plaques and tissue loss in specific anatomic brain locations could predict some aspects of HRQoL (Janardhan & Bakshi, 2000). In light of all these results, the U.S. Food and Drug Administration now mandates the incorporation of HRQoL measures into MS drug trials (Miller & Kinkel, 2008).

In recent years, scholars have become more concerned with the psychological symptoms of MS patients related to HRQoL. Researchers have found that 80% of MS patients show symptoms such as depression, sleep disorders, irritability or emotional instability (Figved et al, 2005). Some data showed that depression heavily affects the overall HRQoL in MS patients (Drulovic, Pekmezovic, Matejic, Mesaros, Manigoda, & Dujmovic, 2007; Amato, Ponziani, Rossi, Liedl, Stefanile, & Rossi, 2001). Lobentanz, Asenbaum, Vass, Sauter, Klösch,

& Kollegger (2004) has shown that in addition to the depressive mood, fatigue and reduced sleep quality also have considerable impact on HRQoL in MS patients.

Comparing relapse patients with those in remission, some studies have found that relapse MS patients showed symptoms of anxiety, negativeness, lack of self-confidence and avoidance of social activities (*Papuc & Pawlowska, 2005*). Furthermore, MS researchers observed that illness perception also has an independent effect on HRQoL in people with MS (*Spain, Tubridy, Kilpatrick, Adams, & Holmes, 2007*). Illness perceptions refer to the cognitive representations people have about their illness. The same study also observed that the perception of negative disease consequences was associated with reduced social activity. Establishing an independent role for illness perceptions might suggest new strategies for psychological intervention in MS patients. Consequently, for physical HRQoL (i.e. pain, energy, sleep), the most important and consistent predictors across time were focusing on the positive. The study of McCabe's (2006) showed that focusing on the positive predicted better HRQoL for MS respondents.

These results demonstrate that the use of coping strategies to deal with symptoms of a physical illness, can impact psychological well-being. In fact, adopting a positive view of one's illness, and not escaping the reality of the illness, is likely to impact most aspects of psychological well-being for respondents with MS. These results also highlight the importance of educational programs for people with MS, including training in the development of positive-oriented coping strategies to assist them to better cope with their illness. The development of these strategies may help them adjust to

their illness, and consequently enhance their HRQoL. As a result, Hart et al. (2005) have maintained that psychological intervention could positively help patients cope with the disease.

Psychotherapeutic Approaches

Cognitive Behavioral Therapy (CBT)

Cognitive behavioral therapy (CBT) is a psychotherapeutic approach recognized as a talking therapy. CBT aims to solve problems concerning dysfunctional emotions, behaviors and cognitions through a goal-oriented, systematic procedure in the present. The modern roots of CBT can be traced to the development of behavior therapy in the early 20th century fathered by B.F. Skinner and the development of cognitive therapy in the 1960s supported by Aron Beck and Albert Ellis, who subsequently merged the two and founded what is known today as CBT (Corey, 2009).

There is an extensive and growing literature on the use of a variety of psychotherapies in chronically ill populations aiming at focusing on one's thoughts. Much of the empirical works on psychotherapy in medical populations, such as MS, have used treatments from a cognitive-behavioral orientation (Crawford, & McIvor, 1985; Edelman, & Kidman, 1999; Goodwin, Leszcz, Ennis, Koopmans, Vincent, Guther, Hunter, 2001; Hart, Fonareva, Merluzzi, & Mohr, 2005; Rigby, S. A., Thornton, & Young, 2008; Van Kessel, Moss-Morris, Willoughby, Chalder, Johnson, Robinson, 2008). Many of these treatments include cognitive, behavioral, and problem-solving components aimed at managing specific symptoms of MS and minimizing the effect that symptoms may have on activities and fulfillment of social

roles.

Among those, stress management therapy programs teach patients coping skills that aim to reduce the occurrence of stressful events and perceived stress by changing the MS patients' perception of threat and capacity to manage stress (*Pakenham, 1999; Arnett, Higginson, Voss, Randolph, Grandey, 2002*). Stress management therapy reduces the number of stressful events as well as perceived stress in MS patients (*McCabe, 2006*). The focus is on helping patients to restructure their perception about the nature of MS and the possibility of effective self-management. In particular, the patient is taught to identify and then modify negative or distorted thought patterns of helplessness and hopelessness (*McCabe, 2006*). As stress management therapies improve patients' abilities to prevent or mitigate the effects of stressful life events, the relationship between coping and MS disease activity raises the prospect that stress management therapy could reduce the risk of new MS disease activity involving new plaques or exacerbations (*Mohr, Goodkin, Bacchetti, 2000; Mohr & Pelletier, 2004*). In short, the therapeutic process of cognitive behavioral therapy involves acquiring cognitive awareness as well as cognitive and behavioral coping strategies resulting in reduction of emotional distress (*Edelman & Kidman, 1999*). Behavioral coping strategies may involve goal setting, assertiveness training, expressive communication (*Edelman & Kidman, 1999*) but are lacking important dimensions like relaxation and meditation.

Mindfulness-Based Therapy (MBT)

Mindfulness-Based Therapy similarly to CBT focuses on people thoughts with some differences. Bishop, Lau, Shapiro, & Carlson (2004) whose article proposed an operational definition define mindfulness as:

a process of regulating attention in order to bring a quality of nonelaborative awareness to current experience and a quality of relating to one's experience within an orientation of curiosity, experiential openness, and acceptance. We further see mindfulness as a process of gaining insight into the nature of one's mind and the adoption of a de-centered perspective on thoughts and feelings so that they can be experienced in terms of their subjectivity (versus their necessary validity) and transient nature (versus their permanence). (p. 234)

There has been substantial interest in mindfulness as an approach to reduce cognitive vulnerability to stress and emotional distress in recent years. Mindfulness in contemporary psychology has been adopted as an approach for increasing awareness and responding skillfully to mental processes that contribute to emotional distress and maladaptive behavior. Besides reducing distress, meditative practices employing mindfulness techniques have been proposed to improve quality of life for people facing health challenges.

The two main areas in which Mindfulness-Based Therapy research has been conducted consisted of Mindfulness-Based Stress Reduction (*Kabat-Zinn, 1982, 1990*) interventions and later Mindfulness-Based Cognitive Therapy (*Seagal et al., 2002*). Both

these approaches defined structured training group programs usually spread over an eight-week period with weekly sessions of approximately two hours. Mindfulness-Based Stress Reduction (MBSR) is used widely to reduce psychological morbidity associated with chronic illnesses and to treat emotional and behavioral disorders (*Kabat-Zinn, 1990, 1998*). Similarly to multiple sclerosis patients, anxiety and depression commonly occur following cancer diagnosis and/or during treatment. Mindfulness is often defined as remembering to “pay attention in a certain way: on purpose, in the present moment, and non judgmentally” (*Kabat-Zinn, Massion, Kristeller, & Peterson, 1992, p. 937*). The findings are encouraging, with recent controlled trials showing impressive reductions in psychological morbidity associated with medical illness (*Speca, Carlson, Goodey, & Angen, 2000*). More specifically, clinical trials have supported the use of the Kabat-Zinn’s Mindfulness-Based Stress Reduction (*MBSR; Kabat-Zinn, 1992*) with cancer patients (*Carlson & Garland, 2005; Carlson, et al. 2003, 2004; Shapiro, et al. 2003*).

Slightly different, Mindfulness-Based Cognitive Therapy (*Segal, et al. 2002*) is a recent refinement of mindfulness based stress reduction for major depression that focuses more specifically on the ruminative processes that may maintain recurrent depressive episodes. Rumination is the process of repetitive, passive thinking or brooding about aspects of negative experience without action to relieve the situation. It is possible that such ruminative processes may impact the changes in distress, mood and quality of life resulting from multiple sclerosis diagnosis and treatment. Randomized controlled trials have shown that MBCT can significantly reduce the rate of relapse in

recurrent major depression (*Teasdale et al., 2000*) and is associated with increased experience of momentary positive emotions as well as greater appreciation of, and enhanced responsiveness to, pleasant daily-life activities.

Furthermore, recent studies provide support for the use of mindfulness group program within oncology settings (*Foley, 2010*) and more specifically within MS population (*Grossman, 2010*) showing improvement in depression, anxiety, fatigue, and distress; all element affecting the quality of life. This pattern of results suggests that MBT may not be diagnosis-specific but, instead, may address processes that occur in multiple disorders by changing a range of emotional and evaluative dimensions that underlie general aspects of well-being supposing that MBT may have general applicability.

However, the group itself is an important element in Mindfulness approaches (*Imel et al. 2008*). For example, Kabat-Zinn (1990) describes an all-day experience combining multiple MBSR groups:

We start talking, 120 people in a circle holding an intimate conversation about our experiences, asking questions and sharing how we felt and what we saw and what we learned. The calmness and peacefulness in the room are such that it really feels intimate, even with so many people. It almost feels as if we are sharing one big mind together around the circle and mirroring different aspects of it back and forth to each other. (p. 127)

From this description, and the fact that both MBSR and MBCT are always

taught as a group intervention, it appears that aspects of group process may be important variables to consider.

Group Therapy

From a cost-effectiveness perspective, group therapy allows individuals more limited financially to receive treatment at lower cost without affecting the overall efficacy of the therapeutic outcome (*Siskind, Baingana, & Kim, 2008*). Groups are also more appropriate for those who find the intimacy of individual therapy to be too intense. Moreover, group therapy brings a unique and essential dimension to the healing process in people sharing same issues such as MS symptoms and limitations. Many theorists and practitioners of group psychotherapy agree that self-disclosure is one of the vital conditions ensuring successful and effective psychotherapy in the group (*Braaten, 1991; Friedman, 1989; Vander Kolk, 1985; Corey, 1990; Yalom, 1980*). Jourard (1964) upholds the view that a person gets to know his/her own self when disclosing oneself to another person. Additionally, self-disclosure of group members is closely linked to such important therapeutic factors as group cohesiveness. Group cohesiveness in turn accelerates the work of a group whereas safe and supportive atmosphere encourages group members to go faster and deeper in their healing journey. The established conditions of trust, interpersonal warmth and support invite group members' self-expression and self-disclosure, which are not always possible in everyday life. Liebmann (1986) lists several reasons for using group therapy such as: people with similar needs offer mutual

support, and aid in shared problem-solving; groups can be catalysts for developing latent resources and abilities in the group members. All group situations reasonably generate opportunities for interaction, communication, learning, and other types of personal exchanges. Being in a group offers the opportunity for social interaction and support between people that individual therapy cannot offer (*Imel et al. 2008*). Malchiodi (2003) states, “Most important, they provide social support, an aspect which has been connected to health and well-being” (p. 310).

Many aims of therapy groups, particularly those addressing special needs in medical illnesses such as MS, tie in with Irvin Yalom’s “curative factors” for group therapy. Yalom’s (1980) curative factors are described as instillation of hope, interpersonal learning, universality, interaction, group cohesiveness, and altruism. Being part of a supportive community promotes hope, particularly when group members recount positive experiences of overcoming specific issues (*Malchiodi, 2003*). Members may recognize that other members’ attitude can be helpful and develop optimism for their own progress. The concept of universality supports that group members discover that other members may share comparable feelings, thoughts and problems, especially related to their medical illness. Sharing familiar experiences may extend to aiding to minimize isolation through more concrete form of communication. Interpersonal learning implies that members can also achieve personal insight by communicating intimate information and listening to deep confidential stories about other members of the group. The healing power of the group becomes even more

significant when using art as a way to express feelings and emotions in addition to talking therapy. Making art within this context provides connection between members of the group during the process of art making and most importantly through sharing at the end of the session their personal experience of art making which leads to group cohesiveness. Finally, altruism corresponds to the act of getting involved during the process and giving assistance to each other. The act of helping engenders a sense of concept and empowerment needed to confront adversity when facing illness. In short, group therapy contributes to developing insight as well as new tools and strengths to deal with present and upcoming issues (*Malchiodi, 2003*). Equally important, images created in the group may hold universal significance, but in unique and personal ways, and resonate within each member of the group.

Art Therapy

The process of art expression is considered an important part of art therapy and art therapy research (*Malchiodi, 1999; McNiff, 1998; Lusebrink, 2004, p. 125*). Art can offer emotional well-being and provide answers during the process of art making as well as once the piece is completed because it can be set aside and examined later in further therapeutic sessions (*Liebmann, 1986*). The process of expression through art media experienced in an art therapy session is perceived predominantly through the tactile and visual sensory as well as perceptual channels. Consecutively, the final products are process for their affect, associations, and meaning through cognitive and verbal channels. These

activities involve different motor, somatosensory, visual, emotional, and cognitive aspects of information processing with the activation of the corresponding neurophysiological processes and brain structures. Consequently, art making connects with neurological structures that might be affected by MS condition.

Literature suggests that art therapy interventions benefit predominantly the following general areas also found in MS disease: (a) reconstitution and rehabilitation of physical impairments (*Slayton, D'Archer, & Kaplan, 2010; Menzen, 2001*); (b) promotion of mental, emotional, and physical healing (*Slayton et al., 2010; Malchiodi, 1999*); and (c) enhancement of cognitive and emotional well-being (*Lusebrink, 2004*). On the cognitive end, art therapy experiences and interaction with art media facilitate the elaboration of conceptual and abstract thought and of problem solving (*Lusebrink, 2004*).

Because MS patients are naturally exposed to strain related to diagnosis and treatment, and this influences their experienced HRQoL, art therapy can play an important role in providing coping resources and additional ways of communication. Multiple sclerosis disease often implies demanding experiences that are not always easy to capture in words. Increasingly, art therapy is used to provide non-verbal ways of improving feelings in connection with such experiences of trauma, illness and treatment (*Malchiodi 1999*). Within the field of Medical Art Therapy, art therapy is defined as a mind–body intervention in supporting the “power of the mind to influence the body in ways which encourage and stimulate health and well-being” (*Malchiodi, 1999, p. 17*). Today, in the Western world, art therapy is slowly becoming part of cancer care and

rehabilitation, providing imaginative communication through individual sessions and open/closed groups supporting meaning-making processes (Collie, 2006). Using art allows people to participate in a group setting simultaneously at their own levels since exclusively the process of doing the art has main importance and no judgment is attributed to the final result (Liebmann, 1986). Several studies with different designs, including case studies, have been documented (e.g. Pratt & Wood 1998; Malchiodi 1999; Luzzatto & Gabriel 2000; Borgmann 2002; Luzzatto et al. 2003; Waller & Sibbett 2005). Unfortunately, no art therapy research has been published with multiple sclerosis patients.

Research attempting to demonstrate the benefits of art therapy provides evidence of positive outcomes despite heterogeneity in samples, settings and art therapy designs (Slayton et al., 2010). Additionally, art therapy can offer an opportunity for the person living with a disease to interpret their experiences and give them acceptance and legitimacy. The results of Öster's *et al.* (2007) study suggest that the person, through image-making and reflection on their images, were able to give legitimacy to their own interpretations and experiences. A significant increase (level of .05) in HRQoL, and physical and psychological health was observed following art therapy in a group of women undergoing radiotherapy treatment for breast cancer (Svensk, Öster, Thyme, Magnusson, Sjödin, Eisemann, ...& Lindh, 2009). A significant positive difference within the art therapy group was also seen, concerning future perspectives, body image and systemic therapy side effects (Svensk et al., 2009). Therefore, art therapy can help patients develop new goals, and discover that they want to live life as fully as possible despite the illness diagnosis.

(Serlin et al. 2000).

Art therapy studies have utilized a variety of art media. Besides painting, collage provides a more structured approach for expression and becomes a very useful tool as well.

Collage Therapy

Collage is a popular form of art where clippings of pictures and words are cut out from magazines and pasted onto drawing paper. Collage constitutes an alternative to drawing or painting that helps to explore feelings in a non-threatening way because it does not demand an ability to draw. Knowing that multiple sclerosis patients often suffer from muscle stiffness and decreased fine motor control, collage seems to be an appropriate art therapy modality while avoiding potential frustration.

Collage therapy was first described as a therapeutic technique by Buck and Provancher (1972) in an occupational therapy journal in the USA, and has gained in popularity since the early 1990s when clinicians and investigators in the field of psychology developed the method from current practice with sandplay therapy in Japan *(Moritani, 1996)*. Sifting through and selecting pictures can be invigorating *(Johnson & Sullivan-Marx, 2006)* as well as build rapport *(Stewart, 2004)*. Successfully creating a tangible product may help patients to maintain a sense of dignity lost in other areas of their lives *(Berardi, 1997)*. In addition, collage therapy appears to foster self-insight and self-understanding, and hence promote recovery from mental health problems including depression *(Takata,*

2002). Repeated completion of a work of collage is thought to provide relief of psychological and emotional issues (Tokunaga, 1999). Ikemi, Yano, Myake, & Matsuoka (2007) present a study describing a method on a focusing-oriented approach to collage work where they address the significant meaning of collage created by the client in reference to stress reduction. Studies expand on the use of collage and evaluate its potential as a facilitator of different feelings. Most importantly for this study research, because individuals dealing with a chronic illness experience a feeling of losing control over their body and life, collage in return provides a sense of control in addition to a feeling of empowerment. Collage therapy becomes an attempt to overcome feelings of hopelessness and to rediscover hope, and a desire to gain control over the situation. This may translate into a greater sense of control in the new life situation (Heywood 2003). Furthermore, Lucas et al. (1974) stipulate that collage also helps to self-disclosure, an important factor supporting healing explored in the previous section.

As shown previously, the concept of current models of psychotherapeutic treatments such as Art Therapy, Group Therapy, and Mindfulness Based Therapy has been quite explored and showed positive results in regard to depression and stress reduction. Concurrently, a promising approach was created in relation to those concepts into what is known today as Focusing-Oriented Art Therapy.

Focusing-Oriented Art Therapy (FOAT)

FOAT was developed by Dr. Rappaport (2009) after integrating art therapy with

Gendlin's focusing approach in relation to a variety of clinical populations including clients diagnosed with schizophrenia, bipolar disorder, depression, anxiety, posttraumatic stress disorder and addiction over a period of thirty years.

Similarly to Mindfulness-Based Therapy, Focusing pays attention to the present moment without judgment. It is more of a mind and body approach, such as guided imagery and meditation, in that it generates a relaxation and healing response. Focusing enables people to access personal meanings that are carried in the body but are difficult to access from conscious awareness. Its creator Gendlin (1981) proposed this technique to “unlock the wisdom of the body” through six simple steps-- Clearing a Space, Choosing an Issue and Felt Sense, Handle/Symbol, Resonating, Asking, and Receiving.

In “Clearing A Space”, the therapist guides the client to metaphorically set stressors aside and notice the place inside that is separate from them. Some benefits of that practice include calming, centering as well as stress reducing (*Gendlin, 1996; Klagsbrun et al., 2005*). On its own, “Clearing a Space” is a potent stress reduction technique. It helps create a distance from pressing problems. Adding art to “Clearing a Space” help clients concretize setting their issues aside and accessing an inner place of wellbeing (*Rappaport, 2009*).

In FOAT, Gendlin's (1981) six-step focusing method is integrated with art (see chart) and is incorporated within a psychotherapy session similar to Gendlin's (1996) focusing-oriented therapy approach where steps are suggested in accordance with the client's moment-by-moment experiential process (not necessarily in a particular order).

The use of art in conjunction with “Clearing A Space” brings an additional dimension for concretizing and deepening the connection to the “All Fine Place”, as well as helping the client to gain some distance from the issues or problems the Focuser is carrying. This healthy detachment happens experientially through the art making process, which is one of the powerful healing aspects of art therapy (*Rappaport, 2006, p.6*). Art becomes a source of communication and expression where it can take tangible and concrete forms. Subsequently, the client has additional energy and a stronger sense of self to work on the identified issues independently. The issues become externalized as the focuser creates art. According to Rappaport (2006), “The visual art also serves as a reminder of the felt experience—the “all fine place”—or wholeness within—which helps to reawaken the awareness and connection to the place within that is already whole” (p. 7). As mentioned earlier, “Clearing A Space” and the creation of art can be used as a practice unto itself for stress reduction, emotion regulation, and dis-identification from difficult feelings. It also helps clients to have an experiential knowing that there is a self that is separate from the illness and related issues, and that there is a place of inherent wholeness within. Additionally, Rappaport (2009) states,

Focusing-Oriented Art Therapy offers opportunities for clients to have a positive relationship with the body and discover its resources, rather than experiencing it as merely illness or pain. The Focusing Attitude helps clients to be friendly to their illness instead of feeling aversion to it.” and “steps of Focusing help the clients to be in a relationship with the illness

where physical, emotional, and spiritual needs can be heard, as the body clarifies meaning and unfolds its wisdom. (p. 171)

Because MS patient are losing control over their body and feel disconnected with body parts (Pfaffenberger, Gutweniger, Kopp, Seeber, Stürz, Berger, & Günther, 2011), it seems reasonable to think that FOAT will be a beneficial therapeutic approach with that population by creating balance in the whole person through a body-mind connection.

Additionally, chronic diseases, in particular those accompanied by disabilities such as MS, are generally associated with severe disturbances of body image (*Ben-Tovim & Walker, 1995*). According to Gillies (1984), the concept of body image includes the inner picture one has of one's physical being together with a heavy overlay of feelings about that inner picture. Surprisingly, despite an extensive literature search directed at chronically ill patients, only one study investigating the subject of body image disturbances and therapeutic interventions aimed at improving body image was found. That study showed slight impact on body image (*Tesar, Baumhackl, Kopp, & Gunther, 2005*). However, since FOAT help clients to be in a friendly relationship with the illness inside the body (*Rappaport, 2009, p. 172*), this approach might provide help to develop a positive perception of the body image, which in turn might have a positive impact of the quality of life.

Studies show that the first step of Focusing, "Clearing a Space", promotes well-being through stress reduction, relaxation, and mobilization of the life-forward direction

(Grindler & Flaxman, 2003; Klagsbrun et al. 2005). In a study by Grindler (1999), Focusing-Oriented Therapy was shown to bring about a positive impact on depression in patients recovering from cancer. The six-month follow-up showed that the impact of Focusing was also maintained over time. The authors concluded that since depression increases disability interventions that reduce depression might be able to reduce disability and increase HRQoL. These findings highlight the importance of such approaches as untreated emotional disorders such as depression can result in prolonged suffering, increased risk of suicide, more frequent clinic visits, extended hospitalization time, and reduced compliance with treatment (Bhattacharjee & Deb, 2007).

Early intervention to treat depression can also prevent declines in HRQoL and even death from suicide (Wallin, 2006). Besides, a substantial literature has examined the utility of treatments that promote emotional expression aimed at helping patients to develop a better understanding of their own internal experience (Spiegel, 1990).

Unfortunately, not enough research has been conducted using experiential therapy. Although Focusing-Oriented Art Therapy itself has been utilized clinically and some case reports have been published (Klagsbrun et al., 2006), no controlled clinical research was conducted in MS subjects and its use in controlled clinical research is timely to further support its validity.

Implication for the field

The field of art therapy needs continuing research to advance the understanding of

how visual art functions in the treatment and well-being of people. Appropriate trial design using psychotherapy such as FOAT in group settings is necessary to provide scientific validation. This pilot randomized-controlled study may enhance interest in the field and prepare the basic foundation for larger studies. Moreover, this study will develop a new approach aiming at helping MS patient, a population in high need for alternative psychotherapy, specifically related to their HRQoL. Therefore, this study hypothesizes that Focusing-Oriented Art Therapy in a group setting will reduce stress therefore impacting quality of life in patients suffering from MS. This study further hypothesizes that improvement would be sustained at a six-month from baseline assessment.

APPENDIX B

Letters of Support

... not included to preserve personal information...

APPENDIX C

Consent Forms

Informed Consent to Participate in a Research Study

Notre Dame de Namur University

1500 Ralston Avenue

Belmont, CA 94002

Title of Research: *Using FOAT for Reducing Stress and Improving HRQoL in MS Patients.*

Name of Principal Investigator/Primary Researcher: *Marise Lariviere*

Phone Number of Principal Investigator/Primary Researcher: *(415) 320-2589*

Names and Phone Numbers of Committee Members:

Dr. Laury Rappaport, (650) 508-3674

A. Purpose and Background

The purpose of the research is to study the effects of Focusing Oriented Art Therapy, with Multiple Sclerosis patients. Specifically, the researcher seeks to determine whether or not there will be a reduction in symptoms of stress and improvement in quality of life in Multiple Sclerosis patients from participating in Art Therapy directives. The research will be conducted by Marise Lariviere, a graduate student at Notre Dame de Namur University, under the supervision of Dr. Laury Rappaport, Associate Professor of Art Therapy Psychology and Dr. Richard Carolan, Professor & Chair of the Graduate Art Therapy Psychology Department and at Notre Dame de Namur University.

B. Procedures

In voluntarily consenting to participate in this research study, I understand the following:

1. I will be asked to participate in 8 sessions consisting in FOAT sessions that will last approximately 2 hours.
2. I will be asked to meet individually to participate in a qualitative interview prior to the beginning of the first session and shortly after the last session.
3. I will be asked to complete the Multiple Sclerosis Quality of Life Inventory, Life Event List, Beck Depression Inventory-II, and Perceive Stress Scale questionnaires prior to the beginning of the session at week 1, week 4, week 7 and 3 month after completion of the last session.
4. I will be asked to participate in FOAT directive including short meditation and collage. There is no limit to the number of collage cards I create, other than completing within the time constraints of the session.
5. Artwork may be reproduced for use in a research thesis and for possible presentation and/or publication. Artwork will be returned to me after being digitally photographed by the researcher.
6. The photographic images of the artwork will remain the property of the researcher.

C. Risks

Potential risks that may occur from participating in this group include the possibility of

emotional reactions that may surface in response to topics discussed in sessions. The art therapy directives are designed to minimize risk and to provide a safe environment for emotional reactions. The researcher will check in with each participant before the end of each session to ensure comfort and emotional safety. Participants have the liberty to withdraw from the group at any time. If there are any concerns stemming from participation in this study, please contact the MS Center of Yale University at (203) 785-4085 .

D. Benefits

The possible benefits of participating in this study are many, some of which are listed below:

1. I may experience a reduction in stress and improvement of quality of life.
2. I may find it fun and relaxing to work with art materials.
3. I may experience personal growth and self-knowledge.
4. I may experience a sense of fulfillment by contributing to a scientific body of knowledge.

E. Confidentiality

The records from this study will be kept confidential. No individuals will be identified in any reports or publications resulting from the study. All artwork, tests, questionnaires, and transcribed material will be coded with a number that matches the

corresponding consent and permission to use artwork forms. All forms will be stored separately from all artwork, tests, questionnaires, and transcribed material and will be accessible to the primary researcher only. After the study is completed and all data has been transcribed, all forms will be held for three years (7 years if published) and then destroyed.

F. Alternatives

I am free to decline to participate in this research study.

G. Costs

There will be no costs to me as a result of participating in this research study.

H. Compensation

There will be no compensation for my participation in this research study.

I. Questions

If I have further questions about the study, I can contact Marise Lariviere by calling (415) 320-2589, e-mailing her at mlariviere@student.ndnu.edu, or writing her at the Art Therapy Psychology Department, Notre Dame de Namur University, 1500 Ralston Avenue, Belmont, CA 94002.

PARTICIPATION IN THIS RESEARCH STUDY IS VOLUNTARY. I am free to choose not to participate in this research study, or I may withdraw my participation at any point without penalty.

Print Name _____
Research Participant

Signature _____ Date _____
Research Participant

Signature _____ Date _____
Principal Investigator

Permission To Use Art Work

I hereby give permission to Marise Lariviere, principal investigator, to use my artwork for research purposes. I understand that names will not be attached to the artwork and my identity will not be released.

I understand that some of the artwork produced may be used in professional art therapy publications and presentations but no information that would indicate the artist's identity would be used in conjunction with them.

Print Name _____
Research Participant

Signature _____ Date _____
Research Participant

Signature _____ Date _____
Principal Investigator

APPENDIX D

Evaluation Forms

Multiple Sclerosis Quality of Life Inventory (MSQLI)

Life Event List (LEL)

Perceived Stress Scale (PSS)

Beck Depression Inventory II Questionnaire (BDI-II)

APPENDIX E

Debriefing Statement

Notre Dame de Namur University

1500 Ralston Avenue

Belmont, CA 94002

Thank you for your participation in the study. The primary purpose of this study was to examine the effectiveness of the use of art therapy in a support group for multiple sclerosis patients. Your participation represents a valuable contribution to the development of art therapy research.

The data collected are for research purposes only. The information will remain confidential. If you have any questions about this research study, please feel free to contact the primary investigator ...

The objective of this group was to provide a safe environment for client to address and explore their feelings and concerns, to build peer support, to gain knowledge and information, and to learn effective coping strategies.

APPENDIX F***“Clearing a Space” Protocol***

- Find a comfortable way of sitting. Take a few deep breaths down inside to your body. Feel the support of the chair that you’re sitting on, the earth beneath your feet, and being here.
- Follow your breath inside of your body, put your attention in the torso area of your body, and notice how it is inside right now. Is it jumpy, calm, tight, warm, or something else? Be friendly to whatever you find.
- Imagine you are sitting somewhere peaceful. It may be a place you already know or one that you make up in your imagination. Once you have it, ask, "WHAT'S IN THE WAY OF FEELING FINE?" Don't answer, but let what comes in your body do the answering. As each thing comes up, imagine wrapping it up into a package, or using other imagery to set it at distance from you. You might imagine placing it on a boat and then letting the boat go a certain distance out on the water. You might imagine placing it in a balloon and letting it go up in the sky. When the list stops, check again, “Except for all of that, I’m all fine, right?”. If something else comes up, set that at a distance outside of your body.
- If there is a background feeling, an always feeling, like always kind of tense, or always kind of anxious, set that at a comfortable distance too.
- Now bring your attention back inside your body and experience a felt sense of feeling ‘all fine’, a cleared space that opens up to you. Take a moment to welcome it.

APPENDIX G

Resume of research principal investigator

... not included to preserve personal information ...

APPENDIX H

Funding Source Identification

The National Multiple Sclerosis Society represent the targeted funding source for this research. The Society helps people affected by MS by funding cutting-edge research, driving change through advocacy, facilitating professional education, and providing programs and services that help people with MS and their families move their lives forward. More precisely, the society provide a variety of resources to assist people in dealing with the emotional aspects of MS, including self-help groups, counseling groups, workshops, and other programs geared toward supporting the quality of life for people living with MS. The Society helps each person address the challenges of living with MS through the 50-state network of chapters and assistance is provided to over a million people annually. Each National MS Society chapter also organizes a variety of events to raise funds and awareness. The Society states,

- “We are moving research forward by relentlessly pursuing prevention, treatment and cure.
- We are moving to reach out and respond to individuals, families and communities living with multiple sclerosis.
- We are moving politicians and legislation to champion the needs of people with MS through activism, advocacy and influence.
- We are moving to mobilize the millions of people who want to do something about MS now.” (www.nationalsociety.org)

Additionally, The National MS Society welcomes applications for studies related to multiple sclerosis that may serve to advance their mission of stopping MS progression, restoring function and **improving quality of life**, and preventing MS. The Society's mission aim at mobilizing people and resources to drive research for a cure and to address the challenges of everyone affected by MS. The Society supports fundamental as well as applied studies, non-clinical or clinical in nature, including projects in patient management, care and rehabilitation. More precisely, The Society provides funds for limited short-term support of research in areas where preliminary data are scant or nonexistent. They fund high-risk pilot grants to quickly test novel ideas. To this end, the present proposal grant will be submitted online through a funding program identified as Pilot Research.

APPENDIX I

RFP from Funding Source

PILOT RESEARCH**PROGRAM TO SUPPORT PILOT RESEARCH**

The National Multiple Sclerosis Society provides funds for limited short-term support of research in areas where preliminary data are scant or nonexistent. This program is designed to support unique or novel ideas with the potential to open significant new areas of research on multiple sclerosis. Projects that are simply extensions of on-going research or that already have ample supporting data will not be considered.

APPLICATION PROCEDURE

The Society utilizes a Web-based facility for the submission of research grant applications. All applicants are required to use this facility for the completion of their proposals. In order to submit a proposal for research support, investigators must first register with our apply online site (www.mssocietyapplyonline.org) and complete a pre-application. Staff of the Research Programs Department will review the pre-application to determine whether the research plan is appropriate and relevant to our goals.

The application is brief, with the project description strictly limited to two pages. Applications that are submitted are then peer-reviewed in an expedited manner.

ELIGIBILITY

Investigators at established research institutions may apply to this program. It is expected that the person indicated as the principal investigator in an application for a grant is the one who is personally and actively responsible for the conduct of the research and who is considered eligible by his or her institution to apply for a research grant. The principal investigator need not be a United States citizen. Applications for Pilot Research Projects under the direction of, or that request stipends for, postdoctoral fellows or for graduate students will not be accepted. Pilot awards must not be used to support dissertation work for a graduate student. Postdoctoral fellows are encouraged to apply for one of the Society's programs of research training.

CONDITIONS OF AWARD

Support for Pilot Research Projects is limited to a maximum of \$40,000 in direct costs for one year. Funds to purchase major items of equipment are discouraged for this program, as are requests for travel funds. The grantee institution, through the officer signing the application, may add an amount for indirect costs up to 10% of the sum requested by the principal investigator except that indirect costs are not allowed in connection with funds requested or expended for: (a) patient costs or (b) purchase, modification or installation of any approved equipment. Indirect costs will not be provided for grants awarded to institutions outside the United States. All other conditions of the Pilot Award are as stated under the "Research Grants" section of the policies and procedures document.

A written report of the work accomplished during the Pilot Research Project and an account of expenditures are required within 30 days after a Pilot Research Project terminates. Forms and instructions for these reports will be sent to investigators as the end date for their project approaches.

PUBLICATIONS AND REPRINTS

As soon as a manuscript is accepted for publication, a copy of it, with the name of the journal and the expected date of publication, should be sent by mail or FAX (212-986-7981) to the Senior Director of Research Information, Research Programs Department. Manuscripts will be respected as privileged communications. As soon as reprints of a published article are available, two copies should be sent to the Senior Director of Research Information, Research Programs Department. In addition, if a press release from the institution is being prepared for distribution, a confidential copy of the press release should be FAXed in advance to the Society's Senior Director of Research Information.

The National Multiple Sclerosis Society must be acknowledged in all dissemination materials (e.g., publications, scientific exhibits, scientific presentations, press releases, etc.) related to research supported in full or in part by the Society. The following acknowledgment, or its equivalent, should be used:

"This investigation was supported (in part) by a Pilot Research Award from the National Multiple Sclerosis Society."

APPENDIX J

Copy of Proposal Forwarding to Funding Source

Grant Proposal to National MS Society

A. SPECIFIC AIMS

Primary Aims: To determine the efficacy of 7 Focusing-Oriented Art Therapy (FOAT) sessions over 3 months, compared to one FOAT session, in improving overall quality of life measured by validated MS questionnaires in randomized participants diagnosed with MS. It is hypothesized that FOAT treated participants will demonstrate significant improvement in quality of life, while control participants will show either no improvement or decline.

Secondary Aims: 1) To explore the sustained efficacy following 7 FOAT sessions, compared to one FOAT session, in improving overall quality of life between month-3 to month-6. It is specifically hypothesized that participants receiving multiple FOAT sessions will maintain their improvement, whereas control participants receiving only one FOAT session will continue to either show further decline or no improvement. 2) To evaluate the efficacy of 7 FOAT sessions over 3 months on stress and depressive symptoms, compared to control participants receiving one FOAT session, in improving validated measures of stressful life events and depression inventory scales.

B. BACKGROUND & SIGNIFICANCE

MS is a frequently disabling autoimmune disease affecting approximately 350,000 people in the United States. It is among the most disabling diseases in young adults. The impact of the illness on people's lives can be profound. Quality of life among people with MS is lower than among people with other chronic illnesses. Many MS patients believe that stressful life events and emotional distress can make their disease worse, mainly affecting their overall quality of life. Two decades of research has supported this belief, finding a relationship between stressful life events, in particular chronic family and work stressors, and subsequent clinical exacerbation and progression of disability. While these data are compelling, even prospective longitudinal studies are susceptible to the effects of confounding variables and reverse-causation. Thus, these studies provide only weak support for a causal relationship between stress and MS.

Here, we propose to examine the relationship between art therapy and MS quality of life using a randomized controlled trial. The work of Grossman et al. (2010) suggests the significance and potential success of interventions aimed toward ameliorating fundamental aspects of psychosocial and existential distress of chronically ill patients, which may be incompletely addressed by currently available medical management programs. Mindfulness-based interventions and MBAT have shown interesting results with MS and cancer patients (Grossman et al., 2010; Foley, Baillie, Huxter, Price, & Sinclair, 2010), but no research has been done combining mindfulness and art with MS patients. The present study is designed to assess the effectiveness of a psychosocial group intervention for MS patients, using Focusing-Oriented Art Therapy (FOAT). The researcher hypothesizes that Focusing-Oriented Art Therapy (Rappaport, 2009), a mindfulness-based approach, will replicate previous results and offer new psychological support and an avenue for a neurodegenerative disease such as MS. This research represents the first randomized controlled trial of FOAT in MS.

C. EXPERIMENTAL DESIGN & METHODS

This study will be a two arm randomized clinical trial (RCT) to evaluate the efficacy of an art therapy intervention (FOAT) aimed at reducing stress and depression symptoms and improving QOL. To ensure equivalence in neurological care across treatment groups, patients meeting inclusion and exclusion criteria will all receive standard care through the Yale MS Center. Participants will be assigned using a 1:1 ratio to either treatment arms: 1) a control group receiving only one art therapy (FOAT) group session or 2) a group receiving seven 2-hour art therapy (FOAT) group sessions every other week for 3 months. Random assignment via a computer-based algorithm that keeps track of number of enrolled participants and previous assignments will be performed. Each treatment arm will consist of 15 patients for a total enrollment of 30. The study will include stress, depression, and QOL outcomes. Treatments and assessments will be carried out at the Yale MS Center.

No sample size or formal power calculation was performed. The study is intended to gather pilot data only and to look at feasibility of a randomized trial using FOAT. However, a robust effect size is always possible. As such, statistical data analysis will be performed once all timepoints have been collected.

Patient Inclusion: 1) Any subjects carrying a diagnosis of RR or SP MS based on McDonald criteria revised by Polman et al. (2005). 2) Entry age greater than or equal to 18 years old. 3) Males and females. 4) EDSS between 0 and 7.0 (5 yards with a walker). 5) Minimal impairment of upper limbs.

Patient Exclusion: 1) History of substance abuse. 2) Oral or i.v. glucocorticosteroid exposure 4 weeks prior to a baseline session. 3) Meet criteria for dementia according to DSM-IV-TR. Patients with this level of cognitive impairment would be unlikely to benefit from a psychosocial intervention. Furthermore, the validity and reliability of their self-reports would be questionable. 4) Participants with suicidal ideation. 5) Pregnant or nursing patients. 6) Patients participating in other ongoing MS clinical trials involving experimental non-approved drugs. 7) History of systemic illness that would limit the likelihood of completing the study. 8) Automatic exclusionary conditions will include uncontrolled hypertension, epilepsy, insulin dependent diabetes, known malignancy other than skin cancer, and

symptomatic cardiac disease. 9) Patient's physician recommends against patient's participation.

Outcome Assessment: Primary Endpoint: HRQoL will be measured using the Multiple Sclerosis Quality of Life Inventory (MSQLI) (Fisher, LaRocca, Miller, Ritvo, Andrews, Paty, 1999) developed by the Consortium of MS Centers. The MSQLI is a validated questionnaire that uses the SF-36 (overall health, vitality, and daily activities) as its core, which permits comparisons across diseases, but supplements the core with established scales to assess MS specific symptoms including fatigue, pain, sexual, bladder, bowel, visual impairment, and social support survey. The SF-36 takes 20 minutes to administer and individual scores ranging from 0 (worst health status) to 100 (best health status). Supplements MSQLI subscales (higher scores indicate better health status) take 10 additional minutes. Reproducibility ranges from .67 to .94 for the SF-36 scales and from .78 to .97 for MSQLI added scales. The MSQLI will be administered at baseline, session 4 (month-1.5), session 7 (month-3), and 3 months after the completion of the last therapeutic session (month-6). Change in MSQLI scores from baseline to month-3 will be the primary outcome of the study. A sustained treatment effect, measured by change in MSQLI scores from month-3 to month-6, will be analyzed at month-6. **Secondary Endpoints:** 1) *Life Events List (LEL)*, a checklist of stressful life events (24 items), will be administered at baseline, month-3, and month-6 (Cohen, 1991). 2) *Perceived Stress Scale (PSS)*, a validated 10-item measure of global perception of stress with strong internal consistency ($\alpha=.88$) (Cohen, 1991:1983), will be administered at baseline, month-3, month-6. 3) *Beck Depression Inventory-II (BDI-II)*, to assess dysphoria and depressive symptoms (Beck, 1996), will be administered at baseline, month-3, month-6. The inventory measures the intensity of 21 depressive symptoms (higher scores are reflective of higher levels of depression). 4) Qualitative interview with the principal investigator will take place at baseline, month-3, and month-6. (See Figure 1 Appendix a)

Treatment: The group format was chosen primarily to increase social support (Liebman, 1986; Imel, 2008) since social support has been shown to act as a buffer between distress and MS autoimmunity (Mohr, 2001). Each group session will be as follow. Participants will engage in a Focusing-Oriented Art Therapy (Rappaport, 2009) directive: "Clearing a Space", "Choosing a theme" and "Felt Sense" aiming at exploring different issues related to MS. Themes will be as follow. Session: 1) Safe Place, 2) Physical Pain/Limitation, 3) Loss, 4) Body Image, 5) Support System, 6) Empowerment, 7) Vision of the future. After Focusing, participants will create a collage representing the Felt Sense experience (Lusebrink, 2004, Takata, 2002, Tokunaga, 1999). Participants will share and discuss their collage process at the end of each session.

Statistical Analysis: Statistical analysis of the MSQLI and all secondary endpoints will be performed under the guidance of a biostatistician using the following assumptions; the use of intent-to-treat (ITT) analyses and statistical methods that can account for repeated measures and missing values. For the primary endpoint analysis, we estimated the need to enroll 30 participants with 80% power to detect an effect with an alpha error of 0.05 for a treatment effect size of 60% (large effect size) separating MSQLI repeated scores between the two arms, favoring the group of subjects receiving 7 FOAT sessions compared to subjects only receiving one session at baseline. Outcome analyses between the two arms will be compared using ANOVA, a statistical method suited for repeated measures (MSQLI scores from baseline to month-3 and from month-3 to month-6). A *p*-value of less or equal to 0.05 will be interpreted as statistically significant. Similarly, secondary endpoint analyses will use a mixed-effects repeated measures model with random subject-specific intercepts to detect treatment effects between the two arms on *Life Events Scale*, *Perceived Stress Scale*, and *Beck Depression Inventory II* scores. Again, a *p*-value of less or equal to 0.05 will be interpreted as statistically significant.

Risks: The risks in psychotherapy are minimal. Art therapy directives are designed to minimize risks and to provide a safe environment for emotional reactions. The researcher will check in with each participant before the end of each session to ensure comfort and emotional safety. Accordingly, participants have the freedom to withdraw from the group and the study at any time.

D. BUDGET

Summary of Budget Request for a One Year Pilot Project	
Budget Category	Year 1
Personnel	36,500
Participants Costs	-
Permanent Equipment	-
Supplies	1,500
Travel	2,000
Other Expenses	-
Total DIRECT cost:	40,000
Indirect Cost (10%):	4,000
Total Annual Request:	44,000
Total request for one YEAR OF SUPPORT	

Justification of budget requests:PERSONNEL

Principal Investigator, Graduate Student in Art Therapy & Marriage and Family Therapy. (20% for one year) will be responsible for the overall study design, implementation, conduct of the study, budget appropriation, personnel administration, data collection and data analysis. Salary+fringe: \$15k/y.

Research Coordinator (TBN) (30% effort), is a clinical research coordinator with several years of experience in managing MS research studies. The Coordinator will be the contact person between participants, the PI and the study biostatistician. The Coordinator will be responsible to enter individual scores in the computerized database and help maintaining research documents and consent forms, collect artworks after each visit. Salary+fringe: \$15k/y.

Biostatistician, PhD, Consultant (TBN), is an experienced statistician with years of experience in clinical trial analysis and modeling of repeated measures. He/she will perform all blinded statistical analyses at the end of the study, work with the research coordinator to maintain database integrity, and provide the algorithm to the research coordinator to generate randomized treatment assignment numbers. Salary+fringe: \$6,500/yr.

MS Physician, Consultant (5% effort, no salary support), will be responsible for identifying eligible participants, assuring availability of space needed to conduct the study, and data analysis.

Supervisor, ATR-BC and/or MFT (700\$) The supervisor (TBD) will be an experienced psychotherapist who will meet with the principal investigator once a week for 50 minutes. (100\$/hour X 7 sessions)

Supervisor, FOAT certified (700\$) The supervisor (TBD) will be an experienced Focusing Oriented Art Therapist who will meet with the principal investigator once a week for 50 minutes. (100\$/hour X 7 sessions)

Personnel: Pursuant to Yale University policy, salaries in the initial budget period are based on current salary scales and include University mandated range adjustments of 3% for Neurology faculty and non-academic staff each July. Fringe Benefits for faculty and professional staff -31.9% and for clerical/technical staff- 54.1%.

SUPPLIES

\$775 is requested to purchase scissors, glue, cardboard, papers, folders, pens, markers, magazines.

OTHER EXPENSES

There will be no cost request for office space rent and no permanent equipment will be purchased.

TRAVEL

Travel costs of \$1,325 are requested. This cost is for travel, lodging, and registration for investigator to travel to one conference per year.

E. LITERATURE CITED

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- Rappaport, L. (2009). *Focusing-oriented art therapy: Accessing the body's wisdom and creative intelligence*. London: Jessica Kingsley.

Appendix a

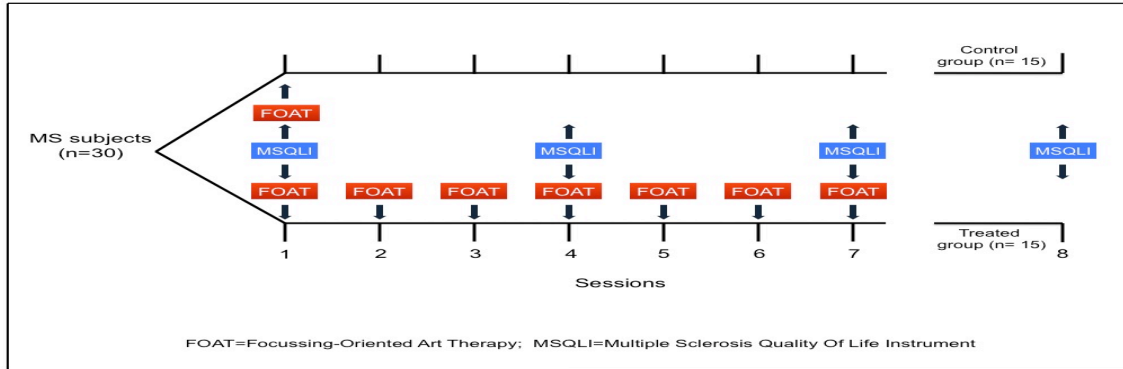


Figure 1