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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| In a middle-aged female with secondary-progressive multiple sclerosis and an EDSS score >7, will a self-efficacy intervention aimed to improve exercise efficacy in addition to a traditional PT intervention, increase the patient’s activity adherence, sustainability of the PT intervention and overall patient quality of life more so than a traditional PT intervention only? |

**AUTHOR**

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| **Prepared by** | Heather Eustis | **Date** | 11/22/14 |
| **Email address** | [Heather\_eustis@med.unc.edu](mailto:Heather_eustis@med.unc.edu) | | |

**CLINICAL SCENARIO**

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| Multiple sclerosis (MS) is a chronic autoimmune disease of the central nervous system characterized by an unpredictable and progressive decline in mobility, cognition and other physiologic functions (22). It is estimated that about 400,000 individuals in the United States are diagnoses with MS, and 2.5 million globally (22, 23). Due to the chronic and progressive nature of the disease, individuals with MS are susceptible to noncompliance of health promoting behaviours like exercise secondary to barriers that span across physical, emotional, social and environmental domains (22). Consequentially, individuals with MS typically experience reduced quality of life due to the financial, functional, and psychological burden of the disease (15). Exercise has received a lot of attention in the literature due to its beneficial effects to improve quality of life (11). However, with MS-related barriers (such as MS fatigue) the sustainability of an exercise program suffers or is non-existent despite knowing the benefits of physical activity. Consequentially, a large proportion, about 71% per some reports, of the MS population remains physically inactive (13, 23). It has been shown that persons with MS are less physically active than non-disease controls (14). Furthermore, individuals with more progressive forms of MS, such as primary-progressive and secondary-progressive, are even more inactive then their relapse-remitting counterparts (12).  The issue of decreased activity participation and adherence is frequently faced in the physical therapy clinic as many people with MS seek out rehabilitative care throughout their lifespan as new MS-related impairments threaten functional mobility. However, gains in PT (particularly for those with more progressive forms of MS) may not be sustainable due to barriers to exercise adherence. This can be a drain on the patient, PT, and caregivers in terms of time and resources. Understanding the social support, environment and how an individual perceives his or her condition is vital to maximize and sustain gains made in PT. It has been shown that despite these low levels of physical activity, many people with MS are interested in learning more about physical activity and strategies to increase it (23). Therefore, a lot of attention has been paid to mediators of physical activity in individuals with MS through behavioural models (22). Utilization of behavioural models have been studied to understand how physical activity behaviour is adapted and sustained, and to provide information on how to incorporate behavioural models into physical activity promoting programs (1). Results have shown that effective interventions are achieved with this understanding of behavioural models and the appropriate integration into practice (18). A mediator of interest has been self-efficacy which is one’s belief to overcome barriers with innate abilities, or one’s judgment of his or her capabilities (12).  Improving someone’s self-efficacy through a behavioural model has been shown to not only improve quality of life, but also increase physical activity in the general population as well as the MS population (12). It has been proposed that self-efficacy is a vital variable to promote long-term exercise behaviour (13). Additionally, self-efficacy is theorized to have an extremely strong effect on behaviour under challenging circumstances, like MS (14). Increasing self-efficacy in someone with MS has been analysed as a way to increase physical activity and improve quality of life by helping to break down some of the barriers to exercise in this population. This is particularly important for those with more advanced forms of MS where disease modifying drugs have little impact and where many are faced with the prospect of a continuous decline in function. It is unsurprising that those with more advanced forms of MS suffer from a greater degree of reduced quality of life and exercise participation. However, the benefits of exercise can be achieved in this population as well. Therefore, it is important to explore the feasibility of utilizing a mediator of physical activity, such as self-efficacy, to help promote the sustainability of an exercise program so that even those with more advanced MS can reap the benefits of physical activity. MS is a national and global concern made up of a population plagued by many barriers to health-promoting behaviours. These struggles are felt by not only the patient, but also the family members, friends and healthcare providers. Clinicians have the surface information to give to these patients (i.e. “you should exercise and this is why…”) but need to address the need of instilling strategies to promote behaviour changes to maximize sustainable health gains and minimize the disease burden. The feasibility and effectiveness of such programs (i.e. self-efficacy promoting intervention) needs to be better defined in the literature as it relates to physical therapy, especially for those with more advanced forms of MS. |

**SUMMARY OF SEARCH**

[Best evidence appraised and key findings]

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| Overall the quality of the evidence for my clinical question is poor to good. Out of the 11 articles I found, 8 of them are randomized controlled trials that range from a score 4/10 to 7/10 based on the PEDro quality assessment rating scale. I also found 1 case report and 2 single group studies with repeated measures. |

**CLINICAL BOTTOM LINE**

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| The results of this study suggest the potential benefits of a self-efficacy building intervention via print-based materials, PowerPoint presentations and group sessions for individuals with MS in terms of improving physical activity participation, fatigue level, symptom management and domains of quality of life. A PT could utilize these results to justify a self-efficacy building program in the clinic for the MS population and initiate the program utilizing the techniques discussed in the research. |

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| ***This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor*** |

*The above information should fit onto the first page of your CAT*

**SEARCH STRATEGY**

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| **Terms used to guide the search strategy** | | | |
| **P**atient/Client Group | **I**ntervention (or Assessment) | **C**omparison | **O**utcome(s) |
| * Multiple Sclerosis * Multiple Sclerosis [MeSH] * Secondary-Progressive multiple sclerosis * Progressive MS * Advanced MS * Multiple sclerosis * Sclerosis, disseminated [MeSH] * MS (Multiple Sclerosis) * Multiple sclerosis, chronic progressive [MeSH] * Chronic progressive multiple sclerosis * Multiple sclerosis, primary progressive [MeSH] * Multiple sclerosis, progressive relapsing [MeSH] * Multiple sclerosis, remittent progressive [MeSH] * Multiple sclerosis, secondary progressive [MeSH] | * Self-efficacy intervention * Self-efficacy building intervention * Self-concept [MeSH] * Personal autonomy [MeSH] * Self-perception [MeSH] * Autonomy, personal * Social-Cognitive Theory * Health Behaviour Change | * Physical Therapy * Physiotherapy * Physical activity intervention * Exercise intervention * Aerobic exercise intervention * Resistance training intervention * Physical therapy intervention * Motor Activity [MeSH] * Locomotor activity * Exercise, aerobic * Exercise, physical * Physical fitness [MeSH] * Exercise therapy [MeSH] * Exercise movement techniques [MeSH] * Rehabilitation | * Quality of life [MeSH] * QOL * Physical activity participation * Activity tolerance * Activity adherence * Exercise adherence * Physical endurance * Ambulation * Endurance |

**Final search strategy:**

*Show your final search strategy from one of the databases you searched. In the table below, show how many results you got from your search from each database you searched.*

**PubMed Search Strategy**

1. (multiple sclerosis OR MS OR multiple sclerosis[MesH])
2. (Exercise OR intervention OR physical therapy OR physiotherapy OR rehabilitation)
3. (Self-efficacy intervention OR self-efficacy OR self-concept OR personal autonomy OR social-cognitive theory)
4. ((Exercise adherence OR compliance) OR (quality of life OR QOL))
5. Combination of #1, #2, #3, #4

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| **Databases and Sites Searched** | **Number of results** | **Limits applied, revised number of results (if applicable)** |
| **PubMed** | 121 | **Limits:** case reports, clinical trial, randomized controlled trial, review, systematic reviews only  **Revised number:** 53  **Limits**: randomized controlled trials, case reports, meta-analysis and systematic reviews only  **Revised number**: 31  **Limits**: meta-analysis, randomized controlled trial, systematic reviews  **Revised number:** 28 |
| **Pedro** | 6 | No limit added |
| **CINAHL** | 8 | No limits added |

## INCLUSION and EXCLUSION CRITERIA

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| **Inclusion Criteria** |
| * Population includes individuals with MS – RRMS, PPMS, SPMS * Subjects aged <40 * EDSS score >7 * Self-efficacy building intervention * Comparison to no intervention or exercise intervention * Outcome measures addressing any of the following: QOL, physical activity participation, physical activity tolerance, self-efficacy to exercise, self-efficacy to overcome MS-related barriers * Discussion on barriers and facilitators of health-promoting behaviours in individuals with MS * Identifies a behavioural theoretical model such as Social Cognitive Theory * Identifies the type of self-efficacy being addressed (i.e. self-efficacy to exercise, self-efficacy to overcome MS-related barriers) * Study types: Randomized controlled trial, controlled trials, uncontrolled trials, systematic review, case study (case study must include female with progressive MS) * Published in English |
| **Exclusion Criteria** |
| * Does not address physical activity promotion * Conference proceedings, letters to the editor, dissertations, narrative review |

**RESULTS OF SEARCH**

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| A total of | 11 | Eleven relevant studies were located and categorised as shown in the following table (based on Levels of Evidence, Centre for Evidence Based Medicine, 2011) and PEDro quality assessment rating scale. PEDro is a 10 point assessment scale where 1/10 indicates a very poor quality study and 10/10 indicates a very high quality study. |

**Summary of articles retrieved that met inclusion and exclusion criteria**

*Note that this table is arranged differently from the example CAT on Sakai. For each article that meets your inclusion and exclusion criteria, score for methodological quality on an appropriate scale, categorize the level of evidence, and note the study design (e.g., RCT, systematic review, case study). Add more rows as necessary.*

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| **Author (Year)** | **Study quality score** | **Level of Evidence** | **Study design** |
| Bombardier et al. (2008)1 | 8/11 | 1b | Randomized Controlled Trial (RCT) |
| Ennis et al. (2006)3 | 8/11 | 1b | RCT |
| Feys et al. (2013)4 | 4/11\* | 4 | Uncontrolled intervention study with repeated measures |
| Hale et al. (2013)6 | 6/11\* | 4 | Single group, pre-test post-test longitudinal study |
| McAuley et al. (2007)10 | 5/11 | 1b | RCT |
| Motl et al. (2011)12 | 8/11 | 1b | RCT |
| Pilutti et al. (2014)16 | 6/11 | 1b | RCT |
| Plow et al. (2014)17 | 8/11 | 1b | RCT |
| Smith et al. (2006)19 | 3/11\* | 4 | Case Report |
| Stuifbergen et al. (2003)21 | 5/11 | 1b | RCT |
| Thomas et al. (2013)26 | 7/11 | 1b | RCT |

**BEST EVIDENCE**

The following 3 studies were identified as the ‘best’ evidence and selected for critical appraisal. Reasons for selecting these studies were:

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| **Thomas et al. 2013**  This study scored a 7/11 based off the PEDro quality assessment scale, which indicates a good quality study (13). Additionally, this study was a randomized controlled trial which is considered a high quality study design based on Jewell’s Hierarchy of Evidence for Articles about Therapy (5). Additionally, this study demonstrated that a 6-session group-based program for managing MS-related fatigue was effective at reducing fatigue and increase fatigue self-efficacy. This study also included subjects who had RRMS and the more progressive forms, SPMS and PPMS. Finally, this study included outcome measures that would be relevant to my clinical question. Great  **Plow et al. 2014**  This study scored a 8/11 based off the PEDro quality assessment scale, which indicates a good quality study (13). Additionally, this study was a randomized controlled trial which is considered a high quality study design based on Jewell’s Hierarchy of Evidence for Articles about Therapy (5). Additionally, this study demonstrated that including a self-efficacy building intervention, such as customized pamphlets used in the study, into a normal exercise intervention may help improve both physical activity and quality of life in persons with MS which strongly related to my research question. Finally, this study included outcome measures that would be relevant to my clinical question.  **Ennis et al. 2006**  This study scored a 8/11 based off the PEDro quality assessment scale, which indicates a good quality study (13). Additionally, this study was a randomized controlled trial which is considered a high quality study design based on Jewell’s Hierarchy of Evidence for Articles about Therapy (5). Additionally, this study demonstrates that a health promotion education program for persons with MS may help improve participation in health-promoting behaviours, self-efficacy and general quality of life. Also, the study consisted of a mix of RRMS up to the more progressive forms, PPSM and SPMS. Finally, this study included outcome measures that would be relevant to my clinical question. |

**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of “A randomized controlled trial of a health promotion education programme for people with multiple sclerosis” by Ennis M, Thain J, Boggild M, Baker GA and Young CA, 2006**

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| **Aim/Objective of the Study/Systematic Review:** |
| The aim of the present study was to evaluate the effectiveness of an 8-week educational group program for persons with multiple sclerosis (MS) in increasing health-promoting behaviour participation, self-efficacy, and quality of life. |
| **Study Design**  [e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]  Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| This study was a randomized controlled trial with random allocation of subjects with MS, which met the inclusion criteria, into a treatment or control group and prior concealment of the randomization process. The control group continued with their current treatment plan for MS and the treatment group attended an 8-week educational group program called OPTIMISE. Outcome measures involved questionnaires that were sent via post to the treatment group 1 week before the start of the OPTIMISE program, immediately after the program and at 3 months after the program. The control group were sent the questionnaires at baseline and at 8 weeks. Due to the nature of the study, subjects and the personnel conducting the OPTIMISE program could not be blinded to which group the subjects were in; however, the researcher who inputting the questionnaire data was blinded to the subject’s group assignment. Finally, utilizing a two-sided test, it was estimated that 77 subjects per group were required to achieve 80% power with 5% significance. |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| The OPTIMISE program was conducted in a hospital environment |
| **Participants**  [N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]  Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| Eighty-six individuals with multiple sclerosis were recruited from a MS clinic at a regional neuroscience centre. Sixty-four of these potential subjects returned the consent form for the study that was mailed to them and were then randomly allocated to a treatment group (n=34) or a control group (n=30). To be eligible for participation in the study, individuals had to have a confirmed diagnosis of MS, a disease duration of at least 6 months, no clinically significant cognitive impairments, and an Expanded Disability Status Scale (EDSS) score between 1.0 and 7.0 where 1.0 indicates no disability and 7.0 indicates the ability to ambulate ≤5 meters with assistance, transfer independently, and utilize a wheelchair as primary means of mobility. Baseline clinical and demographic characteristics were comparable between the treatment and control group. The average subject was female, aged 45 years, had relapsing-remitting MS, was classified as moderately disable based on EDSS (score between 3.5 and 6.0), was unemployed due to MS, married, and managing MS through symptom management.  In more detail, each group was predominantly female (63% for both groups) and were aged between 18 and 65 years with a mean age of 45 and 46 years for the treatment and control groups respectively. The majority of subjects had a diagnosis of relapsing-remitting MS (50% of the treatment and 40% of the control group), followed by secondary progressive (28% of the treatment and 37% of the control group) and primary progressive (16% of the treatment and 20% of the control group). Only 6% of the treatment and 3% of the control group had benign MS. In terms of EDSS level, the majority of the subjects (69% of the treatment and 74% of the control group) were classified as moderately disabled with scores between 3.5 and 6.0. This was followed by those classified as mildly disabled with scores between 0.0 and 3.0 (22% of the treatment and 23% of the control group). Only 9% of the treatment group and 3% of the control group were classified as severely disabled with an EDSS score between 6.5 and 7.0. For medical management of their MS, the majority of subjects (59% of the treatment and 57% of the control group) reported symptom management. This was followed by 22% of the treatment group and 27% of the control group that reported no medical management of their MS. Only 19% of the treatment group and 7% of the control group reported their medical management as symptom management and use of disease-modifying drugs (DMT). Only 7% of the control group (0% of the treatment group) reported DMT use only. In terms of employment, the majority of subjects (34% of the treatment and 27% of the control) were unemployed secondary to MS complications. Finally, the majority of subjects were married (88% of the treatment and 77% of the control group). |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| The control group consisted of 30 participants with multiple sclerosis who completed outcome measures delivered via mail at baseline and 8 weeks later. During the 8 weeks the control group continued with their usual care of their MS. At the conclusion of the study these participants were offered the experimental intervention (the OPTIMIZE program, explained below). |
| *Experimental* |
| The treatment group consisted of 34 participants with multiple sclerosis who participated in an 8-week group program called OPTIMIZE and completed outcome measures delivered to them via main one week prior to the start of the program, at 8 weeks, and at 3 months following the completion of the program. The OPTIMIZE program consisted of eight 3-hour group sessions over the course of 8 weeks (1 session per week). Participants were divided into subgroups of about 8 people per group. The program was designed to educate and address the individual needs of the participants in regards to health-promoting behaviours. The program covered the following topics: exercise and physical activity, lifestyle adjustment/fatigue management, stress management, nutritional awareness, and responsible health practices. Each of these topics was introduced to discuss the rational of their importance for individuals with MS and the relationship between the behaviour and MS. Following topic introductions, participants underwent practical sessions that were related to the discussed topic. This was considered vital in the promotion of self-efficacy because these sessions were designed to stimulate self-reflection and appraisal of the topic information across 4 types of experience: performance, vicarious experiences, verbal persuasion, and physiological feedback. When appropriate, sessions were presented by a relevant health-care professional (ie. Physical therapists and nutritionists). In addition to the group sessions, all participants were given paper versions of the material covered for future reference. Finally, the program concluded with a session that summarized what was learned over the course of the program to the spouses, family members, and/or friends of the participants with a focus on long-term goal planning. |
| **Outcome Measures** (Primary and Secondary)  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| The primary outcome measure was the Health Promoting Lifestyle Profile II (HPLP) to assess engagement in health-promoting activities across all aspects of wellness (ie. Exercise, nutrition, and interpersonal relationships). The HPLP involves 52 items that are divided into 6 of the following subscales: physical activity, spiritual growth, health responsibility, interpersonal relationships, nutrition, and stress management. Each question asks the respondent to rate the frequency they undertake the described activities from 1 (Never) to 4 (Routinely). Thus, the higher the score, the greater the respondent’s reported participation in health-promoting activities.  The secondary measures were the Self-Rated Abilities for Health Practices Scale (SRAHP) to assess self-efficacy to engage in health-promoting activities and the 36-Item Short Form Health Survey (SF-36) to assess health-related quality of life. The SRAHP consists of 28 items with the following domains: nutrition, physical exercise/activity, psychological well-being and responsible health practices. Respondents answer questions about their ability to perform the described activity from 0 (not at all) to 4 (completely). A higher score reflects a greater level of self-efficacy to participate in health-promoting activities. The SF-36 consists of 36 items to produce 8 scaled scores from the following 7 subscales: vitality, physical functioning bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health. Scores are coded, summed and transformed onto a 0 (worst possible health) to 100 (best possible health) scale. Thus, a higher score represents a higher level of health-related quality of life. |
| **Main Findings**  [Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided – if you need to calculate these data yourself, put calculations here and add interpretation later, under ‘critical appraisal’ on next page] |
| Overall the treatment group demonstrated statistically significant (p<0.05; computed via Mann-Whitney U-test) increased participation in health promoting activities (demonstrated by change in HPLP scores) and level of self-efficacy (demonstrated by change in SRAHP scores) compared to the control group. In terms of quality of life assessed by the SF-36, the treatment group demonstrated significant improvements compared to the control group in certain domains (physical, mental health and general health).  In greater detail, HPLP and SRAHP change in mean scores between the treatment and control groups were statistically significant (*Treatment*: HPLP=22.03±16.35 [2.94]\*, SRAHP=15.13±17.67 [3.17]; *Control*: HPLP=5.23±14.79 [2.7], SRAHP=3.2±10.07 [1.84]; p<0.01). The following HPLP subscales were considered statistically significant: health responsibility (*Treatment*: 3.9±3.8 [0.68]; *Control*: 0.93±3.48 [0.64]; p<0.01), physical activity (*Treatment*: 6.61±5.27 [0.95]; *Control*: 0.2±2.19 [0.4]; p<0.01), spiritual growth (*Treatment*: 3.52±3.65 [0.66]; *Control*: 0.53±3.07 [0.56]; p<0.01), and stress management (*Treatment*: 3.22±3.36 [0.6]; *Control*: 0.33±3.08 [0.56]; p<0.01). The following SF-36 subscales were considered statistically significant: physical (*Treatment*: 8.06±14.7 [2.64]; *Control*: 2.83±19.28 [3.52]; p=0.03), mental health (*Treatment*: 5.68±22.86 [4.11]; *Control*: -8.57±13 [2.37]; p<0.01) and general health (*Treatment*: 10.13; *Control*: -1.17±17.96 [3.28]; p<0.01).  Finally, the pre-program mean and standard deviation scores of the treatment and control groups were comparable and were the following: HPLP total score of 11.7.8±13.2 for the treatment group and 116.6±21.3 for the control group; SRAHP score of 71.1±16.5 for the treatment group and 66.8±22.9 for the control group; SF-36 physical subscale score of 28.6±23.8 for the treatment group and 31.2±25.5 for the control group; SF-36 social subscale score of 57.8±22.7 for the treatment group and 53.3±25 for the control group; SF-36 role physical subscale score of 26.6±38.1 for the treatment group and 20.8±36.6 for the control group; SF-36 role emotional subscale score of 63.5±64.6 for the treatment group and 60±45 for the control group; SF-36 fatigue subscale score of 35.7±19.4 for the treatment group and 34.1±19.7 for the control group; SF-36 pain subscale score of 63±28.6 for the treatment group and 55.9±28.5 for the control group; and SF-36 general health subscale score of 44±20.7 for the treatment group and 46.9±20.9 for the control group.  *\*Data represented as the mean ± standard deviation [standard error of the mean]*  *Standard Error of the Mean (SEM) was calculated using the following equation: SD/√(n)* |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| The authors of the present study concluded that the 8-week educational OPTIMIZE program produced significant improvements in health-promoting behaviours, self-efficacy and certain domains of quality of life in a sample of 31 individuals with multiple sclerosis when compared to a control group. Due to these results, the authors conclude that the OPTIMIZE program is appropriate to use by clinicians in the care of individuals with MS. |
| **Critical Appraisal** |
| **Validity**  [Methodology, rigour, selection, sources of bias, quality score on methodology quality rating scale (indicate the quality assessment tool used and the maximum possible score on that scale, e.g., 7/10 on PEDro scale), appropriateness of analytical approach (e.g., adjustments for confounding variables, management of missing data).]  Comment on missing information in original paper. |
| The present study received a 8/11 quality assessment score based on the PEDro scale where 1/11 indicates a very poor quality study and a 11/11 indicates a very high quality study. Due to the nature of the study design and intervention, subjects could not be blinded to their group assignment. This produces a source of performance bias because the subjects were aware of which group they were in which may have influenced how they performed during the study. Additionally, outcome measures were self-report questionnaires which present a procedural bias and the potential for response bias from the subjects. In this regard, the study did not indicate whether or not any of the subjects had to fill out the questionnaires by proxy due to dexterity limitations from MS (ie. Decreased grip strength or issues with MS-related spasticity). Questionnaires filled out by proxy may have also influenced the respondent’s answers.  In terms of other sources of bias, efforts were made to decrease the potential for selection bias, other aspects of performance bias, and detection bias with random allocation of subjects into the two groups and blinding of the researcher of the subject’s group assignment when inputting the questionnaire data.  The analytical approach for this study was appropriate for the data because it was determined per Shapiro-Wilks Scores that the data was not normally distributed. Therefore, non-parametric analysis was utilized. The Mann-Whitney U-test to determine the alpha level was utilized and is an apocopate test to use with non-parametric data.  In terms of the outcome measures utilized in this study, all three are considered appropriate to use in persons with MS and have good clinical relevance because they reflect how the individual patient views his or her condition and medical management of the disease (5). However, the HPLP has been established to be a reliable and appropriate measure to access health-promoting behaviours in adolescent women (27), but has not been specifically tested for psychometric properties in persons with MS. Additionally, there is no MCID established at this time. The psychometric properties of SRAHP have also not been tested in persons with MS but SRAHP is considered an appropriate outcome measure to use with this population. On the other hand, the SF-36 has been tested in individuals with MS but does not have an establish MCID for this population. The MCID has been established for patients with Parkinson’s Disease and is the following: 28 for physical functioning subscale, 45 for physical role limits subscale, 25 for bodily pain subscale, 28 for general health subscale, 19 for vitality subscale, 29 for social functioning subscale, 45 for emotional role limits subscale, and 19 for mental health subscale (20).  Additionally, it must be noted that the researchers conducted a two-sided test that indicated the need for at least 77 subjects per group to achieve 80% power with 5% significance. However, only 31 and 30 subjects were analysed in the treatment and control group respectively.  Finally, the authors of the study report that a larger sample size is needed for a future study to “provide more confidence in the results and allow analysis of the influence of demographics, multiple sclerosis type and disease duration” (page 791) (3). |
| **Interpretation of Results**  [Favourable or unfavourable, specific outcomes of interest, size of treatment effect, statistical and clinical significance, minimal clinically important difference. You may calculate effect size or confidence intervals yourself from the data provided in the article.] Describe in your own words what the results mean. |
| Based on the power analysis conducted prior to the start of the study, the researchers required at least 77 subjects per group to achieve 80% power with 5% significance; however, they were not able to achieve this subject quantity. Therefore, the results lack confidence. Despite this, the results of the present study show that the treatment group demonstrated a greater mean score change in all outcome measures than the control group; however, some were not considered statistically significant based on the alpha level of p<0.05. Table 3 (page 790) in the study indicates that the following scores were statistically significant: HPLP total, SRAHP, Health responsibility HPLP subscale, physical activity HPLP subscale, spiritual growth HPLP subscale, stress management HPLP subscale, physical SF=36 subscale, mental health SF-36 subscale, and general health SF-36 subscale. However, it must be noted that the standard deviation exceeded the mean of the treatment and control group scores for the SRAHP, spiritual growth HPLP subscale, stress management HPLP subscale, physical SF-36 subscale, and mental health SF-36 subscale indicating more variable data within the subject sample. Despite this, the standard error of the mean for each of these scores was relatively low indicated the mean was a good representation of the population mean. |
| **Implications of this study/evidence for clinical practice and future research**  [Comment on how this evidence applies to your clinical question and whether it supports the intervention of interest. Briefly discuss the implications for future research] |
| This evidence applies to my clinical question because it indicates that a health-promoting educational group program can be utilized to increase participation in health-promoting activities, self-efficacy to undertake these activities, and certain domains of quality of life in persons with mild to moderate multiple sclerosis. This study does not fully answer my clinical question because it involved subjects with an EDSS score between 1.0 and 7.0 (my clinical questions involves persons with MS with an EDSS score >7.0). Additionally, this study did not discuss physical therapy or whether or not the usually care of the control group included physical therapy. However, it still highlights the importance of self-efficacy building techniques to help improve participating in health promoting activities, such as exercise, and will help contribute to my search of the answer. Implications for future research should focus on subjects with a more advanced disability level (ie. EDSS score >7.0). The researchers report that the OPTIMIZE program is easily replicated and appropriate for persons with mild to moderate MS (EDSS score of 1.0-7.0); therefore, it would be interesting to ascertain if this program could also be utilized in person with more advanced MS (EDSS score >7.0). Finally, future research could also explore the feasibility and effectiveness of the OPTIMIZE program, or similar program, in physical therapy for persons with MS. |

**(2) Description and appraisal of “A pragmatic parallel arm multi-centre randomized controlled trial to assess the effectiveness and cost-effectiveness of a group-based fatigue management program (FACETS) for people with multiple sclerosis” by Thomas S and Tomas PW et al. 2013.**

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| **Aim/Objective of the Study/Systematic Review:** |
| The aim of the present study was to analyse the effectiveness and cost-effectiveness of a group-based intervention designed to help participants with multiple sclerosis (MS) manage MS-related fatigue utilizing the FACETS program (Fatigue: Applying Cognitive behavioural and Energy effectiveness Techniques to lifestyle). The full study proposal is outlined in the author’s pervious published study in accordance with the Medical Research Council (MRC) guidance for developing and evaluating a complex intervention (25). |
| **Study Design**  [e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]  Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| This study was the fourth stage of a research program following guidance from the MRC for developing and evaluating a complex intervention, with pervious work being pilot studies and a full intervention and study methodology outline (25). The present study is a parallel arm randomized controlled trial with an economic evaluation. Subjects with MS who met the inclusion criteria were recruited from 3 UK centres. Subjects were entered into the study database once 24 subjects returned informed consent from each centre. Subjects were then randomly allocated via a random number generator to an intervention or control group. The intervention group participated in the FACETS program plus current local practice, while the control group only received current local practice. Current local practice was defined as practice that ranged from “general advice and information provision about MS-fatigue to more detailed individualized management advice from a variety of health professionals” (page 1093). Because of the nature of the study, subjects could not be blinded to which group they were allocated to. Outcome measures included self-report questionnaires that were given to each subject in a booklet to be completed at each subject’s convenience within a certain time and then mailed back to the investigators. The FACET group completed outcome measures at baseline (1 week before the start of the intervention) and at 1 month (follow-up 1) and 4 months (follow-up 2) after completion of the intervention. The control group completed outcome measures within an identical time frame as the intervention group. A power analysis indicated a sample size of 146 subjects with 85% power to detect a standardized effect size of 0.5. Analysis of outcome measure data assumed the questionaries to be interval data and utilized absolute change in values at the 1st and 2nd follow-ups compared to baseline. |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| The FACETS program was delivered in hotel meeting rooms with the exception of one centre which was held in a rehabilitation hospital. |
| **Participants**  [N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]  Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| The present study recruited 164 subjects (n=84 in the FACETS group and n=80 in the control group) over the course of 17 months (May 2008 – November 2009). Subjects were recruited from three UK centres from primary or secondary care or through local MS Society newsletters and website. Full inclusion criteria are detailed in the investigator’s previous study (Thomas et al. 2010) but included the main criteria: confirmed diagnosis of MS, fatigue negatively impacting daily life (defined as a Fatigue Severity Scale total score >4), and being ambulatory. The main exclusion criteria included the following: having participated in a fatigue management program within the last year, cognitive impairments, an MS-related relapse within the last 3 months, and having started pharmacological treatment with disease-modifying drugs or antidepressants within the last 3 months. Demographics between groups were comparable. The average subject was female, aged 48 years, white English, had relapsing-remitting MS, an Adapted Patient Determined Disease Steps (APDDS) score of 4 or 5 indicating that MS interferes with walking, had achieved one or more General Certificate of Secondary Education (GCSE) as their highest qualification, were not in paid employment (to include being unemployed, in education, retired, looking after home), were married, and reported 1-5 years since MS diagnosis.  In more detail, each group was predominantly female (73% for both groups), were aged between 23 and 73 years with a mean age of 48 and 50 years for the FACETS and control groups respectively, and were mostly white English ethnicity (68% for the FACETS group and 69% for the control group). The majority of subjects had a self-reported diagnosis of relapsing-remitting MS (43% of the FACETS and 51% of the control group), followed by secondary progressive (20% of the FACETS and 29% of the control group), primary progressive (6% of the FACETS and 10% of the control group), and benign MS (5% of the FACETS and 3% of the control group). Additionally, 26% of the FACETS and 6% of the control group reported they “don’t know” the type of MS they had. Finally, 3 subjects in the FACETS and 2 in the control group did not state which type they had. In terms of APDDS scores, the majority of the subjects (46% of the FACETS and 54% of the control group) had a score 4 or 5. This was followed by a score of 6 or more (32% of the FACETS and 27% of the control group) indicating the need of an assistive device to walk 100 meters, followed by a score of 3 or less (22% of the FACETS and 19% of the control group) indicating no limitations on walking. Three subjects in the FACETS and 2 in the control group did not state their APDDS score. For education level, the majority of the subjects (46% for the FACETS and 38% for the control group) had achieved 1 or more GCSE (or equivalent). In terms of employment, the majority of subjects (63% of the FACETS and 64% of the control) were no engaged in paid employment; defined as being either unemployed, in education, retired, or looking after the home. Finally, the majority of subjects were married (78% of the FACETS and 71% of the control group). |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| The control group (n=80) received current local practice which was defined as ranging from “general advice and information provision about MS-fatigue to more detailed individualized management advice from a variety of health professionals”. |
| *Experimental* |
| The treatment group (n=84) participated in the FACETS program which is fully described in the investigator’s pervious article (Thomas et al. 2010) plus current local practice. In short, the FACETS program is very structured and consists of 6 weekly sessions (1 per week) about 90 minutes long. Sessions were held in groups of 6-12 subjects with 2 health professionals (i.e. physical therapists and occupational therapists) that had experience working with patients with MS and working in group-based programs. Each session consisted of a PowerPoint presentation given by the health professional, flipchart discussions, group activities and homework. Subjects were additionally provided with paper material of the topics and main points of each session. The investigators do not detail the topics covered in present study but refer to their previous study (Thomas et al. 2010). As mentioned, the FACETS group was not restricted to current local practice. The investigators state that this was to increase external validity. |
| **Outcome Measures** (Primary and Secondary)  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| Primary outcome measures aimed to assess fatigue severity, disease-related quality of life, and self-efficacy for overcoming MS-related fatigue. Secondary outcome measures aimed to further assess fatigue, and to assess depression level, physical and psychological well-being, disease burden, health state values, reported utilization of community resources for health and social services, and physical activity level.  In more detail:  **Primary Outcome Measures**  The primary constructs were fatigue severity (assessed by the Global Fatigue Severity (GFS) subscale of the Fatigue Assessment Instrument (FAI) where a high score indicates more fatigue), disease-related quality of life (assessed by the total score on the Multiple Sclerosis Impact Scale (MSIS-29) where a high score indicates more disease impact), and self-efficacy for overcoming MS-related fatigue (assessed by the Multiple Sclerosis-Fatigue Self-Efficacy scale (MS-FSE) that was adapted from the Control subscale of the MS Self-Efficacy (MSSE) scale where a high score indicates more certainty in controlling fatigue).  **Secondary Outcome Measures**  The investigators continue to refer to their previous article (Thomas et al. 2010) for full detail but report that the secondary outcome measures included the following: subscales of the FAI, the Fatigue Symptom Inventory, the Hospital Anxiety and Depression scale, the physical and psychological subscales of the MSIS-29, the Medical Outcomes Short-Form Survey (SF-36), the health state values and quality adjusted life years (QALYs) derived from the EuroQoL 5-Dimensions questionnaire (EQ-5D) and the Short-form 6-Dimensions questionnaire (SF-6D), self-reported utilization within the last 3 months of health and social services resources, and objective measures of physical activity over 48 hours utilizing ActivPAL accelerometers. |
| **Main Findings**  [Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided – if you need to calculate these data yourself, put calculations here and add interpretation later, under ‘critical appraisal’ on next page] |
| The main findings of the present study were that the FACETS intervention group produced a greater increase in self-efficacy to overcome MS-related fatigue at the 1st and 2nd follow up time points, and a greater reduction in perceived disease severity at the 2nd time point when compared to the control group.  In more detail, the results of the study show that the FACETS group (n=70 after drop outs) demonstrated a statistically significant increase in self-efficacy to overcome MS-related fatigue (via the MS-FSE) at follow-up 1 (57±17\*; p=0.001; SES\*\*=0.54; 95% CI 4-14) and follow-up 2 (56±19; p=0.048; SES=0.36; 95% CI 0-12) and fatigue severity (via GFS subscale of the FAI) at follow-up 2 (5.26±1.03; p<0.01; SES=-0.35; 95% CI -0.63 to -0.08) when compared to the control (n=74 after drop outs) group (50±17, 53±17, 5.66±0.93 respectively). The results failed to show statistically significant values between the FACETS and control group for disease burden (via the MSIS-29) at follow-up 1 (FACETS: 47.3±18.2; Control: 42.2±18.4; p=0.46; SES=0.08; 95% CI -2.36-5.24) and follow-up 2 (FACETS: 44.9±19.2; Control: 43.0±17.3; p=0.53;SES=-0.08; 95% CI -6.45-3.34) and fatigue severity at follow-up 1 (FACETS: 5.48±0.92; Control: 5.55±1.17; p=0.86; SES=-0.03; 95% CI -0.33-0.28).  *\*mean score ± standard deviation*  *\*SES = Standard Effect Size* |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| The authors conclude that the FACETS program was effective in reducing MS-related fatigue severity and increasing self-efficacy to overcome MS-related fatigue. In terms of the economic evaluation, the authors conclude that since the QALY data demonstrated no statistically significant difference between trial arms, it is difficult to assess the cost-effeteness of the intervention because improvements in fatigue are not reflected in QALY outcomes. Despite this, the authors highlight that the FACETS program could be a “clinically useful, relatively inexpensive addition to current local practice in appropriate hospital/community settings” (page 1098). |
| **Critical Appraisal** |
| **Validity**  [Methodology, rigour, selection, sources of bias, quality score on methodology quality rating scale (indicate the quality assessment tool used and the maximum possible score on that scale, e.g., 7/10 on PEDro scale), appropriateness of analytical approach (e.g., adjustments for confounding variables, management of missing data).]  Comment on missing information in original paper. |
| The present study received a 7/11 quality assessment score based on the PEDro scale where 1/11 indicates a very poor quality study and a 11/11 indicates a very high quality study. The overall quality of this trial was good because treatment allocation was concealed, the number of subjects needed per the power analysis was met using intention to treat analysis (146 subjects were needed for, 164 were recruited, and 144 fully completed), and sample attrition was low (70/82 and 74/77 subjects completed the outcome measures for the FACETS and control group respectively). Reasons for subject exclusion included the following: non-responders, drop outs (personal reasons, additionally illness diagnoses and “too much on”), being unwell, MS-related relapse, pneumonia, questionnaire lost in post, and bereavement. This study also had high external validity due to the fact that the program was “compared against what is currently happening in the NHS, in a variety of locations, and was mostly delivered by individuals not involved in developing the program but practising clinically” (page 1097).  In terms of psychometrics of the outcome measures, the authors report they were unable to find any published information on the minimal clinically important difference (MCID) for the GFS subscale of the FAI for persons with MS. They did report that they used the MCID of -0.6 points for the Fatigue Severity Scale, which shares 8/9 of the GFS items, for persons with systemic lupus erythematosus as a rough reference. As MS and lupus are both autoimmune diseases that can causes fatigue, it was acceptable to use this as a reference in the absence of published information on the MCID for MS. For the remainder of the outcome measures, the authors refer to their pervious study (Thomas et al. 2010) for full detail which outlines the justification of each measure.  In terms of weaknesses of the study, the authors acknowledge that due to the nature of the study design and intervention, subjects could not be blinded to their group assignment which produces a source of performance bias because the subjects were aware of which group they were in which may have influenced how they performed during the study. Additionally, outcome measures were self-report questionnaires which present a procedural bias and the potential for response bias from the subjects. The authors also discuss the relatively short follow-up period of 4 months and acknowledge that a longer follow-up period would be more appropriate to demonstrate sustainability of the gains main through the FACETS program.  Finally, it must be noted that the authors do not present the data for the objective measures of physical activity over 48 hours utilizing ActivPAL accelerometers, or they did not explain its representation in the demographics data well to be understood. |
| **Interpretation of Results**  [Favourable or unfavourable, specific outcomes of interest, size of treatment effect, statistical and clinical significance, minimal clinically important difference. You may calculate effect size or confidence intervals yourself from the data provided in the article.] Describe in your own words what the results mean. |
| Based on the power analysis conducted prior to the start of the study, the researchers required at least 146 subjects to achieve 80% power with 5% significance. They were able to recruit 164 subjects with 144 completing all the outcome measures. Therefore, with utilization of the intension to treat analysis, the results of this study have good confidence. The results indicate that the FACETs program was effeteness at reducing MS-related fatigue and increasing self-efficacy to overcome MS-related fatigue in a sample of persons with MS when compared to the control group. The effect sizes were moderate and the standard deviations small (to indicate a more narrow spread of data). However, it must be noted that the 95% CI range for change in the Fatigue Self Efficacy Scale for follow-up 2 was 0 to 12 where zero would indicate “no change”. |

**(3) Description and appraisal of “Randomized controlled pilot study of customized pamphlets to promote physical activity and symptoms self-management in women with multiple sclerosis” by Plow M, Bethoux F, et al. 2014.**

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| **Aim/Objective of the Study/Systematic Review:** |
| The present study aimed to investigate the feasibility and efficacy of an intervention to promote physical activity and symptom self-management through customized pamphlets in a sample of women with multiple sclerosis (MS). |
| **Study Design**  [e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]  Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| The present study is a randomly allocated 2-group repeated measures pilot study consisting of an intervention and control group. After consent to participate in the study was collected, thirty eligible subjects underwent baseline data collection for week 1. This was followed by subjects being randomly allocated to either the treatment or control group using a numbered series of 35 prefilled envelopes containing group assignment created by a random number generator. All researchers were blinded to subject group assignment until after baseline measures were taken and subjects opened their envelope. The intervention group received the intervention immediately (n=14) and the control group were delayed in receiving the intervention and instead started at week 12 (n=16). Outcome measures were administered in both groups at week 1, week 12 and week 24 by a certified personal trainer who was not blinded to subject group assignment after baseline data was collected. |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| The study took place in a metropolitan area and was community-based. |
| **Participants**  [N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]  Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| Seventy-eight female subjects were recruited and then assessed for eligibility for the present study. Recruitment was done through physician referrals, fliers in neurologists’ offices, speaking at MS self-help groups, advertising in the MS Society e-newsletters, and Facebook posts. Thirty subjects consented to participate and met the inclusion criteria which was the following: confirmed diagnosis of MS, age 18 to 65 years, and ability to ambulate 25 feet with or without a cane. Exclusion criteria included: exercising ≥ 150 minutes per week, pregnancy, confirmed diagnosis of a cardiopulmonary disease, reports of ≥ 4 falls in the past 6 months, severe cognitive deficits, unable to read or speak English at a 6th grade level, and a co-morbid condition resulting in hospitalization in the past year.  Baseline clinical and demographic characteristics were comparable between the treatment and control group except for the following: percent of subjects who received greater than 15 years of education (57% for the treatment and 38% for the control) and those classified with “gait disability” (MS interferes with activities, especially ambulation), “early cane” (ability to ambulate 25 feet in 20 seconds with an assistive device) and “late cane” (reliance on a cane to ambulate 25 feet) based on the Patient Determined Disease Steps questionnaire (Gait Disability: 29% for the treatment and 6% for the control; Early cane: 7% for the treatment and 25% for the control; Late cane: 7% for the treatment and 25% for the control).  Comparable demographics were the following: Each group was 100% female with an average age of 47±9\* years for the treatment group and 48±10 years for the control group. The average number of years since MS diagnosis was 8±7 years for the treatment group and 10±7 years for the control group. The average number of years since symptoms onset was 13±6 years for the treatment group and 14±9 years for the control group. The majority of the subjects in both groups were either full or part-time employed (57% of the treatment and 50% of the control group). Only 29% of the treatment group and 38% of the control group identified as a “racial minority”. Finally, based on the Patient Determined Disease Steps questionnaire most subjects were classified as “normal” (36% of the treatment and 25% of the control), “mild disability” (14% of the treatment and 13% of the control group), where “normal” indicates some mild mostly sensory symptoms, and “mild disability” indicates noticeable symptoms but only have a small effect on lifestyle.  \*Average value ± standard deviation |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| The control group received the same intervention (see below) as the intervention group except at week 12 (half way through the start of the intervention). |
| *Experimental* |
| The intervention group participated in an intervention modelled after the Social Cognitive Theory and the Transtheoretical model. This intervention involved the following: prescription of a maintenance home exercise program, mailing customized pamphlets about physical activity and symptom management. The subjects were prescribed an exercise program based on two one-on-one sessions about 2 weeks apart by the primary investigator. The pamphlets were customized based on the stage of change and the subject’s physical activity barriers. The first pamphlet was given to the subjects at the second exercise session and subsequent pamphlets were mailed to the subjects about every 3 weeks for the duration of the intervention (24 weeks). Pamphlets alternated between information on physical activity and symptom management. |
| **Outcome Measures** (Primary and Secondary)  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| The outcome measures of the present study assessed the following constructs: physical activity level, physical function, symptom severity and symptom impact. In more detail, the following outcome measures were administered to both groups at week 1, week 12 and week 24: physical activity level was assessed by a revised Physical Activity and Disability Survey (PADS) and the Godin Leisure-Time Exercise Questionnaire (GLTEQ) where a higher score on each indicated greater physical activity level; physical function was assessed by the SF-12 physical composite survey (SF-12 PCS) where a higher score indicated better physical functioning; symptom severity was assessed by the Symptoms of Multiple Sclerosis Scale (SMSS) where a lower score indicated reduced symptom severity; and symptom impact was assessed by the Multiple Sclerosis Impact Scale (SIS) where a lower score indicated decreased symptom impact. To further quantify disease severity the Patient Determined Disease Steps questionnaire and the Senior Fitness Test was administered was administered at baseline. The fitness test consisted of a 6-minute walk test, sit and reach test, back scratch test, chair stands, arm curls and 8-foot up and go test. All questionnaires and the fitness test were administered by a certified personal training that was not blinded to subject group assignment (after baseline measures were taken and subjects opened group assignment envelopes). |
| **Main Findings**  [Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided – if you need to calculate these data yourself, put calculations here and add interpretation later, under ‘critical appraisal’ on next page] |
| The main findings of the present study were that there were significant improvements in the intervention group compared to the control group in terms of improved physical activity levels and health and function outcomes (per MANOVA analysis).  In more detail the intervention group demonstrated a moderate effect size (ES) for the following outcome measures when compared to the control group: GLTEQ with a between subject ES of 0.63 and within subject ES of 0.55 (Intervention/Control group: week 1- 14.36±11.92/16.22±17.29; week 12 - 33.07±21.42/21±18.53; week 24: 30.54±13.23/23.06±17.22), SF-12 PCS with a between subject ES of 0.63 (within subject ES was low at 0.22) (Intervention/control group: week 1 – 43.87±7.29/40.45±11.06; week 12 – 47.07±8.28/41.86±11.53; week 24 – 45.27±9.47/41.86±11.53), and MSIS with a between subject ES of 0.61 (within group ES was small at 0.13) (Intervention/control group: week 1 – 58.57±22.45/62.31±20.74; week 12 – 53.57±17.94/67.13±26.46; week 24 – 52.29±23.51/65.38±28.02). The PADS had a large ES with between subject ES of 0.89 and within subject ES of 0.78 (intervention/control group: week 1 – 0.01±0.83/0.36±1.09; week 12 – 0.98±0.76/0.14±1.13; week 24 – 0.77±0.74/0.68±1.01). Finally, the SMSS had a small ES: SMSS with between subject ES of 0.36 and within subject ES of 0.28 (intervention/control group: week 1 – 2.56±0.58/2.56±0.67; week 12 – 2.32±0.57/2.55±0.72; week 24 – 2.24±0.63/2.42±0.72). |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| The authors conclude that this pilot study “indicates that a customized print-based intervention shows promise in improving physical activity levels and health and function in women with multiple sclerosis” (page 139). |
| **Critical Appraisal** |
| **Validity**  [Methodology, rigour, selection, sources of bias, quality score on methodology quality rating scale (indicate the quality assessment tool used and the maximum possible score on that scale, e.g., 7/10 on PEDro scale), appropriateness of analytical approach (e.g., adjustments for confounding variables, management of missing data).]  Comment on missing information in original paper. |
| The present study received a 8/11 quality assessment score based on the PEDro scale where 1/11 indicates a very poor quality study and a 11/11 indicates a very high quality study. Due to the nature of the study design and intervention, subjects could not be blinded to their group assignment. This produces a source of performance bias because the subjects were aware of which group they were in which may have influenced how they performed during the study. Additionally, the majority of the outcome measures (with exception of the 6 minute walk test) were self-report questionnaires which present a procedural bias and the potential for response bias from the subjects.  The researchers determined whether there were any significant differences in the outcome measures between groups at baseline or if there were any differences between groups in light of any potential confounders at the week 12 and week 24 time points. They also utilized MANOVAs and an intent-to-treat analysis which is appropriate for the data. Finally, the number of subjects was appropriate for a pilot study design. |
| **Interpretation of Results**  [Favourable or unfavourable, specific outcomes of interest, size of treatment effect, statistical and clinical significance, minimal clinically important difference. You may calculate effect size or confidence intervals yourself from the data provided in the article.] Describe in your own words what the results mean. |
| The results of this study demonstrated moderate to high effect sizes for change in GLTEQ, SF-12 PCS, MSIS, and PADS outcome measures. These results indicate that customized pamphlets about physical activity and symptom management have the potential to improve physical activity levels and health and function in ambulatory women with MS. The results do not necessarily indicate whether this intervention would be effective for non-ambulatory women with MS (i.e. EDSS score >7) so may not be appropriate for a more advanced population. |

**IMPLICATIONS FOR PRACTICE and FUTURE RESEARCH**

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| Collectively, this evidence applies to my clinical question because it highlights the importance and potential effeteness of a self-efficacy building intervention in individuals with MS. Ennis et al. 2006 indicates that a health-promoting educational group program can be utilized to increase participation in health-promoting activities, self-efficacy to undertake these activities, and certain domains of quality of life in persons with mild to moderate MS. Thomas et al. 2013 demonstrated that a 6 week group fatigue-management program (FACETS) was effective in reducing MS-related fatigue severity and increasing self-efficacy to overcome MS-related fatigue in a group of subjects with MS, and has the potential to be a clinically useful and relatively inexpensive addition to current local practice interventions for persons with MS. Plow et al. 2014 demonstrated the potential of customized pamphlets for women with MS to help promote physical activity and MS-related symptom self-management. Individually the studies do not fully answer my clinical question.  Ennis et al. involved subjects with an EDSS score between 1.0 and 7.0 (my clinical questions involves persons with MS with an EDSS score >7.0). Additionally, this study did not discuss physical therapy or whether or not the usually care of the control group included physical therapy. However, it still highlights the importance of self-efficacy building techniques to help improve participating in health promoting activities, such as exercise, and will help contribute to my search of the answer. The researchers report that the OPTIMIZE program is easily replicated and appropriate for persons with mild to moderate MS (EDSS score of 1.0-7.0); therefore, it would be interesting to ascertain if this program could also be utilized in person with more advanced MS (EDSS score >7.0). Finally, future research could also explore the feasibility and effectiveness of the OPTIMIZE program, or similar program, in physical therapy for persons with MS.  Thomas et al. involved ambulatory subjects with MS that included benign, relapsing-remitting, secondary progressive and primary progressive. However, because these subjects were all ambulatory (32% of the intervention and 27% of the control group at minimum required an assistive device to walk 100 meters) it cannot be determined by the results whether the FACETS program could be utilized in a more advanced MS population. Despite this, the results are promising and due to the utilization of PowerPoint presentations to deliver the educational material, the intervention could be easier replicated in the PT clinic and tailored to a more advanced MS population.  Plow et al. involved ambulatory women subjects with MS; the type of MS was not specified. The results indicate that customized pamphlets about physical activity and symptom management have the potential to improve physical activity levels and health and function in this sample. However, the results do not necessarily indicate whether this intervention would be effective for non-ambulatory women with MS (i.e. EDSS score >7) so may not be appropriate for a more advanced MS population such as individuals with primary progressive and secondary progressive MS. Regardless, there are other studies to support the potential benefits of self-efficacy building interventions (see above) so the intervention described by Plow et al. shines additionally light on the potential benefits of a print-based self-efficacy building intervention. What was also really good about this study was that it utilized a home exercise program as a component, which the other two articles did not.  Implications for future research should focus on subjects with a more advanced disability level (ie. EDSS score >7.0) and an intervention that incorporates both a self-efficacy building intervention and physical therapy intervention. There should also be additional research none on the cost-effectiveness of such a program to help justify reimbursement of a program in a rehab clinic. Such studies will be very important for insurance companies to understand the benefit of these programs for persons with MS.  Together the results of the above three studies suggest the potential benefits of a self-efficacy building intervention via print-based materials, PowerPoint presentations and group sessions for individuals with MS in terms of improving physical activity participation, fatigue level, symptom management and domains of quality of life. A PT could utilize these results to justify a self-efficacy building program in the clinic for the MS population. |

*Notes on Implications Section*

* *This section synthesizes your comments from the appraisal of your articles, and may mention other related research that you have read or that supports your interpretation and discussion*
* *Comment on whether the intervention is used in practice in your region/country, cost of that treatment, need for education of local therapists/students about this intervention and/or outcome measures used in the CAT*
* *Students may wish/need to discuss implications with clinicians or peers for suggestions -- use the discussion board!*
* *This section should be ¾-1 page*
* *Be sure to address both implications for clinical practice and future research (separately)*

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[List all references cited in the CAT]

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