CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

For a 70-year-old woman with secondary-progressive MS who has limited ambulation (P), is home health PT (I) more beneficial that non-skilled caregiver assisted exercise (C) for long-term mobility and outcomes as seen by the 6MWT (O)?

AUTHOR

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CLINICAL SCENARIO

The patient is a 70-year-old female with secondary progressive MS who has limited walking ability with assistance. This patient lives at home with her 70-year-old husband, who is her primary caregiver. The patient's husband has a hard time physically assisting the patient with daily transfers and with her exercises prescribed by a physical therapist, although she is not currently receiving any physical therapy services. Her husband has difficulty finding caregiver assistance from either CNA's, students, volunteers, etc. that he feels are adequately educated on MS to help the patient with all of her care needs, which largely includes helping her perform her exercises correctly. They are not able to get home health PT services for long term maintenance due to lack of insurance approval. I am wondering if a caregiver assistance with HEP has a comparable impact on the patient's mobility/health as home health or outpatient physical therapy treatment. This is important in addressing the overarching issue in our healthcare system's lack of reimbursement/recognition for the importance of long-term maintenance care physical therapy services for MS.

SUMMARY OF SEARCH
[Best evidence appraised and key findings]

Eight studies met the inclusion criteria, including 3 RCTs, 2 qualitative studies, 2 systematic reviews, and 1 expert review.

The overall quality of studies that addressed my PICO question was low/moderate, even with broadening my inclusion criteria. Only 3 out of 8 studies were level 1 evidence, and only 1 was moderately relevant to my PICO question, the others being low relevance. Additionally, the studies included were not similar in study design or outcome measures used, as most studies addressing caregivers of people with MS do not discuss physical demands of the caregiver relating to assisting with exercise programs for people with MS. Additionally, all studies identified looked at patients with the broad diagnosis of MS and did not perform specific measurements on patients with secondary progressive MS in older age, as mentioned in my PICO question. Overall, more specific research would need to be conducted in order to precisely capture my specific exclusion criterion and to improve the quality of evidence available to address this PICO question.

CLINICAL BOTTOM LINE

Patients with progressive MS should receive physical therapy treatment in order to improve mobility outcomes, with outpatient and home health being more beneficial than no physical therapy services. Additionally, physical therapy intervention can potentially decrease dependence on caregiver for ADLs and mobility in the long term due to long term gains in activity and participation observed both in the inpatient and outpatient settings. More studies must be performed to determine the effect of home exercise programs implemented by caregivers on patients who are completely dependent for mobility with more severe disability due to progressive MS. Telerehabilitation has future potential to improve gaps in care in patients who do not have access to home health or outpatient physical therapy services.

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

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
"Women with secondary-progressive MS", "Secondary-progressive multiple sclerosis", "Multiple sclerosis", MS	Home health, home based, "physical therapy", rehabilitation, physical rehabilitation, exercise,	Non-skilled caregiving, Caregiv*, maintenance care	Long-term mobility outcomes, mobility, impact on mobility, 6MWT, walk*, ambulat*

Final search strategy (history):

Show your final search strategy (full history) from PubMed. Indicate which "line" you chose as the final search strategy.

PubMed

"Multiple sclerosis" AND (caregiver OR "caregiver education" OR "maintenance care") AND (mobility OR "mobility outcomes" OR "long term mobility")

"Secondary-progressive multiple sclerosis" AND "home health physical therapy" AND caregiving AND mobility

multiple sclerosis AND physical therapy AND caregiving AND mobility

multiple sclerosis AND home health AND caregiving AND mobility

multiple sclerosis AND caregiver AND (mobility OR long-term mobility OR outcomes)

"Caregiver impact" AND mobility AND multiple sclerosis

"Multiple sclerosis" AND "long-term mobility" AND exercises

(MS OR "multiple sclerosis") AND ("home health physical therapy" OR "physical therapy" OR caregiver OR "non-skilled")

"Multiple sclerosis" AND (caregiver OR "maintenance care") AND (mobility OR "mobility outcomes" OR "long term mobility") NOT stroke

(MS OR "multiple sclerosis") AND ("home health physical therapy" OR "physical therapy" OR caregiver OR "maintenance care") AND (mobility OR "mobility outcomes" OR "long term mobility")

(MS OR "multiple sclerosis") AND ("home health physical therapy" OR "physical therapy" OR caregiver OR "maintenance care") AND (mobility OR "mobility outcomes" OR "long term mobility") NOT "occupational therapy" NOT stroke NOT Parkinson's NOT "manual therapy" NOT vestibular NOT aquatic NOT sports NOT Alzheimer's NOT fracture NOT diabetes NOT "spinal cord injury"

PEDro

Abstract and title: multiple sclerosis home health

CINAHL

"Multiple sclerosis" OR MS AND mobility AND "home health" or caregiver

In the table below, show how many results you got from your search from each database you searched.

Databases and Sites Searched	Number of results	Limits applied, revised number of results (if applicable)
PubMed	**33**	**7**
PEDro	**25**	**8**
CINAHL	**37**	**6**

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
- Subjects with a diagnosis of Multiple Sclerosis

- Subjects must be receiving either caregiver assist with mobility/ADLs, home health PT, outpatient PT
- At least 1 indicator of long-term health or mobility outcome

Exclusion Criteria

- Subjects with other neurological or medical diagnosis
- Non-human subjects
- Non-English language
- Case studies
- Pharmacological or surgical intervention

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

For each article being considered for inclusion in the CAT, score for methodological quality on an appropriate scale, categorize the level of evidence, indicate whether the relevance of the study PICO to your PICO is high/mod/low, and note the study design (e.g., RCT, systematic review, case study).

Author (Year)	Risk of bias (quality score)*	Level of Evidence**	Relevance	Study design
Aronson et al. (1995)[1]	CASP checklist 8/10	1	**Low – This study largely focused on unaddressed needs of caregivers for people with MS and lack of utility of resources and referrals for assistance. Majority of caregivers reported they were the spouse of the individual with MS. Caregivers report helping mostly with ADLs. The study did not record time that the caregiver spent helping the person with MS perform exercises. Home visits and referral to recreational activities was ranked the lowest importance from caregivers. Respite care is underutilized by caregivers. Caregiver needs need to be considered to prolong home care and postpone early institutionalization of people with MS.**	**Cross sectional survey** **Random selection of patients with MS from MS society database and from 5 MS clinics in Ontario, representing a broad population of urban and rural dwellers. A survey was sent by mail and included responses from 697 people with MS and 345 caregivers.**
Di Fabio et al. (1998)[2]	PEDro scale 4/10	3	**Moderate -** **The treatment group in this study who received long-term outpatient multidisciplinary services including physical therapy for 1 year had significantly reduced severity of symptoms and fatigue compared**	**Nonequivalent pretest/posttest control-group design** **(No random assignment)**

			to no services. This study is not specific to physical therapy intervention and includes supportive services and occupational therapy in as well. The outcome measure used was a MS-related symptom checklist score with mobility components.	
Rae-Grant et al. (2011)[3]	AMSTAR 10/11	1	**Low -** This study focused on the efficacy of self-management programs for individuals with MS and other neuro diagnoses, including counselling, home-based exercise programs, and community fitness programs. The author concludes that there are benefits to promoting self-management to patients with MS to improve overall outcome.	**Systematic Review** which excluded studies that only investigate caregiver intervention, single case reports, commentaries, and articles. Included self-management intervention of neuro disorders. 36 articles in total were included in the review, 3 of which were class I evidence.
Patten et al. (2012)[4]	CASP checklist 7/10	3	**Moderate –** People with MS reported more caregivers and more unmet health needs compared to people without MS and with disability. Unmet needs are overall only partially met by current healthcare services according to this study.	**Descriptive qualitative study** Participation and Activity Limitation Survey (PALS) was a post-census survey collected in Canada in 2006. 22,513 responses were collected from individuals with impairments, 245 of which had MS.
Dunn et al. (2010)[5]	JBI critical appraisal checklist for text/opinion 6/6	2	**Low -** This study focused on the increase in caregiver burden with decreased mobility in people with MS. This study emphasizes that one main goal	**Narrative/expert review** which examined studies from 1980-2009 related to needs and impact of caregiving for patients with MS. Included studies focusing on mobility impairment and loss

			of rehabilitation treatment should be caregiver training, as the caregiver is often not adequately prepared for the physical skills required for transfers while preventing injury to themselves. No report of mobility outcomes nor physical therapy intervention.	of independence impact on caregiving from the caregiver or patient perspective. An exhaustive search was not conducted.
Carton et al. (2000)[6]	**PEDro scale** **3/10**	**3**	**Low -** **This study found that patients with higher disability grades received 4-6 times more informal caregiver help than professional help with ADLs and mobility. The cost of informal care at home and institutionalization of these individuals seems to be equivalent in price. Patients lived in a variety of different settings with varying levels of need for assistance. Data collected included the Kurtzke Disability Status Scale, an interview, and a 4-week prospective diary.**	**Prospective diary with data collection over 19 months. 130 patients with MS with caregivers who could provide reliable information completed the study, although this was not a random sample.**
Amatya et al. (2019)[7]	**AMSTAR** **11/11**	**1**	**Moderate –** **This is a broad review of evidence-based rehabilitation for people with MS. The author concludes that PT modalities improved mobility and strength, reduced impairment, and improved QOL; as well as IP/OP rehab programs lead to longer term gains in activity and participation. Low**	**Systematic Review** **search of Cochrane library database for effectiveness of rehabilitation for MS. 15 reviews, including 164 RCTs and 10,396 participants, were used. A wide variety of interventions were included, such as OT, PT, nutrition, and others.**

			quality evidence suggests symptom management programs and telerehabilitation improved some outcomes, which may be comparable to caregiver or home-based non-skilled care.	
Wiles et al. (2001)[8]	**PEDro Scale 7/10**	**2**	**High -** **This study compared the benefits of HH, OP, and no therapy on mobility, specifically walking ability. This study found ongoing PT, either in HH or OP to be beneficial to mobility, well-being, and mood in patients with chronic MS.**	**Randomized controlled crossover trial including patients with chronic MS who have difficulty walking. Subjects were referred from a neurology clinic. Treatment given was either home health PT, outpatient PT, or no PT and consisted of 3 eight-week treatment periods, separated by eight-week intervals.**

*Indicate tool name and score

**Use Portney Table 36-1: Summary of Levels of Evidence (2020). If downgraded, indicate reason why.

BEST EVIDENCE

The following 2 studies were identified as the 'best' evidence and selected for critical appraisal. Rationale for selecting these studies were:

> Amatya et al. (2019) was identified as level 1 evidence, 11/11 quality using the AMSTAR, and was of moderate relevance to my PICO question. This Cochrane review addresses multiple interventions for rehabilitation of patients with MS and only a portion of the review had a focus on physical therapy intervention with this patient population. However, this review provides an in-depth analysis of the evidence-based benefits of PT in different settings on long-term mobility. Overall, the high reliability and low risk of bias in this review allows for increased confidence in the evidence presented in this review and utility in clinical practice.

> Wiles et al. (2001) was identified as level 2 evidence, 7/10 quality using the PEDro scale, and was of high relevance to my PICO question. This RCT identified the mobility benefits of participation in either OP or HH PT programs as compared to no PT intervention in people with MS. The authors also describe potential positive effects of both OP and HH PT on mood and well-being. Overall, the high relevance of this study for the clinical scenario at hand compared to other relevant studies led to the selection of this study.

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of *Rehabilitation for people with multiple sclerosis: an overview of

***Cochrane Reviews* by Amatya et al., 2019**

Aim/Objective of the Study/Systematic Review:
The purpose of this systematic review is to evaluate Cochrane reviews for the effectiveness of rehabilitation for people with MS, improve outcomes, and identify remaining gaps in evidence.
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 is a systematic review of all Cochrane published systematic reviews addressing rehabilitation for patients with MS. The authors searched the Cochrane database for effectiveness of rehab broadly for MS. 15 reviews, including 164 RCTs and 10,396 participants, were used. A wide variety of interventions were included, such as OT, PT, nutrition, and others. The reviews included were published between 2003 and 2016 and included RCTs, CCT, and in some cases RCTs with a follow-up period of 6 months or longer.

Inclusion criteria were all modalities of rehabilitation in people with MS, such as physical therapy, occupational therapy, endurance training, resistance training, orthotics, casting, TENS, vocational therapy, etc. or multidisciplinary rehab programs with two or more disciplines.

Search terms are listed below as directly listed in the study (p.28):

Multiple Sclerosis, Demyelinating Diseases, Transverse myelitis, Optic Neuritis, Acute disseminated encephalomyelitis
Rehabilitation, Ambulatory Care, Physical Therapy Modalities, physiotherapy, Exercise therapy, Cognitive therapy, psychotherapy,
Behavior/behavior therapy, Social work, Counselling, Occupational Therapy, Dietetics/Nutrition, Orthotics/brace/orthoses, Acupuncture
Patient Care Team, multidisciplinary/ integrated team, cold treatment/cooling, assistive technology device, hydro/pool therapy,
Electromagnetic therapy, nerve stimulation, vibration therapy, social participation/support, vocational rehabilitation
Systematic review/meta-analysis, Review, Adult; Humans

Systematic reviews included in this study were assessed based on quality of evidence using the GRADE assessment, which ranks reviews either low, moderate, or high quality based on several factors including risk of bias, inconsistency, indirectness, imprecision, and publication bias. Additionally, reviewers assigned a score of 1-4 to criteria of the R-AMSTAR tool to each review for quality assessment. The sum of total scores ranged from 11-44 and were used to grade overall methodological quality.

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

Settings included in the reviewed systematic reviews were ambulatory outpatient settings either located within hospitals or at a specialty rehab clinic, home-based settings including telehealth and home health visits, and inpatient rehab settings within hospitals with 24-hour care. The countries in which the included studies were performed in each systematic review was not mentioned. Physical therapy intervention specifically included inpatient, ambulatory, and long-term/community setting reviews.

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.

A total of 10,396 participants were included across all 15 reviews in this study. 2770 participants total were from studies regarding exercise related interventions. Participants in each review included adults aged 18 years old or older with all subgroups of MS, including (relapsing-remitting, secondary-progressive, primary-progressive, and progressive-relapsing MS). This study does not provide a table of more specific details on mobility deficits nor other details of participants included in each review.

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control

The control groups in each review are poorly defined as either placebo, non-exercise control, lower-level intervention, usual care, or no treatment.

Experimental

Experimental interventions included either single discipline or multidisciplinary care for rehabilitation of people with MS. All experimental groups included were multidisciplinary rehabilitation, physical therapy, hyperbaric oxygen therapy, whole body vibration, occupational therapy, neuropsychological, cognitive rehabilitation,

memory rehabilitation, information provision, dietary intervention, vocational rehabilitation, telerehabilitation, and spasticity management interventions.

Interventions listed in reviews focused on mobility outcomes were non-pharmacological spasticity management, exercise therapy, multidisciplinary rehab, telerehabilitation, whole body vibration, and OT. I am particularly interested in those experimental interventions that were compared with no treatment, simulating a patient receiving no skilled services at home with their caregiver. These interventions were telerehabilitation and exercise, broadly.

Outcome Measures

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

A variety of outcome measures were used in the included reviews in this study due to the varied presentation of MS-related disability and goals of interventions within each specific study. Specific outcome measures were not a part of the inclusion criteria for this study. Primary outcome measures reported include the following as listed from the study (p.5):

Function: FIM, TUG, BI, 10-meter-walk test, other subjective measures alone

Symptoms: VAS for pain, MAS for spasticity, Tardieu scale

Quality of Life: MSQOL

Impact on caregivers and measurement of goal achievement were reported as a secondary outcome in this review. Specifics of these outcome measures were not reported in each review, as many reviews included studies with non-homogenous assessments.

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. You may summarize results in a table but you must explain the results with some narrative.]

In a review of the effect of exercise therapy on fatigue, they found a significant effect of exercise therapy compared to no exercise for endurance training (SMD -0.43, 95% CI -0.69 to -0.17; $P < 0.01$), mixed training (SMD -0.73, 95% CI -1.23 to -0.23; $P < 0.01$), and other training (SMD -0.54, 95% CI -0.79 to -0.29; $P < 0.01$). Exercise compared to no exercise resulted in a significant effect on fatigue (95% CI -0.73 to -0.33; $P < 0.01$).

In another review that evaluated the effect of exercise on ADLs and QOL compared to no exercise, there was strong evidence that exercise improved muscle power, exercise tolerance, and mobility related activities. Moderate evidence suggested improvement in mood in exercise groups.

Low quality evidence was present for telerehabilitation of any form to have a positive effect in reducing short term disability or impairments, or long-term functional activities, psychological outcomes, or QOL.

Moderate quality evidence was present for physical therapy modalities including exercise on reducing patient reported fatigue. Low quality evidence was present for the benefit of outpatient and home-based multidisciplinary programs in providing short term improvement in symptoms. However, moderate quality evidence was present for inpatient or outpatient multidisciplinary rehabilitation programs improving participation outcomes up to 12 months.

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

Moderate quality evidence suggests that PT modalities improved mobility and strength, reduced impairment, and improved QOL; as well as inpatient and outpatient rehab programs lead to longer term gains in activity and participation. Low quality evidence suggests symptom management programs and telerehabilitation improved some outcomes. Telerehabilitation overall lacked high quality evidence, however the author states that it may still be desirable for cost-effectiveness and more convenient for patients who are unable to or have difficulty leaving their homes. Additionally, telerehabilitation may be beneficial for patients in more remote areas. Overall, this review contains a wide variety of interventions for rehabilitation of people with MS. The author concluded that many of the evaluated exercise interventions included were very broadly defined, specifically aerobic, strength, flexibility, mobility, range of motion, postural control, balance training, bicycle, and ergometry. Failure to provide specific details on setting, intensity, frequency, and duration, make it difficult to identify what the causative factor in the interventions were. Finally, the author concludes that the type and setting of rehabilitation should be tailored to the patient's specific needs. With such broad variety in evidence for rehabilitation treatment for people with MS, several combinations of modalities may be used depending on the patient preference and provider's clinical judgement.

Critical Appraisal

Validity

[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.]

Overall, this review presents with high quality internal validity as noted by the author's attempt to rank risk of bias and quality of included reviews. Most reviews only included English published studies in their review. Additionally, only Cochrane published systematic reviews were included. Both factors serve as possible limitations in the completeness of this review and the attempt to be comprehensive in rehabilitation for people with MS. These factors were listed by the author, indicating awareness of this potential limitation and implication for future reviews. Several reviews included studies with relatively small sample sizes, heterogeneity of MS type, clinical presentation, and goals for treatment. These factors overall make for a systematic review that may be difficult to implement in a specific clinical scenario, but rather is better for indicating trends among the population of people with MS. Lack of description of usual care or control groups was provided in most cases, in addition to lack of description of exercise groups, further creating difficulty for reassurance of the validity of the interventions included in the review. Additionally, there was lack of blinding of participants, assessors, and lack of description of randomization methods in many studies. This causes concern regarding the internal validity of the studies included in the reviews. This review does not include a statistical analysis of data due to the broad report of outcomes, patients, and time periods. The grading system for quality of evidence seems more subjective than objective, although the AMSTAR overall is a common measure used in the assessment systematic reviews.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

I find this review to have strengths in identifying major rehabilitation modalities that are supported by higher quality evidence in the literature. However, this review is quite non-specific. Treatment interventions as well as control interventions were under defined both in this review as well as the reviews included. Overall, the results of this study do reveal the clinical significance for physical therapy intervention on improving mobility, strength, and quality of life in patients with MS across all settings. Additionally, telerehabilitation may be a cost-effective option for patients who are unable to meet in person for physical therapy treatment and may increase motivation and adherence to exercise in this population over no rehab all together, however outpatient or home health would be the best options. Additionally, maintenance care for people with MS in both outpatient and inpatient settings seems have more evidence for long term benefit over short term benefit, suggesting that people with MS should be encouraged and provided the opportunity to participate in these long-term maintenance programs. Additionally, all patients with MS present with different challenges and individual circumstances must be considered when implementing a treatment plan. Collaboration with multidisciplinary teams has potential to improve overall outcomes in this population.

Applicability of Study Results

[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.]

This Cochrane review is obviously very broad when discussing evidence supported MS rehabilitation treatment and does not directly answer my PICO question. My thought process in selecting this article for my CAT analysis was to look at collective data from many studies that can begin to address my PICO question, since I was unable to find a study that directly investigated my PICO question. As stated above, this study does not go into detail regarding specific dosage recommendations for physical therapy intervention in people with MS and only discusses the benefit of intervention in general, making clinical replicability extremely difficult. Additionally, this study does not define usual care, no intervention, control groups and whether these patients in these groups were active on their own or participated in other community exercise groups, which might skew the results of the studies. We can apply the general finding of moderate quality evidence supporting outpatient and home health physical therapy services on mobility and long-term outcomes in patients with MS, which is relevant to the clinical scenario.

(2) Description and appraisal of *Controlled randomised crossover trial of the effects of physiotherapy on mobility in chronic multiple sclerosis* by Wiles et al., 2001

Aim/Objective of the Study/Systematic Review:

The objective of this study was to determine if physical therapy can improve mobility in multiple sclerosis and determine if there is a difference in treatment outcomes in home health vs. hospital outpatient settings.

Study Design

This study is a randomized controlled crossover trial that consists of patients diagnosed with MS who were referred from a neurology clinic to participate in the study. The treatment groups included home health PT, outpatient PT, or no PT. Each patient received three separate 8-week treatment periods of all three interventions (no therapy, home health therapy, and outpatient therapy) with random allocation of what order they would receive the treatment (six possible permutations). Each treatment period was separated by an 8-week rest period before beginning the next treatment period. All assessments and outcome measures used were carried out the week before and the week after each 8-week treatment period. There were two physical therapists who performed the treatment sessions. The same physical therapists treated the same patients for both active treatment periods. A separate blind assessor performed the assessments and outcome measures. Sealed envelopes were given to the treating physiotherapists to blind them from the allocation of groups.

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

Participants were treated in their homes as well as in outpatient neurology hospital clinics associated with the University Hospital of Wales in a metropolitan area of the UK. The outpatient clinics had access to adequate space and equipment for treatment sessions, whereas participant's houses vary in size and equipment available.

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.

45 patients with MS who complained of difficulty walking were referred, and 42 were recruited from the University Hospital of Wales to participate in this study. The recruited patients were called and screened for eligibility in the study. Inclusion criteria were at least 18 years old, able to walk 5 meters with or without an assistive device, and able to attend the outpatient hospital clinic twice per week for 8 weeks as well as agree to therapy in their home for the same amount of time. The exclusion criteria were that the participant could not be in a current relapse, nor could they have any other major medical or surgical disorders, or pregnant. The average age was 47.2 years old and 27 out of 42 participants were women. The EDSS of participants ranged from 4.0 to 6.5, with the majority at a 6.0-6.5 EDSS. 2 participants dropped out during the study; therefore 40 participants were used for statistical analysis. One participant did not complete all assessments.

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control

The control treatment period in this study was the eight weeks of no physical therapy intervention. Participants were assessed the week before and after this eight-week period for changes in outcome measure scores for comparison to the two treatment groups, home health PT and outpatient PT. Each participant underwent a period of no therapy, either before the two other treatment periods, in the middle of the treatment periods, or after the two treatment periods. The assessments were performed by a blind assessor who was not one of the physical therapists working with the patient during the other two treatment periods. It was not specified whether the patients were completely inactive during this period of no physical therapy or if they were able to independently complete a home exercise program.

Experimental

The experimental treatment groups consisted of home health physical therapy and outpatient physical therapy sessions. All participants received both treatments for 45-minute sessions, two sessions per week on different days of the week, for 8 weeks separated by an 8-week rest period. The physical therapy sessions at home focused on specific functional activities and the sessions in the outpatient clinic focused on facilitation techniques, although both were similar in some regards. Each participant underwent both experimental treatment periods in randomized orders. The assessments were performed by a blind assessor who was not one of the physical therapists working with the patient during the treatment periods. The author of the study included an appendix of the techniques used by the physical therapists during the treatment sessions, which I have condensed into Table 1.

Table 1:		
Techniques used during all treatment sessions	**Home session specifics to treatment**	**Hospital outpatient specifics to treatment**
Goal setting; trunk mobility; pelvic control; facilitation of movement into different postures, movements, and through alterations in tone; facilitation of normal movement in trunk, limbs, head, and neck; proprioception, mobilizing shortened tissue, stretches, gait re-education, HEP, advice on seating, wheelchair, bathing, posture, exercise, and continence; referrals as appropriate, functional activities, and provision of information about MS	Functional activities such as stairs, bath access, bed mobility, seating, access to house and car, community locations; restriction of space and equipment; interference and incorporation of social activities during sessions; and increased patient ability to identify objectives related to their home environment	More treatment time on facilitation techniques, therapists set objectives for session, colleagues available for collaboration, less distractions, available adjustable equipment for more specific treatment

Outcome Measures

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

All measures were given by a blind assessor. The RMI was performed the week before and after each treatment period as well as 8 weeks after the final treatment period. All other secondary measures were performed after each visit. The primary outcome assessment was the RMI (Rivermead Mobility Index), which is scored from 0-15. The measure includes 15 yes or no questions for ability to perform several functional mobility tasks, progressing from turning over in bed to running. The scale also includes stair climbing, walking 10 meters, transfers, balance, and bathing.

The secondary measures reported included visual analogue scales of 3 outcomes and an anxiety and depression scale. A visual analogue scale of patient mobility, caregiver mobility, and falls concern were taken immediately after each treatment session from the patient and their caregiver. This was given to assess to what extend the therapy objectives were achieved. A hospital anxiety and depression scale was also given to the patient both pre and post treatment periods.

Other secondary outcome measures included Barthel ADL index, Frenchay activities index, Nottingham extended ADL, single leg balance time, functional ambulation category, 6-meter walk, nine-hole peg test, assessor's global view of mobility change, and short orientation-memory- concentration test. The author did not provide a rationale for selection of outcome measures.

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.]

The primary outcome measure, the post-test RMI, showed a significant difference (p<0.001) between either home health, outpatient, or no treatment. However, no significant difference was found between the order that the treatment periods. The study found hospital outpatient treatment over no treatment was more beneficial by 1.4 units (95% CI 0.6 to 2.1) and home treatment was more beneficial over no treatment by 1.5 units (95% CI -0.65 to 0.87). There was no statistically significant difference between home and outpatient treatment.

Other measures included in the ANOVA analysis were single leg balance time, 6-meter walk time, nine-hole peg test time, and global mobility change scale (scored from 0-100), and HADS-anxiety and depression scales (scored from 0-21). Visual analogue scales were scored from 0-100. Balance scores, anxiety, and depression scores all increased post treatment as well, however not at a statistically significant amount. No statistically significant improvement in the 6-meter walk was found between either home or outpatient care and no care, although home care compared with no care had a p value of 0.001, which was very close to statistical significance. Additionally, both global mobility change scores and visual analog scale for patient mobility scores were statistically significant post-treatment when compared with no treatment, with no significant difference between home treatment and outpatient treatment. Interestingly, the results of the remaining secondary outcome measures were not included in the analysis, as the author reports the results did not change the outcome of the study. However, the author does state that the Barthel Index scores likely showed a ceiling effect, balance scores improved with treatment, and anxiety and depression scores improved after both home and hospital outpatient treatment.

Table 2:

Outcome Measure	Setting Comparison	Effect size	95% CI	P-value
Rivermead Mobility Index	Outpatient/no therapy	1.4	0.62 to 2.14	<0.001
	Home/no therapy	1.5	0.73 to 2.26	<0.001
	Home/outpatient	0.1	-0.65 6o 0.87	0.77
6-meter walking time	Outpatient/no therapy	4.82	1.57 to 8.07	0.004
	Home/no therapy	5.49	2.19 to 8.80	0.001
	Home/outpatient	0.68	-2.64 to 3.99	0.69
Global mobility change scale	Outpatient/no therapy	19.8	14.0 to 25.7	<0.001
	Home/no therapy	22.4	16.6 to 28.3	<0.001
	Home/outpatient	2.6	-3.2 to 8.4	0.38
VAS-patient mobility	Outpatient/no therapy	25.2	18.3 to 32.0	<0.001
	Home/no therapy	24.2	17.3 to 31.0	<0.001
	Home/outpatient	-1.0	-7.8 to 5.8	0.77

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

The author concludes that mobility can be improved at a significant amount in patients with MS outside of the inpatient setting. The results of this study showed no difference in benefit of home therapy or outpatient therapy, as both were beneficial over no therapy all together, although caregivers preferred the home setting. The author specifies that participants may have benefitted from the intervention periods even during the no treatment period as a result of the physical therapy intervention, potentially raising these scores and masking the true benefit of therapy treatment vs no therapy treatment. Additionally, the author was unable to state the dosage of treatment required to obtain these effects, as the sessions in this study varied on an individual basis. The author addresses the potential for positive effects of education and motor behavior to carry over from treatment period to treatment period, depending on what order the participant had them in, although they did not see this occur in the results. There was a small, insignificant improvement in depression scores after outpatient intervention, which may suggest positive psychological benefit for the patient to participate in therapy outside of their home. Overall, physical therapy treatment twice per week for 8 weeks compared to no treatment results in improved mobility, wellbeing, and mood in patients with MS. These benefits, however, are short-lived, suggesting ongoing physical therapy may be necessary to sustain benefits in mobility and prevention of decline.

Critical Appraisal

Validity

[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.]

Overall, the internal validity is fair in this study, as the assessors and therapists were blinded to allocation of treatment periods and the study was randomized. However, the study presents with several external validity flaws. The same physical therapist performed both outpatient and home health sessions for the same patients, which doesn't typically happen clinically. This allowed for continuity in treatment progression and goals, whereas this might vary if patients receive a new physical therapist when transitioning from outpatient care to home care. Additionally, each participant had an 8-week rest period in between treatment periods. The authors did not state the mobility instructions, if any that were given to the patient during this period, if any. Patients who are more active on their own may have continued to improve during rest periods, whereas other participants may have experienced a decline in function during the rest period, but these results were not given in the data. Finally, the author did not provide a rationale for their outcome assessment selections. More specific mobility and psychosocial scores exist for MS specifically that may have detected more meaningful

change in this population. For example, the 6-minute walk test may have been used rather than the 6-meter walk test, which has more evidence supporting efficacy in this population. Since so many diverse outcome measures were used, not all of them showed clinically significant changes as expected. However, it is nice that they utilized a wide variety of scores for the potential to detect clinically significant changes if they did occur. It would have been helpful for the author to report MCIDs for the selected outcome measures to determine clinically meaningful changes in scores. Finally, this study compared individual patient's responses to both treatments compared to the control, which was critical in detecting change at an individual level, however results varied overall due to patients receiving all treatments and potential carry over in motor performance may have occurred, making comparison of true benefit of physical therapy treatment to no physical therapy treatment in this study.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

According to the data provided in this study, home therapy and outpatient therapy provide statistically significant improvements in mobility as shown by the RMI post-test scores. Many of the other outcome measures they performed in this study did not provide statistically significant results, nor did the author provide a good reasoning for selection of these measures. Single leg balance and walking not only did not have statistically significant improvements but had wide confidence intervals (95% CI -23 to -5 for outpatient and 95% CI -23 to -6 for home), suggesting participants varied in response to these measures. Additionally, the interventions implemented by the physical therapist may not have been directed towards improving these specific scores, as the specific interventions were not standardized from patient to patient nor were they listed. Balance did improve in home therapy more than outpatient therapy, however not at a significant amount (p=0.69).

Applicability of Study Results

[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.]

Overall, this study is highly relevant to my PICO question, as it compares the mobility benefits of home health PT and outpatient PT to no PT. The study overall found that ongoing PT, either in home health or outpatient clinics, to be beneficial to mobility and well-being in patients with chronic MS. However, no specific intervention frequency, duration, time, or intensity was reported along with the results, making it difficult to implement the results of this study into practice. This study did not discuss caregiver assisted home exercise programs in people with MS and included a variety of mobility deficits in subjects, leaving these two factors unknown when implementing this study to the specific clinical scenario.

SYNTHESIS AND CLINICAL IMPLICATIONS

[Synthesize the results, quality/validity, and applicability of the two studies reviewed for the CAT. Future implications for research should be addressed briefly. Limit: 1 page.]

The two above studies vary significantly in outcome measures, type of MS, impairment level, and analysis of results. Both studies do not provide specific details on control group interventions or treatment group interventions, limiting the clinical applicability of both studies to a single patient case. Both studies reveal the overall benefit of physical therapy in either the home health or outpatient clinic setting on improved mobility outcomes, such as the RMI, FIM, TUG, Barthel Index, and 10-meter walk test. Home therapy and outpatient therapy provide statistically significant improvements in mobility as shown by the RMI post-test scores in the Wiles et al. study. Additionally, Amatya et al. found inpatient and outpatient rehab programs led to longer term gains in activity and participation. Both studies present with good overall internal and external validity, with concerns regarding lack of blinding of both subjects and assessors to the allocated treatment, which is challenging to do in these types of studies. Future research should focus on comparing to control groups consisting of participants of equivalent mobility level and specification of usual care, no treatment control groups for comparison of the intervention. Additionally, future studies should identify and compare the impact of caregiver assisted exercise programs and physical therapy with those individuals who are severely physically or cognitively impaired and unable to perform exercises independently.

REFERENCES
[List all references cited in the CAT]

1. Aronson KJ, Cleghorn G, Goldenberg E. Assistance arrangements and use of services among persons with multiple sclerosis and their caregivers. *Disabil Rehabil*. 1996;18(7):354-361. doi:10.3109/09638289609165894

2. Di Fabio RP, Soderberg J, Choi T, Hansen CR, Schapiro RT. Extended outpatient rehabilitation: its influence on symptom frequency, fatigue, and functional status for persons with progressive multiple sclerosis. Arch Phys Med Rehabil. 1998;79(2):141-146. doi:10.1016/s0003-9993(98)90290-8

3. Rae-Grant AD, Turner AP, Sloan A, Miller D, Hunziker J, Haselkorn JK. Self-management in neurological disorders: systematic review of the literature and potential interventions in multiple sclerosis care. J Rehabil Res Dev. 2011;48(9):1087-1100. doi:10.1682/jrrd.2010.08.0159

4. Patten SB, Williams JVA, Lavorato DH, et al. Perceived met and unmet health-care needs in a community population with multiple sclerosis. Int J MS Care. 2012;14(1):2-8. doi:10.7224/1537-2073-14.1.2

5. Dunn J. Impact of mobility impairment on the burden of caregiving in individuals with multiple sclerosis. Expert Rev Pharmacoecon Outcomes Res. 2010;10(4):433-440. doi:10.1586/erp.10.34

6. Carton H, Loos R, Pacolet J, Versieck K, Vlietinck R. A quantitative study of unpaid caregiving in multiple sclerosis. Mult Scler. 2000;6(4):274-279. doi:10.1177/135245850000600409

7. Amatya B, Khan F, Galea M. Rehabilitation for people with multiple sclerosis: an overview of Cochrane Reviews. *Cochrane Database Syst Rev*. 2019;1:CD012732. doi:10.1002/14651858.CD012732.pub2

8. Wiles CM, Newcombe RG, Fuller KJ, et al. Controlled randomised crossover trial of the effects of physiotherapy on mobility in chronic multiple sclerosis. J Neurol Neurosurg Psychiatr. 2001;70(2):174-179. doi:10.1136/jnnp.70.2.174