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Does Hydrotherapy Improve Health-related Quality of Life (HR-QoL) in Adult Men and Women with Multiple Sclerosis (MS)?

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ABSTRACT

Objective: The objective of this selective EBM review is to determine whether or not hydrotherapy improves health-related quality of life (HR-QoL) in adult men and women with multiple sclerosis (MS).

Study Design: Review of three randomized controlled trials (RCTs) published between 2012-current, all in the English language.

Data Sources: Three randomized controlled trials (RCTs), all of which evaluate the effectiveness of hydrotherapy compared to a control group that was asked either not to change their exercise habits or to participate in land-based activities. All studies were found using PubMed and Embase.

Outcomes Measured: Each of the three articles analyzed the effects of hydrotherapy on improving health-related quality of life. The Short form-36 (SF-36), Multiple Sclerosis Quality of Life-54 (MSQOL-54), and Multiple Sclerosis Impact Scale-29 (MSIS-29) were the questionnaires used to measure HR-QoL.

Results: The studies by Castro-Sanchez et al.[7] and Kargarfard et al.[5] found that hydrotherapy significantly improved HR-QoL in adult MS patients compared to the control group. The study by Bansi et al.[8] was inconclusive because HR-QoL improved both in the experimental and control group, with no significant difference between the two.

Conclusions: Hydrotherapy was shown to improve HR-QoL in all three studies. However, in one study, HR-QoL improved independent of the therapy used, with no significant difference between the hydrotherapy and land-based exercise groups.[8] Therefore, evidence is inconclusive.

Keywords: Multiple Sclerosis, Hydrotherapy

INTRODUCTION

Multiple sclerosis is an immune-mediated relapsing-remitting or progressive demyelinating disease of the CNS characterized by chronic inflammation, gliosis, and neuronal loss.[1] The exact cause of MS is unknown. Risk factors include vitamin D deficiency, exposure to Epstein-Barr virus after early childhood, and cigarette smoking.[1] Symptoms vary greatly from person to person and can range from asymptomatic to severe disease. Characteristic symptoms include exercise-induced weakness, optic neuritis, and heat sensitivity. Other common symptoms include spasticity, diplopia, paresthesias, ataxia, bladder dysfunction, depression, and fatigue.

There are approximately 2.3 million individuals worldwide and 350,000 people in the United States with MS[1], but there has not been a scientific, national study of prevalence since 1975.[2] Hospital admissions for MS are increasing, with the most recent data showing 102,473 ± 3,485 in 2001, rising to 144, 716 ± 3,902 admissions in 2010.[3] Total costs for all people with MS in the U.S. is approximately $28 billion annually.[4] Annual costs, including both direct and indirect costs for a patient with MS in the U.S. is approximately $69,000.[4] Approximately $39,000 consists of health care costs.[4]

There is no cure for MS, only medications and other therapies to control symptoms, prevent exacerbations and slow the progression of the disease. Therefore, different forms of complementary and alternative medicine (CAM) are important considerations to reduce symptoms and improve daily functioning for MS patients. The mainstay of treatment for acute attacks is glucocorticoids. Plasma exchange can be used if the patient is refractory to steroids. Maintenance treatment can be achieved with disease-modifying agents that are injectable medications, such as IFN-β-1a (Avonex) and IFN-β-1a (Rebif); oral medications, such as fingolimod (Gilenya) and teriflunomide (Aubagio); or infused medications, such as mitoxantrone

(Novantrone) and alemtuzumab (Lemtrada).[1] Aside from medications, comprehensive care of MS includes PT/OT, cognitive rehabilitation, vocational rehabilitation, and speech-language pathology. The goal of these treatment modalities is to improve and maintain function and to increase the quality of life for MS patients.

With no definitive cure for MS, additional treatment modalities, including hydrotherapy, are being researched to determine their efficacy in improving the symptoms of MS. Hydrotherapy, also known as water therapy, aquatic therapy, pool therapy, and balneotherapy, is a type of alternative medicine that uses water in various ways to provide therapeutic effects. It is thought that the cooling effect of the water may help MS patients since the neurological symptoms associated with MS can be produced by an elevation in the body's core temperature.[1] The potential benefits from hydrotherapy are based on the ideas that the pool water can reduce the body temperature and increase exercise tolerance compared to land-based exercise.[5] It is also thought that the buoyancy of the water can decrease resistance against the body, allowing patients to endure longer periods of physical activity with less resulting fatigue.[5] A study in 2011 has found that walking is the most common type of physical activity reported by patients with MS, followed by gardening and weight training.[6] Hydrotherapy may be a new promising recommendation by health care providers over traditional land-based exercises if the research supports its use. This paper evaluates three randomized controlled trials analyzing the effects of hydrotherapy as an adjunctive treatment for men and women with multiple sclerosis.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not hydrotherapy improves health-related quality of life (HR-QoL) in adult men and women with multiple sclerosis (MS).

METHODS

The criteria used for the selection of the three RCT studies in this systematic review was based on the population demographics, interventions utilized, and the outcomes measured. The populations studied in these RCTs were men and women over the age of 18 with a formal diagnosis of multiple sclerosis. The intervention being studied is hydrotherapy. The control groups in two of the studies consisted of land-based exercises, including a land cycle ergometer and abdominal breathing combined with contraction-relaxation exercises. The third study utilized a control group that did not have any additional exercise requirements and were asked to make no changes to their normal routine. Health-related quality of life (HR-QoL) is the outcome being measured by these studies using patient-oriented evidence.

Research for this systematic review was collected using Pubmed and Embase to find randomized controlled trials in peer-reviewed journals that were published no earlier than 2006. All three articles were published in the English language. Articles were selected based on their relevance to the objective of this systematic review and if outcomes measured were POEMs (patient-oriented evidence that matters). The keywords used to search for relevant articles were "multiple sclerosis" and "hydrotherapy". The inclusion criteria for this systematic review required that patients were men and women over the age of 18. Anyone under the age of 18 and anyone who recently relapsed were excluded. Refer to Table 1 for inclusion and exclusion criteria specific to each of the three studies. These studies analyzed data using t-tests and ANOVA. Values reported were mean change from baseline, p-values, and confidence intervals.

Table 1 - Demographics & Characteristics of included studies

Study	Type	#Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Bansi[8] (2013)	Randomized Controlled Trial	60	46-56 years old	Patients with MS diagnosis with EDSS between 1.0-6.5	Patients were excluded if incontinence, persistent infections, cardiovascular and pulmonary diseases, or if immunosuppressive therapy was existent.	8	Daily 30 minute endurance training on an aquatic bike x3 weeks
Castro-Sanchez[7] (2012)	Randomized Controlled Trial	73	18-75 years old	Patients 18-75 years old with MS diagnosis who have VAS pain score > 4 for at least 2 months and EDSS ≤ 7.5	Treatment with another CAM (complementary & alternative medicine) currently or within past 3 months, relapse or steroid treatment within the past 2 months	2	Twice-weekly 20-week Ai-Chi aquatic exercise program
Kargarfard[5] (2012)	Randomized Controlled Trial	32	Avg age = 32.6	Women with diagnosis of MS for ≥ 2 years, no relapse within the 4 weeks prior, ability to participate, EDSS ≤ 3.5	Relapse during intervention period, comorbidities (cardiovascular, pulmonary, skeletal disease)	11	60 minute aquatic exercise program three times per week x8 weeks

OUTCOMES MEASURED

The outcome measured in these studies was health-related quality of life (HR-QoL), which looks at physical, mental, emotional and social functioning, focusing on how quality of life is impacted by health status. Castro-Sanchez et al. assessed HR-QoL using the MSIS-29 scale.[7] This scale measures HR-QoL using a 29-item self-report measure associated with a physical and psychological scale that questions patients about the impact MS has on their day-to-day lives. Kargarfard et al. assessed HR-QoL using the Multiple Sclerosis Quality of Life-54 (MSQOL-54), which consists of 54 items that are designed to measure composite scores for physical and mental health.[5] Composite scores are determined using subscales, which assess physical function, physical and emotional role limitation, pain, emotional well-being, energy, health perceptions, social function, cognitive function, health distress, overall quality of life, and sexual function.[5] Higher scores indicate better HR-QoL. Bansi et al. used the Short Form-36 (SF-36) to assess HR-QoL, which looks at physical, mental and social aspects of health and how they impact quality of life for MS patients.[8]

RESULTS

Three randomized controlled trials were used to determine if hydrotherapy served as an effective treatment to improve HR-QoL in MS patients over the age of 18. Data from these studies were continuous data and could not be converted to dichotomous form. Therefore, results evaluating treatment efficacy could not be calculated.

Castro-Sanchez et al.[7] followed 73 patients, with 36 patients in the experimental group (26 females) and 37 patients in the control group (24 females). Two patients in the control group were excluded due to relapse. Power calculations were performed, estimating a minimal sample size of 33 participants per group for a power of 80% and standard deviation (SD) of 3.1. There

was no significant difference in demographic characteristics between the groups. The intervention for the experimental group was an Ai-Chi exercise program conducted in a swimming pool with a water temperature of 36 °C. Exercises included a combination of deep breathing and broad movements of the arms, legs, and torso to work on strength, balance, flexibility, relaxation, and breathing. Tai-Chi music was also played during the sessions, which lasted 60 minutes each. The intervention for the control group consisted of exercise sessions that were conducted on land in a therapy room with a temperature of 26 °C. The patients underwent the same exercise program as the experimental group. No music was played during these sessions. The sessions were led by the same physiotherapist for the experimental and control groups. Both groups received treatment twice a week for 20 weeks. There was follow-up at weeks 24 and 30. For the purpose of this systematic review, focus will be on effects immediately post-treatment at 20 weeks. HR-QoL was measured using two scales. Using the MSIS-29 Physical scale, there was a significant improvement in HR-QoL in the experimental group at week 20 ($P < 0.013$) that was also maintained at follow-up at weeks 24 ($P<0.017$) and 30 ($P<0.025$). The control group showed no significant difference in HR-QoL at any time point during the study. As shown in Table 3, there were significant differences between the experimental and control groups at week 20 ($P<0.014$), as well as at follow-up at week 24 ($P<0.019$) and week 30 ($P<0.027$). Using the MSIS-29 Psychological scale, both the experimental and control group showed a significant improvement in HR-QoL at week 20 ($P < 0.009$ and $P<0.046$, respectively) that was maintained at the week 24 and week 30 follow-up. There were significant differences between the experimental and control group at week 20 ($P<0.023$), as well as at week 24 follow-up ($P<0.027$) and week 30 follow-up ($P<0.038$), as shown in Table 3. This data demonstrates effects on HR-QoL that were superior in the

experimental group compared to the control group.[7]

Table 2. Median and standard deviation values at baseline and week 20 with associated p-values

	MSIS-29 Physical		**MSIS-29 Psychological**	
	Experimental	**Control**	**Experimental**	**Control**
Week 0	Median = 48 St. dev = 15.91	Median = 46 St. dev = 18.34	Median = 34 St. dev = 29.47	Median = 30 St. dev = 23.53
Week 20	Median = 41 St. dev = 12.37	Median = 45 St. dev = 17.14	Median = 21 St. dev = 15.73	Median = 25 St. dev = 19.36
% change from baseline	78% improvement	6% improvement	81% improvement	37% improvement
p-value	P<0.013	P<0.05	P <0.009	P <0.046

Table 3. Median (SD) MSIS-29 scores, Comparing experimental and control groups at week 20

Group	**Median (St. deviation)**	**P-value**
MSIS-29 Physical		
Experimental	41 (12.37)	P<0.014
Control	45 (17.14)	
MSIS-29 Psychological		
Experimental	21 (15.73)	P<0.023
Control	25 (19.36)	

Kargarfard et al.[5] recruited 32 women with relapsing-remitting MS into their study. Six patients from the exercise group and five patients from the control group were excluded from analysis due to relapse, personal circumstances, being unable to regularly participate in exercise training, or refusing to participate in measurement of outcomes at both 4 and 8 weeks. A sensitivity analysis was performed, which showed that the results of statistical significance were the same whether ITT or complete data were employed. Therefore, the results presented here are based on 21 patients, with 10 from the experimental group and 11 from the control group. There

was no significant difference in demographic characteristics between the groups. The intervention for the experimental group was a 60-minute aquatic exercise program three times per week for 8 weeks. The aquatic exercise took place in a swimming pool at a temperature maintained between 28-30°C. Exercises included those that focused on joint mobility, muscle strength, balance and posture, along with functional activities and intermittent walking. The control group was asked to maintain their current treatment and behavior over the 8 weeks. The Multiple Sclerosis Quality of Life-54 (MSQOL-54) scale was used to assess HR-QoL using two subscales, MSQOL-54-physical and MSQOL-54-mental. For MSQOL-54-physical and MSQOL-54-mental, the control group showed no significant difference from baseline to week 8. The experimental group did show a statistically significant difference in HR-QoL from baseline to week 8 for MSQOL-54-physical ($P<0.001$) and MSQOL-54-mental ($P<0.001$). Refer to Table 4 for intragroup statistics and P values. Additionally, MSQOL-54-physical and MSQOL-54-mental scores were significantly different between the experimental and control groups at week 8 to the favor of the experimental group. Refer to Table 5 for intergroup statistics and P-values.[5]

Table 4. Pairwise comparisons examining quality of life at baseline and 8 weeks with data expressed as mean differences ± SE

	MSQOL-54-Physical		**MSQOL-54-Mental**	
	Experimental	**Control**	**Experimental**	**Control**
Difference between baseline and 8 weeks	21.5 ± 1.7	0.7 ± 1.0	25.8 ± 3.1	1.1 ± 1.6
p-value	P<0.001	P>0.05	P <0.001	P >0.05

Table 5. Comparison of quality of life between experimental and control groups at week 8

Group	Mean ± SD	P-value
MSQOL-54-Physical		
Experimental	65.4 ± 6.6	P<0.001
Control	44.2 ± 4.4	
MSQOL-54-Mental		
Experimental	70.2 ± 5.7	P<0.001
Control	43.6 ± 8.9	

Bansi et al.[8] followed 52 patients, with 24 patients in the experimental group and 28 patients in the control group. Sixty patients were initially included in the study, but eight had been excluded due to immunosuppressive therapy being given during the study or inability to comply with the daily schedule of activities. There was no significant difference in demographic characteristics between the groups. The intervention for the experimental group was daily 30-minute endurance training sessions on an aquatic bike for 3 weeks. Water temperature was held constant at 28 °C. The control group participated in daily 30-minute endurance training sessions on land cycle ergometers for 3 weeks. The Short form-36 (SF-36) was used to assess HR-QoL in this study. Both the experimental and control groups showed a statistically significant difference in SF-36 scores over the 3 weeks, as shown in Table 6. SF-36 scores did not show statistically significant group differences over the 3 week training period. There were beneficial effects on HR-QoL independent of the training setting. Refer to Table 6 for P-values.[8]

Table 6. Time and group effects for the experimental and control group over 3 weeks

SF-36 Total Score	Time point Mean (95% CI)			ANOVA p values	
	t_1	t_2	Difference $t_2 - t_1$	Time	Group

Experimental Group	59.3 (50.8-68.2)	63.4 (55.7-71.7)	4.2 (-9.2 to 0.8)	0.031	0.766
Control Group	53.9 (46.3-61.4)	58.4 (50.1-66.5)	4.46 (-9.3 to 0.4)	0.031	

No adverse events related to the interventions utilized in these studies were reported. In the study by Kargarfard et al.[5], lifeguards and pool safety equipment were available at all times. Also, patients were allowed to use a noodle or foam hand bars while performing exercises in this study.[5] Hydrotherapy is a safe intervention with no obvious adverse effects related to its use.

DISCUSSION

This systematic review explored the efficacy of hydrotherapy as an adjunctive treatment for patients with MS to improve health-related quality of life. The studies by Castro-Sanchez et al.[7] and Kargarfard et al.[5] showed significant improvements in HR-QoL, with no adverse effects noted. The third study by Bansi et al.[8] showed improvement in HR-QoL independent of the type of exercise therapy.

There were several limitations to these studies. In the study by Castro-Sanchez et al.[7], the hydrotherapy group had the addition of ambient music during their training sessions, while the control group had no ambient music played during their land-based exercise training sessions. The contributions of this factor should be further explored. For the same study, it could not be guaranteed that participants were blinded to the nature of their group since they all belonged to the same organization. Generally speaking, there is a need for studies with larger sample sizes; the largest sample size in a study utilized in this systematic review was 71. Lastly, the time factor varied among the studies, with the effects of hydrotherapy measured from a range of 3 weeks – 30 weeks. It would be beneficial to measure effects of the therapy over a longer duration of time.

Hydrotherapy does have limitations to its use. The cost could be a deterrent to patients who are on a budget. Insurance coverage for hydrotherapy varies, and paying out of pocket could easily add up over time. Some insurance companies, such as BlueCross BlueShield, require hydrotherapy to be administered by a certified physical therapist. Various insurance plans will not cover group exercise programs, but rather one on one sessions with a licensed provider. Additionally, only a certain number of sessions may be covered, which could lead to cessation of therapy before full effects of the treatment have been achieved.

No contraindications were defined in the research regarding the use of hydrotherapy.

CONCLUSIONS

Based on the current research available, the evidence is inconclusive on whether hydrotherapy improves HR-QoL in adult men and women with MS. Two out of the three studies show significant improvement in HR-QoL using hydrotherapy compared to the control group.[5,7] While the third study showed improvement in HR-QoL in both the group receiving hydrotherapy and the control group, there was no statistically significant difference between the two groups.[8] With this in mind, MS requires a multidisciplinary approach. With no notable adverse effects, hydrotherapy can be considered a safe alternative to traditional land-based exercise.

There has been limited research on this topic, and further studies are warranted. With hydrotherapy being a broad term, the actual exercise regimens used varied greatly from study to study. In the two studies that showed improvement in HR-QoL, hydrotherapy consisted of exercises defined by various movements performed while standing in the water. The study that had inconclusive evidence to the benefits of hydrotherapy utilized an underwater bike for training sessions. It could be beneficial for future studies to focus on a more standardized exercise routine to have a more exact definition across the board of what hydrotherapy entails.

References

1. Hauser SL, Goodin DS. Multiple Sclerosis and Other Demyelinating Diseases. In: Kasper D, Fauci A, Hauser S, Longo D, Jameson J, Loscalzo J. eds. *Harrison's Principles of Internal Medicine, 19e* New York, NY: McGraw Hill; 2014. http://accessmedicine.mhmedical.com/content.aspx?bookid=1130&sectionid=79756278. Accessed October 01, 2017.
2. National Multiple Sclerosis Society. *MS Prevalence.* www.nationalmssociety.org/About-the-Society/MS-Prevalence. Accessed October 1, 2018.
3. Sanober Nusrat, David Levinthal, and Klaus Bielefeldt, "Hospitalization Rates and Discharge Status in Multiple Sclerosis," Multiple Sclerosis International, vol. 2013, Article ID 436929, 7 pages, 2013.
4. National Multiple Sclerosis Society. *Health Policy Fact Sheet #2*. https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Documents/Health-Policy-Fact-Sheet-2-Costs.pdf. Accessed October 1, 2017.
5. *Kargarfard M, Etemadifar M, Baker P, Mehrabi M, Hayatbakhsh R. Effect of Aquatic Exercise Training on Fatigue and Health-Related Quality of Life in Patients With Multiple Sclerosis. Archives of Physical Medicine and Rehabilitation. 2012;93(10):1701-1708.*
6. Weikert M, Dlugonski D, Balantrapu S, Motl RW. Most common types of physical activity self-selected by people with multiple sclerosis. Int J MS Care 2011;13:16-20.
7. Castro-Sánchez AM, Matarán-Peñarrocha GA, Lara-Palomo I, Saavedra-Hernández M, Arroyo- Morales M, Moreno-Lorenzo C. Hydrotherapy for the treatment of pain in people with multiple sclerosis: A randomized controlled trial. *EVID BASED COMPLEMENT ALTERN MED*. 2012;2012:1-8.
8. Bansi J, Bloch W, Gamper U, Riedel S, Kesselring J. Endurance training in MS: short-term immune responses and their relation to cardiorespiratory fitness, health-related quality of life, and fatigue. *Journal of Neurology*. 2013;260(12):2993-3001.