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Original Research Article

Evaluate the effectiveness of hydrotherapy versus land-based exercises outcome on pain and quality of life among patients with rheumatoid arthritis: triple-blind randomized controlled trial

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ABSTRACT

Background: Evaluate the effectiveness of hydrotherapy versus land-based exercise outcomes to decrease pain and improve the quality of life among patients with rheumatoid arthritis.
Methods: Triple-blind, randomized controlled, parallel-group, multiple arm trial was conducted between 29/09/2019 to 30/09/2021 at the Department of PMR, KG University Lucknow India and randomization was done through the SNSOE. Eligible 90 patients suffering from rheumatoid arthritis. The intervention (RJHLERA) was administered in both study groups. NRPS used for pain and RJQOL-22 Scale was used for QoL.
Results: The pre-test results showed all the subject's average pain scores and quality of life had either poor or neither poor nor good levels of the RJQOL-22 scale. At the post-test, in terms of pain, the hydrotherapy exercise group showed the maximum response with an average pain score of 3.64±1.89, the land-based exercises group showed the next to maximum response with an average pain score of 5.88±1.37 while the control group showed the least response with an average pain score of 7.63±1.41. and in terms of quality of life, the hydrotherapy exercise group showed the maximum response with 67.9% very good, and 21.4% good. The land-based exercises group showed the next to maximum response with 19.2% good while the group the clear control group showed the least response.
Conclusions: Effectiveness of hydrotherapy versus land-based exercises, in comparison to land-based exercises the Hydrotherapy exercises group showed the maximum response to reduce the pain and improve the quality of life among chronic rheumatoid arthritis patients.

Keywords: Hydrotherapy Exercise, Land-Based Exercise, RJQOL-22 Scale, RJHLERA

INTRODUCTION

Rheumatoid Arthritis (RA) is a non-communicable autoimmune disease that affects the joints and causes pain, swelling, tenderness and decreased range of motion due to joint deterioration.[1-4] There are many studies (RCT) done on chronic rheumatoid arthritis that show that along with medication exercises are an important part of the management of rheumatoid arthritis patients.[5] Hydrotherapy and Land-based exercises are well, defined, structured and supervised exercises for rheumatoid arthritis and revealed specific health benefits to reduce the pain and improve the quality of life and reduced musculoskeletal deformity.[6-8] The major goal of the study is to evaluate the effectiveness of hydrotherapy versus land-based exercise outcomes to decrease pain and improve the quality of life among patients with rheumatoid arthritis.

METHODS

Study design

Triple-blind, randomized controlled, parallel-group, multiple arm trial was conducted between 29 September 2019 to 30 September 2021 at the Department of PMR, KG University Lucknow India and randomization was done through the SNSOE. Eligible 90 patients were adults aged from 17 to 75 years old suffering from rheumatoid arthritis and blind study participants, investigator and data clean-up people completely blind (outcome Assessor and Statistician).

Participants

Eligible 90 adults patients (45 males and 45 females aged from 17 to 75 years old suffering from rheumatoid arthritis subject to written informed consent) and the excluded criteria i.e. the patient does not come under the criteria of Rheumatoid Arthritis, Cognitive impairment, Age less than 17 years and more than 75 years, Weight more than 100 kg, Subjects who have undergone joint surgery or rehabilitation elsewhere for the last three months, systematic illness and cardio-respiratory dysfunction such as Patient suffering from poorly controlled epilepsy, hypotension, and hypertension, diabetes mellitus, incontinence of faces, fear of water, pregnant women, methicillin-resistant staphylococcus aureus in the upper respiratory tract, fever, any communicable disease.

Randomization

Randomization through the sequentially numbering sealed opaque envelope method (SNSOE), is a cheap, effective, and bias-free method unpredictable and equal opportunity for every participant.

Masking

Triple Blinding technique was used.[9] In this study patient/participant, investigator, and data clean-up people were completely blind (outcome assessor and statistician).

Procedure

The intervention (RJHLERA) administered was hydrotherapy exercise (Weekly 30-minute session for 6 weeks and exercises in a hydrotherapy bathtub submerging body, water temperature (30-35 degrees Celsius) and land-based exercises (Weekly 30-minute session for 6 weeks and exercises on land and 11 minutes planned set of an active exercise (as a placebo) on land for the control group. NRPS Scale was used for pain and RJQOL-22 Scale was used for assessing the quality of life.

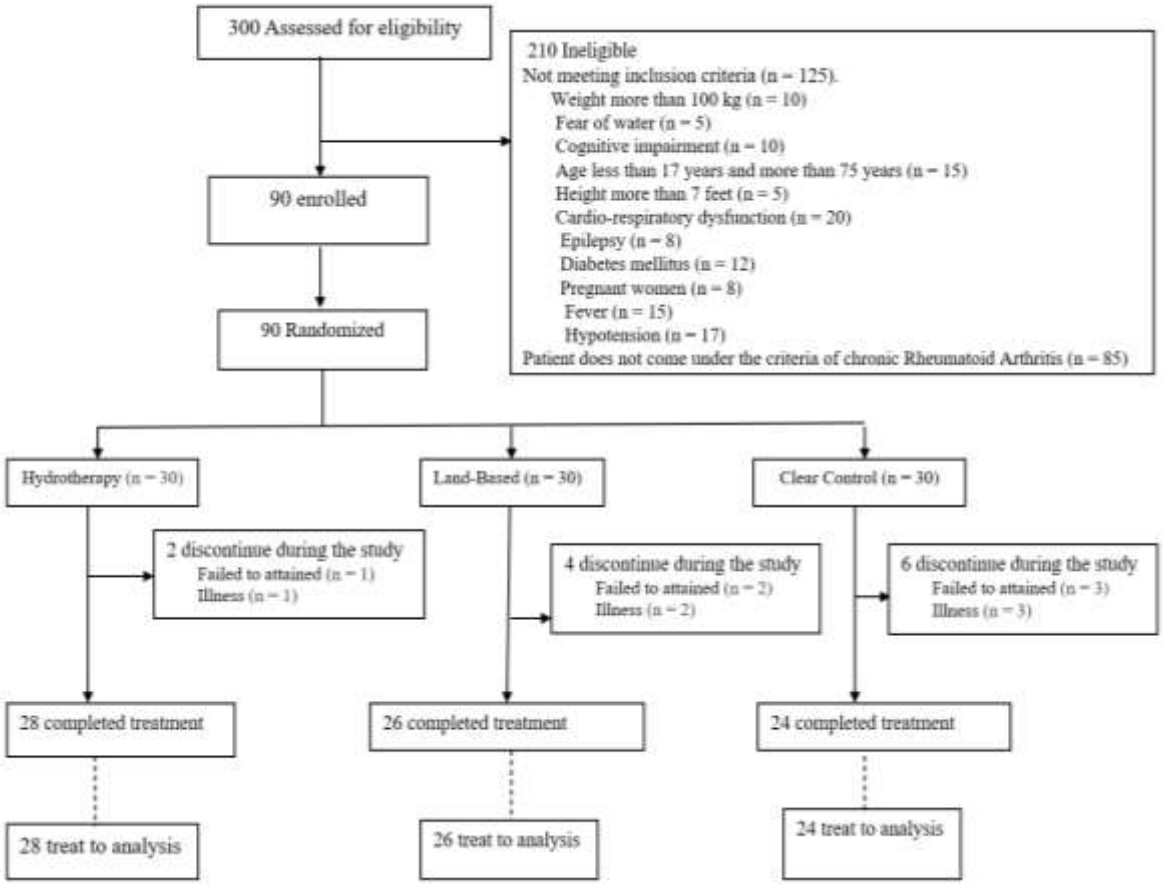

Figure 1: Trial profile.

Outcomes

The major goal of the study is to evaluate the effectiveness of hydrotherapy versus land-based exercise outcomes to decrease pain and improve the quality of life among patients with rheumatoid arthritis. At the post-test, in terms of pain, the hydrotherapy exercise group showed the maximum response with an average pain score of 3.64±1.89, the land-based exercises group showed the next to maximum response with an average pain score of 5.88±1.37 while the control group showed the least/poor response with an average pain score of 7.63±1.41. and in terms of quality of life, the hydrotherapy exercise group showed the maximum response with 67.9% very good, and 21.4% good. The group land-based exercises group showed the next to maximum response with 19.2% good while the group the control group showed the least/poor response with nil cases in the good/very good category. So, effectiveness of hydrotherapy versus land-based exercises, in comparison land-based exercises the Hydrotherapy exercises group showed the maximum response (much better) to reduce the pain and improve the quality of life among chronic rheumatoid arthritis patients.

RESULTS

Data was collected between 29 September 2019 to 30 September 2021, and eligible 90 patients were randomized through the SNSOE. As shown in (Figure 1) a total of 30 patients were assigned to each treatment and control group. In the hydrotherapy exercise arm, two patients and Land-Based exercise arm four patients and clear control arm six patients were lost to the follow-up, as they did not attend their planned follow-up visits, and were excluded from the analysis. In both three-arm, 78 participants were included (hydrotherapy arm 28, land-Based arm 26, clear control arm 24) in the intention-to-treat analysis.

In Table 1, major outcomes, at the pre-test, all the subjects had almost the same average pain score for selected subjects in each group and no significant difference was observed in the average pain score among the groups (p=0.989). So, no baseness was involved.

Table 1: Intergroup and pre-post-test comparison of overall pain score with treatment groups.

Item	Hydrotherapy (N=30)		Land-based (N=30)		Control (N=30)		Intergroup	
	Mean	SD	Mean	SD	Mean	SD	F value	P value
Pain pre test	8.07	0.94	8.07	0.91	8.10	1.16	0.01	0.989
Item	**Hydrotherapy (N=28)**		**Land-based (N=26)**		**Control (N=24)**		**Intergroup**	
Pain post test	3.64	1.89	5.88	1.37	7.63	1.41	41.29	<0.001
Pre to post	t=12.92, p<0.001		t=7.79, p<0.001		t=1.09, p=0.288			

ANOVA Test, *Significant=0.001

Table 2: Bi-group comparison of overall pain score with pairs of treatment groups.

Comparison	Mean Diff. (I-J)	SE	P value
Hydrotherapy vs land-based	-2.24	0.43	<0.001
Hydrotherapy vs control	-3.98	0.44	<0.001
Land-based vs control	-1.74	0.45	0.001

Table 3: Intergroup and pre-post-test comparison of overall RJQOL-22 scale score with treatment groups.

Item	Hydrotherapy		Land-based		Control		Intergroup	
	Mean	SD	Mean	SD	Mean	SD	F value	P value
RJQO-22L pre-total	41.13	4.04	42.13	3.77	41.10	5.11	0.55	0.580
RJQOL-22 -post total	89.00	13.73	59.85	7.46	49.17	8.38	104.25	<0.001
Pre to post	t=19.45, p<0.001		t=9.99, p<0.001		t=3.86, p=0.001			

At the post-test, the hydrotherapy exercise group showed the maximum response with an average pain score of 3.64±1.89. the land-based exercises group showed the next to maximum response with an average pain score of 5.88±1.37 while the clear control group showed the least/poor response with an average pain score of 7.63±1.41. A highly significant difference was foaming the groups' mean pain score groups (p<0.001). The further intragroup comparison showed significant changes in the hydrotherapy exercise group & the land-based exercises group (p<0.001) but not in the clear control group (p=0.288). In Table 2, primary outcomes the bi-group comparison showed a highly significant difference was found in the mean pain score between the hydrotherapy exercise group & the land-based exercises group (p<0.001), the hydrotherapy exercise group & the control group (p<0.001) and the land-based exercises group & the control group (p=0.001). The difference between the

hydrotherapy exercise group & the control group was a maximum while between the land-based exercises group & the control group was a minimum.

In Table 3. major outcomes, during the pre-test, all the subjects had almost the same average RJQOL-22 scale score for selected subjects in each group and no significant difference was observed in the average RJQOL-22 scale score among the groups (p=0.580). So, no biasness was involved. At the post-test, the hydrotherapy exercise group showed the maximum response with an average RJQOL-22 score of 89.00±13.73.

The land-based exercises group showed the next to maximum response with an average RJQOL-22 score of 59.85±7.46 while the clear control group showed the least/poor response with an average RJQOL-22 score of 49.17±8.38. A highly significant difference was found in the mean RJQOL-22 score among the groups (p<0.001). The further intragroup comparison showed significant changes in the hydrotherapy exercise group, the land-based exercises group & the clear control group in all the groups (p<0.01) with a maximum in the hydrotherapy exercise group (maximum t value) and minimum in the clear control group (minimum t-value). In (Table 4) primary outcomes, the bi-group comparison showed a highly significant difference was found in the mean RJQOL-22 score between the hydrotherapy exercise group & the land-based exercises group(p<0.001), the hydrotherapy exercise group & the clear control group (p<0.001) and the land-based exercises group & the clear control group (p=0.001). The difference between the hydrotherapy exercise group & the clear control group was a maximum while between the land-based exercises group & the clear control group was a minimum.

Table 4: Bi-group comparison of overall RJQOL-22 scale score with pairs of treatment groups.

Comparison	Mean Diff. (I-J)	SE	P value
Hydrotherapy vs. Land-Based	29.15	2.83	<0.001
Hydrotherapy vs. Control	39.83	2.89	<0.001
Land-Based vs. Control	10.68	2.94	0.001

DISCUSSION

The research hypothesis of the study is there will be a significant difference between pain and quality of life scores among the patients who will receive hydrotherapy exercise and land-based exercise as compared to the control group at a p value <0.01. For the majority of the patient, in terms of pain the bi-group comparison, showed a highly significant difference was found in the mean pain score between the hydrotherapy exercise group & the land-based exercises group (p<0.001), the hydrotherapy exercise group & the clear control group (p<0.001) and the land-based exercises group and the clear control group (p=0.001). The difference between the hydrotherapy exercise group and the clear control group was maximum while between the land-based exercises group & the clear control group was minimum. For the majority of the patient, in terms of quality of life, At the post-test, the hydrotherapy exercise group showed the maximum response with an average RJQOL-22 score of 89.00±13.73.

The land-based exercises group showed the next to maximum response with an average RJQOL-22 score of 59.85±7.46 while the clear control group showed the least/poor response with an average RJQOL-22 score of 49.17±8.38. A highly significant difference was found in the mean RJQOL-22 score among the groups (p<0.001). The further intragroup comparison showed significant changes in the hydrotherapy exercise group, the land-based exercises group and the clear control group in all the groups (p<0.01) with a maximum in the hydrotherapy exercise group (maximum t value) and minimum in the clear control group (minimum t value). The above-mentioned findings are supported by the following study: Valente et al showed effectiveness of aquatic exercises in women with rheumatoid arthritis Conducted a study on hydrotherapy in rheumatoid arthritis. The finding of the present study shows that participants in the study included 133 women who suffered from rheumatoid arthritis. And women were randomly allocated into 3 groups and interventions were performed 3 times per week assessment of functional ability health assessment questionnaire revealed that hydrotherapy was much more effective other than land exercises patients with rheumatoid arthritis.[10]

Limitations

Limitations of current study were only a single-centre study and only 90 participants were in this study.

CONCLUSION

This study demonstrates that hydrotherapy exercise versus land-based exercise is hydrotherapy exercise much better to reduce pain and improve the quality of life rather than land-based exercise and is a less effective control group in chronic rheumatoid arthritis patients.

Recommendations

Based on the findings researcher recommended that, Increase the health care worker's awareness about hydrotherapy exercise, (RJHLERA) as a non-pharmacological therapeutic intervention for reducing pain and improving quality of life in rheumatoid arthritis patients.

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