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Original Research Article

A triple-blinded randomized controlled trial to evaluate the effectiveness of hydrotherapy versus land-based exercises outcome on pain among patients with rheumatoid arthritis

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ABSTRACT

Background: The goal of the study was to determine the effectiveness of hydrotherapy versus land-based exercise outcomes to reduce pain in chronic rheumatoid arthritis (RA).
Methods: A triple-blinded, randomized controlled, parallel-group, multiple arm trial was conducted between 29/09/2019 to 30/09/2021. Single centre, the study was done at the department of physical medicine and rehabilitation, KGMU (India). Eligible 90 patients were adults aged from 17 to 75 years old suffering from chronic RA) and randomization through the SNSOE method. The intervention (RJHLERA) administered was hydrotherapy exercise (Weekly 30-minute for 6 weeks exercises in a hydrotherapy bathtub, and land-based exercises (Weekly 30-minute for 6 weeks of exercises on land and 11 minutes of active exercise for the control group. NRPS scale was used for pain assessment.
Results: The result revealed that pain score, In the pre-test, all the subjects had almost the same average pain score for selected subjects in each group. In 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. Hall et al and conclusion of the study is hydrotherapy produced the greatest improvement.
Conclusions: The study recommends hydrotherapy and land-based exercise as safe, inexpensive interventions. Amongst hydrotherapy exercises and land-based exercises, Hydrotherapy showed the maximum (much better) to reduce the pain.

Keywords: Hydrotherapy exercise, Land-based exercise, RJHLERA, Pain

INTRODUCTION

Rheumatoid arthritis (RA) is autoimmune, a non-communicable disease that produces inflammation of the joints that can cause pain, swelling, tenderness as well as the decreased range of motion due to the joint deterioration.[1]

The approximate prevalence of RA (2020) is 0.3 to 1% globally and has an annual incidence rate of 3 per 10,000 adults in India. Prevalence in North America and Europe may be higher than in Asia.[2,3] It is not clear due to the geographical variability that exists due to study design differences, genetic and environmental.[4] RA affects any age but most commonly affects ages between 40 to 50 years.[5] One of the most common non-pharmacological

interventions in the treatment of RA is hydrotherapy and land-based exercises.

There are many randomized controlled trials done on RA showing that medication exercises are an important part of the management of RA patients and showing improve pain.[5]

Hydrotherapy and land-based exercises, were defined as well-structured and supervised exercises in RA and revealed specific health benefits in the musculoskeletal system like planned exercise and increase physical activity reduced musculoskeletal deformity.[6,7]

The goal of the study was to determine the effectiveness of hydrotherapy versus land-exercise outcomes reduce pain in chronic RA.

METHODS

Study design

A randomized controlled, parallel-group, multiple arm trial with triple-blinding and blinds study participants, investigator and data clean-up people completely blind (Assessor and Statistician).[8,9] The study occurred at a single centre, at the department of physical medicine and rehabilitation (PMR), KGMU (Lucknow, India).

The institutional ethics committee of King George's medical university (Lucknow, India) reviewed and approved the trial protocol (Registration no: ECR/262/INST/UP/2013/RR-19).

Which was registered at the https://ctri.icmr.org.in/.[8] (Registration No: ECR/262/INST/UP/2013/RR-19) as well as study according to the CONSORT guideline 2010 format.

Participants

Participants were recruited through the sequentially numbering sealed opaque envelope method (SNSOE) sampling technique, which fulfilled the inclusion of criteria 90 adult patients (45 male and 45 females aged from 17 to 75 years old suffering from chronic RA subject to written informed consent) and the excluded criteria i.e. the patient does not come under the criteria of chronic RA, 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 as well as any communicable disease.[10]

Randomization

Randomization through the SNSOE is a cheap, effective, and bias-free method of randomization and each participant picks a sealed envelope that will contain a card with a unique code randomly generated by Microsoft excel. that will be marked with the group assignment, So, participants are allocated to the study group in an unpredictable and equal opportunity of every participant.

Masking

Triple blinding this is the gold standard approach of masking and through this blinding most effective study is free from bias.[9] In this study patient/participant, investigator, and data clean-up people were completely blind (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 exercises for the clear control group. NRPS scale was used for pain assessment.

Outcomes

The primary outcome of the study was showing the Hydrotherapy exercises group had a maximum response (much better) and the land-Based group shows the next maximum response among the clear control group to reduce the pain among chronic RA patients.

The secondary outcome of the study was to find out the significant difference between the pre-test score of hydrotherapy versus land-based exercise on pain with selected demographical and clinical variables.

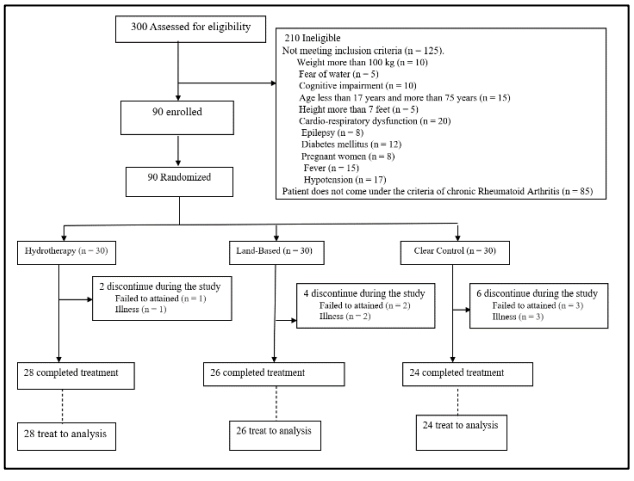

Figure 1: Trial profile.

Statical analysis

Sample size at 80% Power. The total sample size was 60. The sample size is calculated based on variation in VAS after 18 weeks in two exercise groups using the formula:

$$n = \frac{2\left(z_\alpha + z_\beta\right)^2(\sigma_1^2 + \sigma_2^2)}{d^2}$$

Where,

σ_1=23.1, The SD of VAS in the hydrotherapy group,

σ_2=27.5, The SD of VAS in conventional group,

d =min (σ_1, σ_1), the difference considered to be clinically significant,

type I error α=5% corresponding to 95% confidence level,

type II error β=20% for detecting results with 80% power of the study,

Loss to follow-up=10%,

So, the required sample size, n=28 each group

Clinical trials registry-India (CTRI No: 2021/03/032360 registered on: 26/03/2021)

Role of the funding source

There was no funding source for this study.

Informed consent

Taken by the participant.

RESULTS

The study starts from 29/09/2019 to 30/09/2021, A total of 90 patients were enrolled and randomized into the treatment groups. As shown in fig.1, a total of 30 patients were assigned to each treatment and clear 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.

Table 1 describes the frequency, percentage distribution, and p value of demographic variables of patients with hydrotherapy exercise concerning age, gender, occupational status, area of residence, monthly income, socio-economic status, and diet.

The distribution of subjects according to demographic characteristics revealed that maximum subjects belong to age group 46-60 years (50.0%) followed by age groups 31-45 years (28.9%). Most were females (54.4%) and primary educated/illiterates (25.5%) were relatively less than higher educated. Homemakers were in maximum proportion (38.9%) followed by government employees (31.1%). Urban residents were more than the rural (66.7% vs 33.3%). Respondents with income less than 10,000 were more (38.9%) than other income groups. Non-vegetarian was more than vegetarian (56.7% vs 43.3%).

Table 2 shows secondary outcomes, the intergroup comparison of pre-test pain scores with treatment groups showed that all the differences were found to be insignificant for various categories of sociodemographic variables age, gender, education, occupation, residence, income and diet (p>0.05).

Table 3 shows distribution of subjects according to clinical profile revealed that all subjects had duration of illness of more than 3 months. They all had stiffness and joint pain early morning. They were not taking alternate medicine. Their severity high. Mallet finger deformity in max proportion (36.7%) followed by swan neck deformity (34.4%). No other comorbidities were found.

Table 4 shows secondary outcomes, the intergroup comparison of pre-test pain scores with treatment groups showed that all the differences were found to be insignificant for various categories of clinical variables duration, stiffness, history of hospitalization, alternative medicine, severity, deformity of joint and other comorbidities (p>0.05).

Table 5 A shows the primary 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.

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 and the land-based exercises group (p<0.001) but not in the clear control group (p=0.288).

Table 5 B shows primary outcomes, bi-group comparison showed a highly significant difference was found in mean pain score between hydrotherapy exercise group and land-based exercises group (p<0.001), hydrotherapy exercise group and clear control group (p<0.001) and

land-based exercises group and clear control group (p=0.001). Difference between hydrotherapy exercise group and clear control group was a max while between land-based exercises group and clear control group min.

Table 1: Distribution of subjects according to demographic characteristics, (n=90).

Demography variables		Total	
		N	%
Age (Years)	31-45	26	28.9
	46-60	45	50
	61-75	19	21.1
Gender	Male	41	45.6
	Female	49	54.4
Education	Illiterate	10	11.1
	Primary education	13	14.4
	Secondary education	26	28.9
	Senior secondary education	20	22.2
	Graduate and above	21	23.3
Occupation	Homemaker	35	38.9
	Self-employed/own business	1	1.1
	Private employee	26	28.9
	Government employee	28	31.1
Residence	Rural	30	33.3
	Urban	60	66.7
Income (INR)	Less than 10,000	35	38.9
	10,001-20,000	1	1.1
	20,001-30,000	32	35.6
	More than 30,000	22	24.4
Diet	Vegetarian	39	43.3
	Non-vegetarian	51	56.7

Table 2: Association between the pre-test score of hydrotherapy versus land-based exercise of pain with selected demographical variables (n=90).

Demographic variables		Pain-pre-test						Intergroup	
		Hydrotherapy		Land-based		Control		ANOVA	
		Mean	SD	Mean	SD	Mean	SD	F value	P value
Age (Years)	31-45	7.67	1.12	8.22	0.97	8.25	1.39	0.71	0.504
	46-60	8.29	0.73	8.14	0.95	7.94	0.97	0.58	0.562
	61-75	8.14	1.07	7.71	0.76	8.40	1.52	0.60	0.561
Gender	Male	8.13	1.19	8.45	0.82	7.60	0.83	2.59	0.088
	Female	8.00	0.65	7.84	0.90	8.60	1.24	2.81	0.071
Education	Illiterate	8.00	0.00	7.50	0.58	9.00	1.73	1.95	0.212
	Primary education	8.00	0.82	7.80	0.45	8.50	0.58	1.48	0.274
	Secondary education	8.11	0.78	8.29	1.25	8.00	1.33	0.13	0.881
	Senior secondary education	8.17	1.17	8.29	0.76	8.14	0.90	0.05	0.956
	Graduate and above	8.00	1.31	8.14	1.07	7.50	1.05	0.54	0.594
Occupation	Homemaker	7.80	0.63	7.77	0.83	8.50	1.38	1.98	0.155
	Self-employed/own business	8.00	-	-	-	-	-	-	-
	Private employee	8.44	1.01	8.43	0.98	7.90	0.88	0.98	0.390
	Government employee	8.00	1.15	8.20	0.92	7.75	1.04	0.42	0.665
Residence	Rural	8.55	0.93	8.10	1.10	7.78	0.83	1.60	0.221
	Urban	7.79	0.85	8.05	0.83	8.24	1.26	0.99	0.377
Income (INR)	Less than 10,000	7.80	0.63	7.77	0.83	8.50	1.38	1.98	0.155
	10,001-20,000	8.00	-	-	-	-	-	-	-
	20,001-30,000	8.36	0.92	8.33	0.87	8.00	0.85	0.59	0.559
	More than 30,000	8.00	1.31	8.25	1.04	7.50	1.05	0.74	0.489
Diet	Vegetarian	7.93	1.10	7.86	0.66	8.40	1.07	1.05	0.361
	Non-vegetarian	8.20	0.77	8.25	1.06	7.95	1.19	0.43	0.651

*ANOVA Test

Table 3: Distribution of subjects according to clinical profile, (n=90).

Clinical profile		Total	
		N	%
Duration	More than 3 months (Chronic)	90	100
Stiffness and joint pain	Early in the morning	90	100
History of hospitalization in the last 3 months	No	90	100
Alternative medicine	No	90	100
Severity	High	90	100
Deformity of joints	Swan neck deformity	31	34.4
	Mallet finger	33	36.7
	Z deformity in the thumb	26	28.9
Other comorbidities	No	90	100

Table 4: Association between the pre-test score of hydrotherapy versus land-based exercise of pain with selected clinical variables, (n=90).

Clinical variables		Pain-pre-test						Intergroup	
		Hydrotherapy		Land-based		Control		ANOVA	
		Mean	SD	Mean	SD	Mean	SD	F value	P value
Duration (Months)	More than 3 (Chronic)	8.07	0.94	8.07	0.91	8.10	1.16	0.01	0.989
Stiffness and joint pain	Early in morning	8.07	0.94	8.07	0.91	8.10	1.16	0.01	0.989
History of hospitalization in last 3 months	No	8.07	0.94	8.07	0.91	8.10	1.16	0.01	0.989
Alternative medicine	No	8.07	0.94	8.07	0.91	8.10	1.16	0.01	0.989
Severity	High	8.07	0.94	8.07	0.91	8.10	1.16	0.01	0.989
Deformity of joints	Swan neck deformity	8.10	0.88	8.30	0.95	8.18	0.98	0.11	0.892
	Mallet finger	8.09	1.22	7.91	0.70	8.00	1.26	0.08	0.927
	Z deformity in thumb	8.00	0.71	8.00	1.12	8.13	1.36	0.04	0.964
Other comorbidity	No	8.07	0.94	8.07	0.91	8.10	1.16	0.01	0.989

*ANOVA test.

Table 5 A: Intergroup and pre-post test comparison of overall pain score with treatment groups.

Variables	Hydrotherapy, (n=30)		Land-based, (n=30)		Control, (n=30)		Intergroup	
	Mean	SD	Mean	SD	Mean	SD	F value	P value
Item								
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 5 B: Bi-group comparison of overall pain score with pairs of treatment groups.

Comparisons	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

Tukey's post- hoc tests, *Significant

DISCUSSION

The research hypothesis of the study is there will be a significant difference between pain scores among the patients who will receive hydrotherapy exercise and land-

based exercise as compared to the control group as measured by the numeric rating pain scale (NRS) at a $p<0.05$.

The discussion divided into three sections.

Section 1: Demographic characteristics

For the majority of the patient, the distribution of subjects according to demographic characteristics revealed that the maximum subjects belong to the age group 46-60 years (50.0%) followed by the age groups 31-45 years (28.9%).

Most were females (54.4%) and primary educated/illiterates (25.5%) were relatively less than higher educated. Homemakers were in maximum proportion (38.9%) followed by government employees (31.1%). Urban residents were more than the rural (66.7% vs 33.3%). The respondents with income less than 10,000 were more (38.9%) than other income groups. Non-vegetarian was more than vegetarian (56.7% vs 43.3%).

The majority of the patient, about the association between demographic features and treatment, selected it was found that for the three treatments selected, no significant difference was found in the proportion of various categories of age, gender, occupation, residence, income and diet ($p>0.05$). Hence the treatments selected were unbiased with demographic factors. It means demographic variables did not play as confounding variables in the study.

Section 2: Clinical characteristics

For the majority of the patient, the distribution of subjects according to clinical profile revealed that all subjects had a duration of illness of more than 3 months. They all had stiffness and joint pain early in the morning. They were not taking alternate medicine. Their severity was high. Mallet finger deformity was in maximum proportion (36.7%) followed by the swan neck deformity (34.4%). No other comorbidities were found.

The majority of the patient, about the frequency, percentage distribution and p-value of the clinical profile of the patient with chronic RA concerning diagnosis, duration of illness, the severity of illness and any other comorbidity.

According to the association between clinical features and the treatment selected, it was found that for the three treatments selected, no significant difference was found in the proportion of various categories of deformity of joints ($p=0.998$).

All the other clinical features were common in each treatment group. Hence the treatments selected were unbiased with clinical factors. It means clinical variables did not play as confounding variables in the study.

Section 3: To compare the effect of hydrotherapy and land-based exercise among clear control groups on pain based on pre and post-test

For the majority of the patient, 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 biasedness was involved.

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 found among the groups' mean pain scores ($p<0.001$).

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 ($p=0.288$).

The majority of the patient, in the bi-group comparison, showed a highly significant difference was found in the mean pain score between the hydrotherapy exercise group and the land-based exercises group ($p<0.001$), the hydrotherapy exercise group and 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 and the clear control group was minimum.

Hall and Skevington et al conducted a study on hydrotherapy in RA and evaluate the therapeutic effects of hydrotherapy exercises along with warm water immersion. The finding of the present study shows that participants in the study included 139 patients who attained 30-minute sessions twice weekly for four weeks and measure the outcomes through the arthritis impact measurement scale 2 questionnaires. And the conclusion of the study is hydrotherapy produced the greatest improvement.[12]

Limitations

Only those patients who were suffering from chronic RA visited the department of physical medicine and rehabilitation (PMR) at the physiotherapy unit KGMU, Lucknow, U.P. The generalization of the finding will be limited to population studies.

CONCLUSION

Based on these findings the study shows a decreased level of pain after the completion of 6 weeks of exercise sessions among the patients who received hydrotherapy

exercise and land-based exercise compared to the control group.

This study demonstrates that hydrotherapy exercise versus land-based exercise is hydrotherapy exercise much better to reduce pain than land-based exercise and is less effective clear control group in chronic RA patients.

Recommendations

Based on the findings it is recommended that, Increase the health care worker's awareness about hydrotherapy exercise and land-based exercise (RJHLERA) as a non-pharmacological therapeutic intervention for reducing pain in chronic RA patients.

The healthcare worker uses this technique to reduce pain and improve the quality of life among chronic RA patients and ultimately improving patients 'outcomes. Explore the influences of other confounding variables, such as age, gender, education level and prior pain experience to evaluate the effectiveness of hydrotherapy exercise and land-based exercise as a pain management intervention. Replication of this study is recommended with several design changes such as using a large sample size, using a double and triple-blind randomized controlled trial to achieve an appropriate representation of the studied population: and conducting the study on a larger scale to include a multicenter.

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