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Research Article

A Triple-Blinded Randomized Controlled Trialto Evaluate the effectiveness of Hydrotherapy versus Land-based exercises outcome on Quality of Life among patients with Rheumatoid Arthritis

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ABSTRACT

Background: One of the most common non-pharmacological interventions for rheumatoid arthritis is hydrotherapy and land-based exercises. The goal of the study was to determine the effectiveness of hydrotherapy versus land-based exercise outcomes to improve the quality of life among chronic rheumatoid arthritis.

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 & Rehabilitation, KGMU (India). Eligible 90 patients (45 males and 45 females aged 17 to 75 years old suffering from chronic rheumatoid arthritis) and randomisation through the Sequentially Numbering Sealed Opaque Envelope method (SNSOE).

The intervention (RJHLERA) administered was hydrotherapy exercise (Week30-minutes 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 in land and 11 minutes planned set of an active exercise (as a placebo) on land exercises for the clear control group. Assess the Quality of life using by RJQOL-22 Scale.

Findings: For the quality of life, the pre-test results showed all the subjects had either poor or neither poor nor good levels of RJQOL-22 selected in each group. At post-test, 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 clear control group showed the least/poor response with nil cases in the good/very good category.

Interpretation: The study recommends hydrotherapy and land-based exercise as safe, inexpensive interventions. Amongst hydrotherapy exercise and land-based exercises, Hydrotherapy showed the maximum (much better) to improve the quality of life in chronic rheumatoid arthritis patients.

Key Words: *Hydrotherapy Exercise, Land-Based Exercise, RJQOL-22, RJHLERA*

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INTRODUCTION

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

The approximate prevalence of rheumatoid arthritis (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], [4],.[5]. One of the most common non-pharmacological interventions in the treatment of rheumatoid arthritis (RA) is hydrotherapy and land-based exercises.

There are many randomized controlled trials done on rheumatoid arthritis showing thatmedication exercises are an important part of the management of rheumatoid arthritis patients and show improved quality of life [5].

Hydrotherapy and Land-based exercises, define well-structured and supervised exercises in rheumatoid arthritis 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-based exercise outcomes to reduce pain in chronic rheumatoid arthritis.

METHODS

Study design

A Triple-Blind, Randomized Controlled, Parallel-Group, Multiple Arm Trial was conducted between 29/09/2019 to 30/09/2021. with [9], and blinds study participants, investigator and data clean-up people completely blind (Assessor and Statistician).The study occurred at a single centre, at the Department of Physical Medicine & 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 https://ctri.icmr.org.in/ [8], (**Registration No: ECR/262/INST/UP/2013/RR-19**).

Participants

Participants were recruited through the Sequentially Numbering Sealed Opaque Envelope method (SNSOE) sampling technique [10], which fulfilled the inclusion criteria 90 adult patients(45 males and 45 females aged from 17 to 75 years old suffering from chronic rheumatoid arthritis are subject to written informed consent) and the excluded criteria i.e. the patient does not come under the criteria of chronic 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 of randomization and each participantpicks a sealed envelope that will contain a card with a unique code randomly generated by Excelsoft excel. that will be marked with the group assignment, So, participants are allocated to the study group in an unpredicted table and equal opportunity patients participant.

Masking

Triple Blinding [9]. This is the gold standard approach of masking and through this blinding most effective study is free from bias. In this study patient, investigator, and data clean-up people a completely blind (outcome Assessor, Participant and Statistician).

Procedure

The intervention (RJHLERA) administered was hydrotherapy exercise (Weekly 30-minute session for 6 weeks and exercises in a hydrotherapybathtub 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 active exercises) on land exercises for the clear control group. Quality of life was assessed by using the RJQOL-22 Scale.

Outcomes

The primary outcome of the study was showed 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 improve the quality of life among chronic rheumatoid arthritis 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 quality of life with selected demographical and clinical variables.

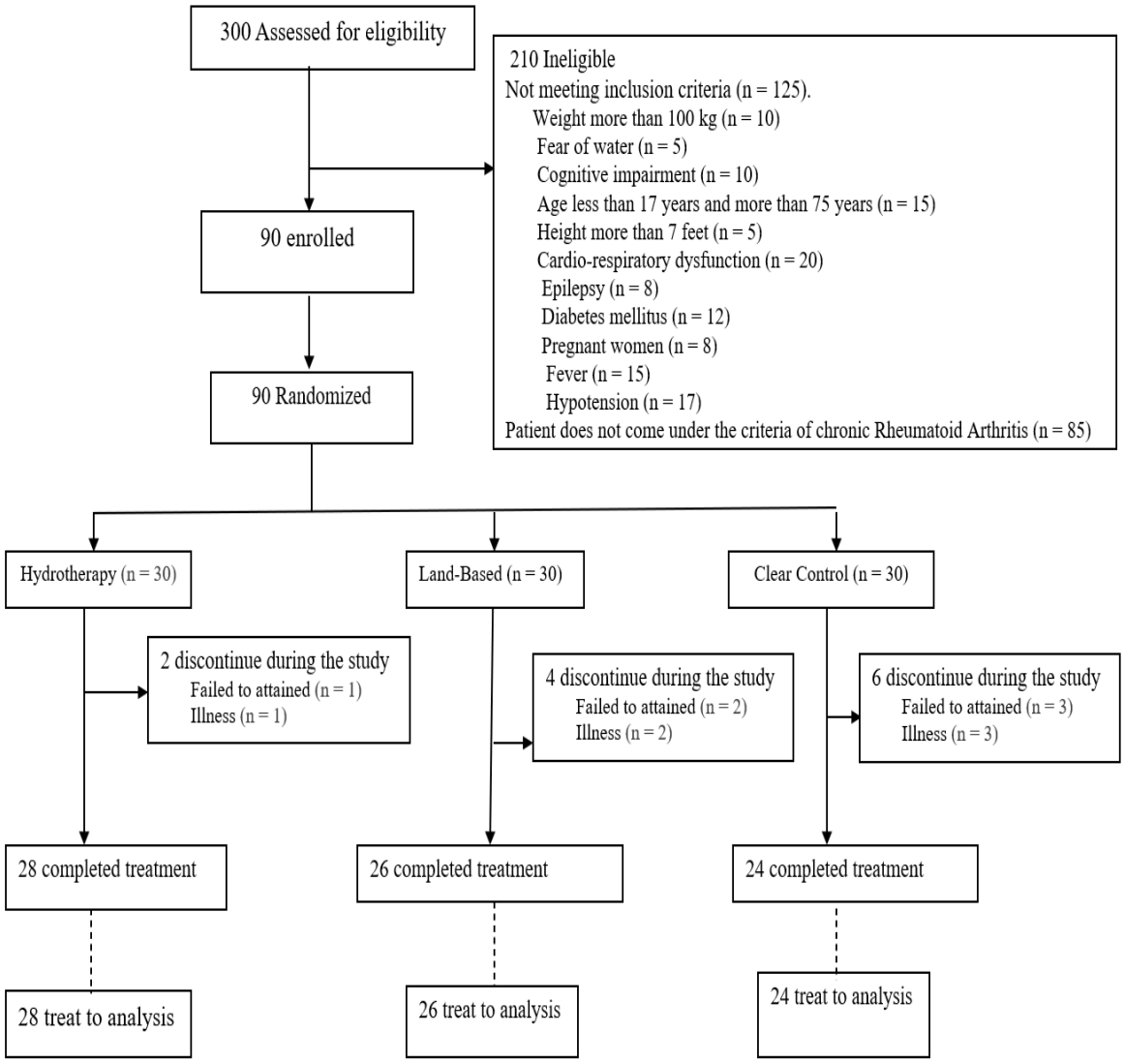

Figure 1: Trial profile

STATICAL ANALYSIS

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

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

Were

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

σ_2 = 27.5, The SD of VAS in the Conventional group

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

type I error α = 5% corresponding to a 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 for 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".

RESULTS

The trial was conducted between 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: Distribution of Subjects according to Demographic Characteristics (N=90)

Demography Variable		Total	
		No.	%
Age	31-45 years	26	28.9%
	46-60 years	45	50.0%
	61-75 years	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 & 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	Less than Rs 10,000	35	38.9%
	Rs 10,001-20,000	1	1.1%
	Rs 20,001-30,000	32	35.6%
	More than Rs 30,000	22	24.4%
Diet	Vegetarian	39	43.3%
	Non-Vegetarian	51	56.7%

Table No.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 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 ememployees31.1%). 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%).

Table – 2: Association between the pre-test score of hydrotherapy versus land-based exercise of RJQOL-22 with selected demographical variables (N=90).

Demographic Variable	RJQOL -22 Pre Test			Intergroup
	Hydrotherapy	Land-Based	Control	ANOVA

		Mean	SD	Mean	SD	Mean	SD	F-value	p-value
Age	**31-45 years**	42.33	4.18	41.67	3.39	40.25	5.47	0.49	0.617
	46-60 years	40.36	3.18	42.00	4.52	41.82	4.56	0.67	0.517
	61-75 years	41.14	5.49	43.00	2.77	40.00	6.96	0.53	0.599
Gender	**Male**	40.73	5.05	41.45	4.48	42.67	3.92	0.70	0.502
	Female	41.53	2.83	42.53	3.36	39.53	5.78	2.24	0.118
Education	**Illiterate**	41.67	0.58	41.75	2.06	39.00	9.54	0.28	0.766
	Primary education	42.00	4.32	42.80	3.11	40.00	2.31	0.81	0.472
	Secondary education	40.44	3.09	43.86	3.76	41.20	5.81	1.22	0.314
	Senior secondary education	40.83	6.01	42.00	3.46	40.14	3.76	0.31	0.738
	Graduate & above	41.50	4.63	40.29	5.09	43.83	4.49	0.92	0.416
Occupation	**Homemaker**	42.20	2.94	42.92	2.60	39.83	6.04	1.82	0.179
	Self-employed/own business	43.00	-	-	-	-	-	-	-
	Private employee	39.44	5.03	43.14	4.45	41.20	4.47	1.24	0.308
	Government employee	41.40	4.12	40.40	4.30	42.88	4.32	0.76	0.479
Residence	**Rural**	39.18	4.53	43.50	4.60	41.78	3.83	2.62	0.092
	Urban	42.26	3.35	41.45	3.19	40.81	5.63	0.59	0.560
Income	**Less than Rs 10,000**	42.20	2.94	42.92	2.60	39.83	6.04	1.82	0.179
	Rs 10,001-20,000	43.00							
	Rs 20,001-30,000	39.73	4.56	42.89	3.89	41.00	4.16	1.39	0.266
	More than Rs 30,000	41.50	4.63	40.00	4.78	43.83	4.49	1.17	0.333
Diet	**Vegetarian**	42.07	4.95	42.21	3.21	40.10	4.84	0.81	0.452
	Non Vegetarian	40.20	2.73	42.06	4.30	41.60	5.29	0.77	0.469

*ANOVA Test

Table No.-2: This table shows secondary outcomes, The intergroup comparison of Pre-test RJQOL-22 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: Distribution of Subjects according to Clinical Profile (N=90).

Clinical Profile		Total	
		No.	**%**
Duration	More than 3 months (Chronic)	90	100.0%
Stiffness & Joint Pain	Early in the morning	90	100.0%
History of hospitalization in the last 3 months	No	90	100.0%
Alternative Medicine	No	90	100.0%
Severity	High	90	100.0%
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	100.0%

Table No.3: 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.

Table – 4: Association between the pre-test score of hydrotherapy versus land-based exercise of RJQOL-22 with selected clinical variables (N=90).

Clinical Variable		RJQOL -22 Pre Test						Intergroup ANOVA	
		Hydrotherapy		Land-Based		Control			
		Mean	SD	Mean	SD	Mean	SD	F-value	p-value
Duration	**More than 3 months (Chronic)**	41.13	4.04	42.13	3.77	41.10	5.11	0.55	0.580
Stiffness & Joint Pain	**Early in the morning**	41.13	4.04	42.13	3.77	41.10	5.11	0.55	0.580
History of hospitalization in the last 3 months	**No**	41.13	4.04	42.13	3.77	41.10	5.11	0.55	0.580
Alternative Medicine	**No**	41.13	4.04	42.13	3.77	41.10	5.11	0.55	0.580
Severity	**High**	41.13	4.04	42.13	3.77	41.10	5.11	0.55	0.580
Deformity of joints	**Swan neck deformity**	40.70	3.27	41.60	3.75	40.27	4.08	0.34	0.713
	Mallet finger	41.18	5.29	41.91	3.08	41.55	5.50	0.06	0.938
	Z deformity in thumb	41.56	3.43	43.00	4.74	41.63	6.28	0.25	0.784
other comorbidity	**No**	41.13	4.04	42.13	3.77	41.10	5.11	0.55	0.580

*ANOVA Test

Table No.-4: This table shows secondary outcomes, The intergroup comparison of Pre-test RJQOL scores with Treatment Groups showed the 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: Intergroup & Pre-Post Test Comparison of Overall RJQOL-22 scale 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
RJQO-22L - Pre-Total	41.13	4.04	42.13	3.77	41.10	5.11	0.55	0.580
Item	**Hydrotherapy (N=28)**		**Land-Based (N=26)**		**Control (N=24)**		**F-value**	**p-value**
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**			

ANOVA Test, * Significant

Table – 5: In this table shows the primary outcomes, At 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).

Table – 5A: Intergroup & 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**			

Tukey's post- hoc tests, * Significant

Table – 5A: In this table shows the primary outcomes, At 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.

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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).

Table – 5B: 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	**<.001**
Hydrotherapy vs Control	39.83	2.89	**<.001**
Land-Based vs Control	10.68	2.94	**.001**

Tukey's post- hoc tests, * Significant

Table – 5B: In this table shows the 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.

DISCUSSION

The research hypothesis of the study is there will be a significant difference between the quality-of-lifescore ofpatients who will receive hydrotherapy exercise and land-based exercise as compared to the control group as measured by the RJQOL-22 Scale at a **p-value <0.05.**

The discussion divided into three sections

Section 1: Demographic characteristics

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 a government employee (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 the 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

The majority of the patient, about 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 clinical profile of the patient with chronic rheumatoid arthritis concerning diagnosis, duration of illness, the severity of illness and any other comorbidity.

According to the association between clinical 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 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 quality of life-based on pre and post-test.

The majority of the patient, about the intergroup comparison of Pre-test RJQOL-22 Items with Treatment Groups, showed any item of RJQOL-22 did not show a significant difference among the three treatment groups (p>0.05). So before the treatments, all the groups were unbiased assigned according to RJQOL-22 responses.

The majority of the patient, about the pre-test, all the subjects had almost the same average RJQOL-22 score for selected subjects in each group and no significant difference was observed in the average RJQOL-22 score among the groups (p=0.580). So, no biasness was involved.

The majority of the patient, about the intergroup comparison of Post-test RJQOL-22 Items with Treatment Groups, showed the all the items of RJQOL-22 showed highly significant differences among the three treatment groups (p<0.001). At the post-test, the hydrotherapy exercise group showed maximum response while the clear control group showed the least responsible for each item.

The majority of the patient, At the pre-test, all the subjects had either poor or neither poor nor good level of RJQOL-22 selected in each group and no significant difference was observed in the proportion of the RJQOL-22 different levels among the groups (p=0.812). So, no biasness was involved.

At post-test, the hydrotherapy exercise group showed the maximum response with 67.9% very good, 21.4% good. The land-based exercises group showed the next to maximum response with 19.2% good while the clear control group showed the least/poor response with nil cases in the good/very good category. A highly significant difference was found in the proportion of the RJQOL-22 different levels among the groups (p<0.001).

At 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).

The above-mentioned findings are supported by the following study:

J Hall and SM Skevington et al. (1996), Conducted a study on hydrotherapy in rheumatoid arthritis 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 [11].

Limitations of the study

Only those patients who were suffering from chronic rheumatoid arthritis visited the Department of Physical Medicine & Rehabilitation (PMR) at the Physiotherapy unit KGMU, Lucknow, U.P.
The generalization of the finding will be limited to population studies.

Recommendations

Based on the findings it is recommended that, Increase the healthcareworker's awareness of hydrotherapy exercise and land-based exercise (RJHLERA) as a non-pharmacological therapeutic intervention for reducing pain and improving quality of life score in chronic rheumatoid arthritis patients.

The healthcare worker uses this technique to improve the quality of life among chronic rheumatoid arthritis patients and ultimately improve 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.

CONCLUSION

Based on these findings the study shows an improved quality of life after the completion of 6 weeks of exercise sessions among the patients who received hydrotherapy exercise and land-based exercise than compared to the control group.

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

Contributors

The authors have made the following contributions consistent with authorship: All authors made meaningful contributions to manuscript preparation, review, and editing. In addition, the authors made contributions as follows:
-Rajendra Kumar Jinjwaria principal investigator of the development of the tool wrote the draft manuscript, and maintain overall responsibility for conduct and reporting.
- Ast. Professor Rashmi P John gave suggestions entire the study.
-Professor Sanjay Kumar helped in developing a tool.

Declaration of competing interest

The authors have no finical or personal relationships with other people or organizations that could represent a conflict of interest.

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Data Sharing

Individual participant data that underlie the results reported in this article will be shared, after de-identification (text, tables, figures, and appendices). Additionally, the study protocol and statical analysis plan will be made available. Data will be provided to researchers who provide a methodologically sound proposal, to achieve the aim stated in an approved proposal.

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