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Research Article

The effect of an exercise program in water on pain level and functional status in chronic nonspecific low back pain patients: A single-blind randomised controlled trial

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Abstract

Background: Lower back pain is one of the most widespread health issues today. Water-based exercise is an effective treatment to reduce pain intensity and disability.

Objective: To assess the effect of a water exercise program on pain level and functional status in patients suffering from chronic nonspecific low back pain.

Methods: One hundred and twenty-four volunteers with chronic nonspecific low back pain, aged 19 to 70, were randomly assigned to either a water exercise group or a land exercise group. Both groups performed exercises that combined local deep muscles transversus abdominis and the multifidus with diaphragm activity, with the integration of movements of routine daily life. Both programs lasted three months, with twice-weekly sessions of 45-minutes each.

Results: Significantly better improvement of all pain variables and functional status was found in the water group. The major significant ($p<0.001$) contribution of the water group was obtained for pain description improvement. A multivariate linear regression model examined the predictors for pain and functional status improvement.

Conclusions: The water program has a greater potential than the land program for pain reduction and improving functional status of patients with chronic nonspecific low back pain.

Introduction

Lower Back Pain (LBP) is one of the most common and widespread health issues today, causing restricted movement, disability, and economic loss. It is estimated that 50-85% of the population will experience LBP at some stage in life, and that 10%-30% of the population is suffering from LBP at any given moment [1].

Chronic nonspecific LBP is pain that lasts for more than 12 weeks for which the patient cannot find any specific cause. A main characteristic of chronic nonspecific LBP is heavy pain, worsening with exertion [2].

An important component of the prevention of LBP and avoiding its recurrence is the ability to integrate stability of the spine with the maintenance of lower back mobility. This

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combination enables functional and precise movements [3]. The stability of the spine on affects the functionality of two deep local lumbar muscles – the transversus abdominis and the multifidus, as well as of diaphragm activity.

The transversus abdominis and the multifidus are involved in most of our routine daily activities and the likelihood of LBP increases when their functioning is deficient [4]. The diaphragm activity is associated with a voluntary contraction of the transversus abdominis when drawing in the abdominal wall; these contractions occur during postural tasks [5].

Research examining the effect of exercising the transversus abdominis and the multifidus on pain measures and post-exercise functional status has yielded inconsistent results. Some studies showed a positive influence [6,7], while others failed to reveal any significant impact [8,9]. The studies which examined the stabilizing function of the diaphragm found positive effect [10,11]. The present study attempts to address the exercising of these muscles for LBP patients with a program in water.

We hypothesize that exercising in water contributes significantly more to people with LBP than does exercising on land. Studies have shown that even the entry into the water reduces the level of pain, thus enabling different movements [12] and enables the re-practicing the movements and positions of everyday life such as standing, sitting, and transitions between them, as they would be correctly performed. Such practice is not possible on land due to disruption of these movements and postures caused by pain [13].

In addition, the water's sway destabilizes postural control, increases postural instability [14] and requires a constant activity of the muscular system and the proprioceptive system, which enable maintaining balance [15]. Moreover, practicing in water reduces the compressive and shear forces impacting on movements on land, enables the release of joint stiffness caused by pain, and increases the range of motion [16].

Only a small number of researchers have investigated the effect of water-based exercise on LBP. some studies revealed the effectiveness of exercising in water [12,17], while others found no difference between land-based exercise and water-based exercise [18,19]. Waller and colleagues [20] conducted a systematic literature review, and found sufficient results supporting the greater benefits of water-based exercise for people suffering from LBP; they noted the important potential of water-based exercise, but nevertheless emphasized the need for high-quality trials.

The aim of the present study is to assess the effect of a water-based exercise program that includes exercising the transversus abdominis, the multifidus, and diaphragm activity together with activities similar to routine daily activities, on pain level and functional status of patients suffering from chronic nonspecific LBP.

Materials and methods

The study was approved by the Helsinki Committee of the Meir Hospital in Kfar Saba, Israel (Request No. 97440), according to the public health regulation (Clinical Trials on Human Beings, 1980). The procedures followed were in accordance with the Declaration of Helsinki, 1975. The CONSORT guidelines were followed [21]. The study was planned and carried out in cooperation with the Spine Unit of the Meir Hospital, Kfar Saba, Israel.

Sample size was calculated in order to achieve sufficient statistical power for the comparison between groups of the two main outcome variables – pain severity and pain interference, using independent t tests. The patients' responses were made on a 7-point scale (0-6). A difference in the pain-associated outcomes between the two groups of at least a 1 point-value (improvement of at least 1 level in the scale of pain severity and pain interference), would be of clinical significance. We used an estimated standard deviation of 1.0 (scale / 6). Calculation of the required sample size was performed using the software program Power and Precision [22].

In order to ensure a statistical power of at least 90% with a significant level of 5% for a two-sided test, a sample size of at least 45 participants in each group was needed. Assuming a dropout rate of 10%, this meant that the minimum sample size had to be 100 subjects for the entire study population.

Participants

Volunteers were recruited by advertising in clinics in the centre of Israel and by the assistance of the Spine Unit in Meir Hospital. Participants were male and female adults, aged 19-70, who reported the presence of LBP for at least three months that was not caused by a specific, known condition. Exclusion criteria were those patients with acute LBP; those with severe conditions such as spinal disc pathology, radicular pain, spinal fracture, or spondylolisthesis; those with any systemic disease of spine, any surgery on the spine, or serious problems like the presence of a tumor or an infection; and women who are pregnant. These all caused exclusion from the study [2,23].

Study design

The present study was a single-blind randomised controlled trial with the allocation of participants into two groups: water and land. Written informed consent was obtained from all volunteers prior to the commencement of the study. They were informed about the purpose and procedure of the study and gave their informed written consent to participate. They were told that their participation in one of the two groups – water or land – would be chosen randomly. The volunteers were blind to the study hypothesis. The randomisation was done as follows. The same numbers – 1 and 2 – of two were placed in envelopes. The envelopes were put into a box and mixed around, and then each participant chose one envelope. The participant was randomly assigned to the water or land group according to the number – 1 or 2 – in the envelope he/she chose. The participants filled out the study questionnaires, and BMI measurements were performed. Data were stored in a secure file that could be accessed only by the study team. Questionnaires and BMI measurements were administered by two assessors. The assessors and the collectors of the data were blind to the group to which each subject belonged.

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The water and land intervention programs were conducted in three sport clubs. The program for the water group was conducted in a swimming pool, in which the water temperature was 29-30°C. Four groups of participants took part in each program. The program for the land group was conducted in a gymnasium, and included three groups of participants. All the groups included both men and women.

Each of the two intervention groups exercised for a period of three months, with twice-weekly sessions lasting 45 minutes each.

A professional movement therapist specializing in LBP movement therapy in water and on land guided both intervention programs. The movement therapist was blind to the study hypothesis.

At the end of the intervention period, participants again filled out study questionnaires and BMI measurements were performed.

Intervention program

Water program: The stability exercises were practiced by activation of the local muscles transversus abdominis, with co-activation of the multifidus followed by active respiration of the diaphragm. Prior to doing the exercises, the participants were instructed to perform an abdominal hallowing maneuver with diaphragmatic breathing, to activate transversus abdominis. The purpose was to increase the activity of the local muscles while keeping the global muscles' activity at a minimum. Global muscles means the rectus abdominis, and the erector spinal that enable trunk movements. Gradually, after practicing the activation of the local muscles followed by active respiration of the diaphragm, the participants did global muscles' activity incorporated with local muscles' activity. The exercises were initially performed in shallow water, where the participants could stand, and activities such as walking forward, backward, and sideways were practiced as spinal stability exercises. After two weeks of activity in shallow water, the majority of the exercises were performed in deep water, with no contact of the feet with the pool floor. The stability exercises were practiced in various positions using supportive stabilization devices, such as floating devices, neck collars, low back support belts, and triangles for maintaining balance in the water and to assist in attaining and maintaining a correct neutral pelvic position during exercise. After stability and control of the neutral pelvic position were attained, the participants were taught how to activate the local muscles automatically prior to limb movements. In the advanced stage of the program, the final aim of exercising in deep water was to integrate the global muscles, with the automatic execution of movements similar to those in routine daily life. These exercises, which combine various movements, are diverse in terms of positions and speeds. They were more dynamic, and greater efforts were needed to stabilize the trunk during a range of leg and arm positions.

Land program: The stability exercises on land were as similar as possible to those of the water program. The exercises practised the activation of the transversus abdominis with co-activation of the multifidus, followed by active respiration of the diaphragm. In an advanced stage, as in the water program, the aim of the exercises was to integrate the movements similar to those in the routine of daily life. The participants in the land group exercised on mattresses and on the floor in the gymnasium, using different positions such as sitting, standing, and lying. A bar was used by the participants to maintain balance. The exercise practice was assisted by auxiliary equipment such as stable and unstable surfaces at various heights, as well as accessories such as wobble cushions and pool noodles.

Outcome measures

The West Haven-Yale Multidimensional Pain Inventory (WHYMPI): WHYMPI is a self-administered self-report of chronic pain behaviour assessing the entire range of psychosocial effects in chronic pain patients [24].

The McGill Pain Questionnaire (MPQ)**:** The MPQ represents an attempt to systematize verbal descriptions by imposing an organization of the adjectives describing pain, thereby achieving the quantification of the language of pain [25].

The Roland-Morris Questionnaire (RMQ)**:** A self-administered functional status questionnaire, consisting of 24 items chosen to cover a variety of daily life activities [26].

The Health and Demographic Questionnaire**:** The health and demographic questionnaire administered in this study was based on the International Physical Activity Questionnaire (IPAQ). It collects information on demographic variables such as age, gender, education, and overall physical activity performed in the past year (i.e. any regular physical activity or sport performed at least twice a week for 45 minutes at a time), and also covers a list of common health problems [27].

Body Mass Index (BMI): Participants (wearing light clothing) were weighed twice on a portable medical electronic scale to the nearest 0.1 kg. Height was measured twice to the nearest 0.1 cm using a wall-mounted stadiometer, with the subjects standing barefoot and erect against the wall to align the spine with the stadiometer; the head was positioned with the chin parallel to the floor. The means of the two weight and height measurements were used to calculate body mass index (BMI), defined as weight in kilograms divided by the square of the height in meters ($BMI = kg \cdot m^{-2}$).

Study variables

The study involved four continuous outcomes that were measured before and after the intervention program. The outcomes were pain severity and pain interference (from the WHYMPI), pain description (the MPQ), and functional status (from the RMQ). The independent variable was the assigned exercise group – water or land, and the confounding variables were: age in years; gender, education – 8-12 years/over 12 years; and any regular physical activity or sport performed at least twice a week for 45 minutes at a time. All of the independent variables were adopted from the IPAQ.

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Statistical analysis

The data were entered into an Excel worksheet, and analyses were performed using SPSS for Windows version 22.0. Skewness and kurtosis were calculated for all dependent variables prior to the analysis to determine whether parametric or non-parametric statistical tests should be used. All data were analysed on an intention-to-treat (ITT) basis to avoid bias due to dropouts.

Independent t tests and $\chi 2$ tests were conducted to compare continuous variables and categorical variables, respectively, between the two exercise groups.

Repeated measures ANOVA with one nested variable was used to compare differences in the dependent variables between groups, before and after the intervention.

In order to consider the differences between the two groups while controlling for the difference in pre-intervention pain and functional status values, new relative variables were computed and calculated for each subject: the 'pre-intervention value' was subtracted from the 'post-intervention value', and the difference was divided by the 'pre-intervention value' [(post – pre)/pre].

Multiple linear regression models were designed to estimate the impact of the intervention on the assigned groups, while controlling for confounders. The dependent variables were: in Model 1 – pain severity improvement; in Model 2 – pain interference improvement; in Model 3 – pain description improvement; and in Model 4 – functional status improvement. Predictor variables included in the models were entered in three successive blocks: The confounders entered into the model were age, gender, and physical activity (entered in Block 1); the independent variables were the corresponding pre-intervention pain measures and functional status values (entered in Block 2), and the study group water or land (entered in Block 3). All dependent variables used in the models were tested for normal distribution by a one-sample Kolmogorov-Smirnov test, and in addition the independent variables were tested for interaction.

Results

One hundred forty-two volunteers were recruited for the study. One hundred thirty-seven volunteers completed the Health and Demographic Questionnaire. One hundred twenty-four volunteers met the inclusion criteria based on the health questionnaire – aged 19 to 70, 44 men (35%) and 80 women (65%). The average age of the participants was 55 ± 14 (range 19 to 70), and 60 (48%) of them had completed 12 or more years of education. The mean BMI (kg/m^2) of the participants was 27.4 ± 4.2, and 86 (69%) were physically active at least twice a week (45 minutes each time).

During the intervention period, 26 participants dropped out 14 from the water group and 12 from the land group. Ninety-eight participants completed the intervention, the questionnaires and the BMI measurements. The dropout rate from the study was 10%, and was controlled for in the data processing. No significant difference was found in the dropout rate between the two groups (Figure 1).

Baseline characteristics of the two groups revealed no differences between the groups in terms of age, education, BMI, or physical activity. The land group contained significantly more women (Table 1).

Significant differences between the two study groups were found in the baseline characteristics of three outcomes; the water group exhibited higher levels of pain severity, pain interference, and functional status. This indicates the need to control for baseline values of these variables in the statistical analysis.

The outcomes were analysed as ITT. ITT analysis means that all participants who were enrolled and randomly allocated to treatment were included in the analysis, and were analysed in the groups to which they were randomly assigned. Significant improvement in pain levels and functional status after intervention (F^1) was observed in both groups. The water-based group demonstrated greater improvement in these two measures compared with the land group (F^2) (Table 2).

Although all measures demonstrated significant improvements, those experienced by the water-based group were more pronounced. All four outcomes showed significant improvement, in both groups, following the intervention. In order to consider the differences between the two groups while controlling for the difference in pre-intervention pain and functional status values, new relative variables were computed and calculated for each subject: the 'pre-intervention value' was subtracted from the 'post-intervention value', and the difference was divided by the 'pre-intervention value' [(post – pre)/pre]. Table 3 compares the relative differences in pain and functional status between the groups. Significantly greater relative improvement was exhibited by the water group compared with the land-based group in all measures, even after controlling for the pre-intervention differences between the groups (Table 3).

To determine whether the treatment had an independent effect on the pain and functional status variables after the intervention, multiple linear regression analyses were computed, controlling for confounders and pre-intervention pain and functional status values. The confounders entered into the model were age, gender, and physical activity (entered in Block 1); the independent variables were the corresponding pre-intervention pain measures and functional status values (entered in Block 2), and the study group (entered in Block 3).

Table 4 shows the results of the regression models developed to examine the predictors for pain and functional status improvement (four models, one for each of the four outcomes). The independent predictors for pain and functional status were the pre-intervention status and the assigned group. The coefficients of determination, which provide a measure of how well future outcomes are likely to be predicted by the model, were significantly high.

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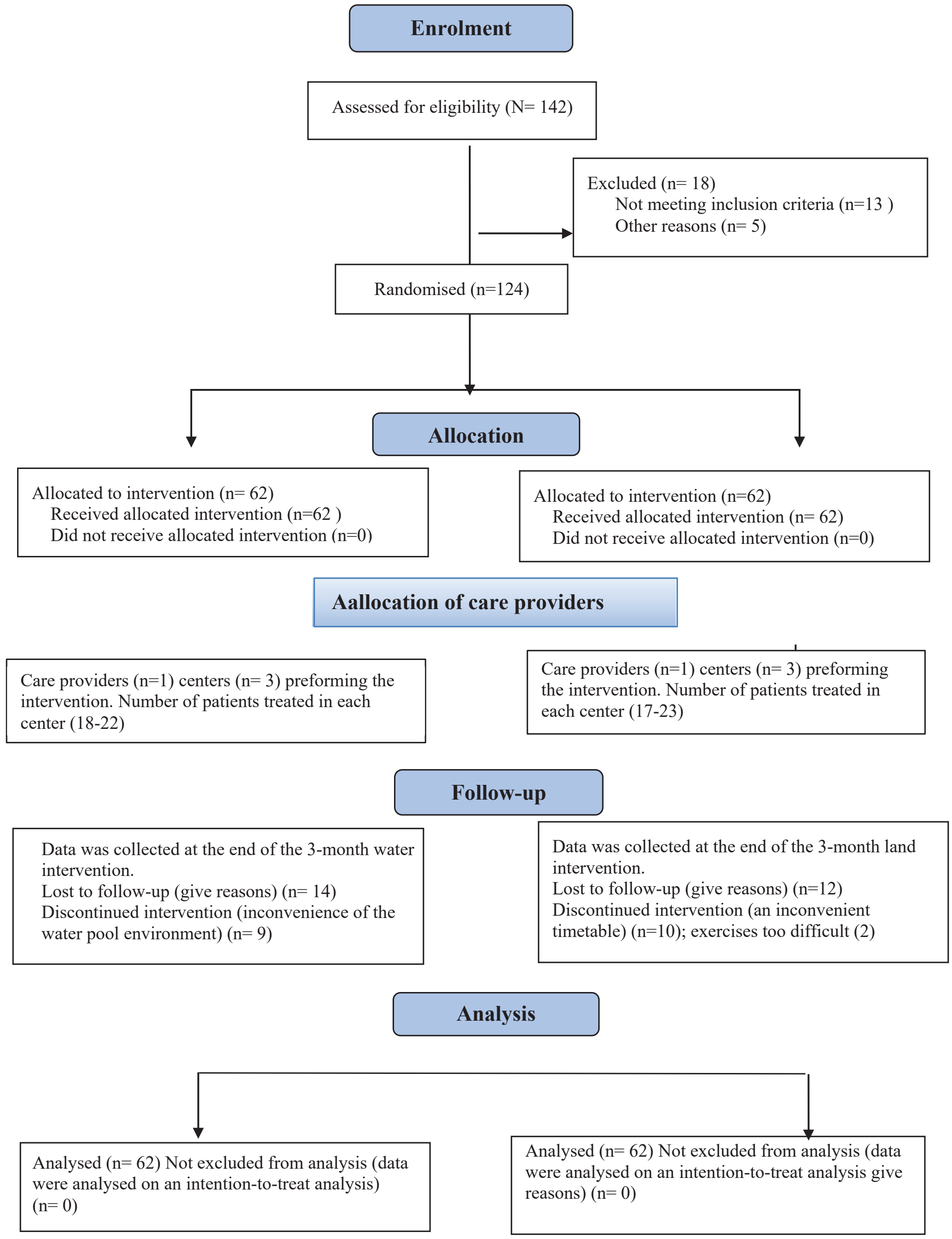

Figure 1: CONSORT Flow Diagram for individual randomised, controlled trials of non-pharmacologic treatment.

Discussion

The study investigated the effects of an intervention program in water on the pain level and functional status of chronic nonspecific LBP. The results showed that the water group showed greater improvement than the land group on all measures of pain level and functional status. These findings were not dependent on age, BMI, gender, education, or any other overall potentially confounding factors that were controlled for in the statistical analysis.

Similar to the results of the present study, some other studies also revealed the effectiveness of exercising in water [12,17,20], in contradiction to others that found no difference between land-based and water-based exercise [18, 19, 28]. However, it is noteworthy that in the above-mentioned studies the participants performed traditional exercises and not the spinal stability exercises.

Two other studies were published comparing the effect of stability exercise in water and on land for LBP patients. However, no difference was found in these studies between the water program and land program [19,29]. Earlier studies from the 1980s and 1990s reported positive effect of water exercise

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[30,31]. Others found no difference between exercises in water and on land [32,33].

The results of the current study could be explained by the principles of the water properties, and the ways in which the program causes effects. Participants in the water program performed the exercises in the beginning in shallow water, and were able to perform the movements accurately because they experienced a decrease in pain level [12]. Exercising in water reduces compressive and shearing forces that are stronger when performing movement on land, thus enabling an extension of the range of motion [16,34]. Since upon entering shallow water the body is forced to respond to the movement of the water and to the continuously changing conditions, the proprioceptive system is continuously being exercised. The information received from the proprioceptive system is reinforced and assimilated [35,36]. As mentioned, the first stage of the program took place in shallow water. The second stage was a combination of activity in shallow and deep water. The final goal of the program was to gradually increase the time of activity in the deep water. One of the reasons for encouraging deep water activity was to stimulate the diaphragm activity by increasing the hydrostatic pressure. The diaphragm is the main respiratory muscle that also contributes spinal stability by activating prior to external perturbations [10]. Trunk stability and postural trunk control may also play an important role in the aetiology of LBP. The function of the diaphragm may affect how the trunk is stabilized [5]. The diaphragm is the first muscle whose activity stabilizes the lower back, and it acts in a synergy with other stabilizers – the transversus abdominis and the multifidus. Hydrostatic pressure means the deeper the patient gets into the water, the more pressure is put on its body. The first reason for exercising in deep water is the great pressure that applied to the lungs. The lungs are required to adopt more muscles during breathing, which helps to strengthen these muscles and the entire respiratory system – especially the action of the diaphragm. The second reason was that keeping one's balance requires non-stop activation of the transversus abdominis and multifidus, in order to create immediate stability, and balancing of the neutral zone. The third reason as aforementioned was re-practicing the movements relating to the transition between movements activating solely local muscles that integrate with routine daily movements. The fourth reason is that the hydrostatic pressure

Table 1: Study group characteristics of the two study groups before intervention.

	Study group		Test	P
	Water (n=62)	Land (n=62)		
Age (years) mean (±SD)	53.2 (14.8)	56.5 (12.8)	t = 1.3	0.187
BMI (Body Mass Index) mean (±SD)	27.5 (3.6)	26.9 (4.4)	t = 2.95	0.448
Gender Male n (%)	29 (47%)	16 (26%)	χ2 = 5.69	0.017*
Female n (%)	33 (53%)	46 (74%)		
Education 12 years n (%)	34 (55%)	31 (50%)	χ2 = 0.297	0.586
Over 12 years n (%)	28 (45%)	31 (50%)		
Physical activity No n (%)	40 (65%)	47 (76%)	χ2 = 0.198	0.137
Yes n (%)	22 (35%)	15 (24%)		

*** p< 0.05**

Table 2: Intention-to-treat analysis of the dependent variables of the two study groups before and after intervention (n=124).

Dependent variable	Water (n=62)		Land (n=62)		F^1	F^2
	Before Mean	After Mean	Before Mean	After Mean		
Pain severity score	3.0 (1.2)	1.4 (1.2)	2.3 (1.1)	1.7 (1.0)	125.6**	532.9**
Pain interference score	3.2 (0.9)	2.3 (0.8)	2.8 (1.0)	2.3 (1.0)	119.4**	14.2 **
Pain description score	9.8 (4.2)	2.1 (1.6)	8.7 (4.8)	6.0 (4.5)	160.2**	36.4 **
Functional status score	10.1 (3.8)	2.9 (2.2)	7.2 (3.9)	5.4 (4.0)	170.7**	61.9 **

** p< 0.01
The repeated measures analysis determines significance on two aspects:
F^1 :Test for main effect for time (the repeated measure)
F^2 : Test for interaction effect (group by time)

Table 3: Relative differences in pain and functional status variables of the two study groups as revealed in ITT* analysis (N=124).

Variables	Water (n=62)	Land (n=62)	t test	P
	Mean	**Mean**		
Relative differences in pain severity	- 0.5 (0.3)	- 0.2 (0.5)	-3.8	< 0.001
Relative differences in pain interference	- 0.3 (0.2)	- 0.1 (0.2)	-2.7	< 0.001
Relative differences in pain description	- 0.7 (0.2)	- 0.1 (0.7)	-6.5	< 0.001
Relative differences in functional status	- 0.7 (0.1)	- 0.1 (0.6)	-6.6	< 0.001

* ITT = Intention-To-Treat

Table 4: Relation of pain level and functional status improvement.

	Pain severity			Pain interference			Pain description			Functional status		
Variable	B	SE	t	B	SE	T	B	SE	t	B	SE	t
Constant	0.231	0.80	0.288	0.826	0.61	1.351	1.315	2.81	0.468	0.72	2.53	0.285
Gender	0.075	0.18	0.409	0.227	0.13	1.668	0.018	0.68	0.026	0.58	0.62	0.952
Age	-0.010	0.01	-1.430	-0.010	0.01	-1.991	-0.004	0.02	-0.141	-0.02	0.02	-0.73
Physical activity	-0.136	0.19	-0.697	0.229	0.14	1.584	-0.223	0.75	-0.298	0.04	0.68	0.065
Pain /function before	-0.699	0.07	-9.32**	0.504	0.07	7.00**	-0.768	0.07	-10.4**	-0.69	0.07	9.15**
Group	-0.804	0.17	-4.69**	-0.452	0.11	-3.5**	-4.249	0.61	-6.98**	-3.73	0.58	6.468**
R^2			0.62			0.48			0.64			0.62

* ITT: Intention-To-Treat

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supports the body [16], prevents pain, and offers the possibility for multiple repetitions.

The advantages of this study, compared with other studies, are the relatively large number of subjects [37-39] and the consistent and precise implementation of the intervention program in water and on land.

The main limitation of the study is the absence of a follow-up on the long-term effects of the exercise programs. Therefore, it is impossible to determine whether the programs' effects were retained over time, and whether the advantage of the water-based program over the land-based program was retained as well. In addition, the participants and the movement therapist were obviously not blinded to the group assignment, which might have decreased the external validity of the study's findings; however, neither the participants nor the movement therapist was aware of the study hypothesis.

Conclusion

We found that for chronic nonspecific LBP, exercising in an aquatic environment is preferable over exercising on land – when the program that is implemented combines the local deep muscles transversus abdominis and the multifidus with diaphragm activity and with integration of the movements of routine daily life, and also emphasizes the precision of movement and the quality of exercise.

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