

THU0470

**EFFECT OF LAND AND WATER-BASED EXERCISE ON PHYSICAL FUNCTION IN WOMEN WITH FIBROMYALGIA: PRELIMINARY FINDINGS FROM THE AL-ÁNDALUS RANDOMISED CONTROL TRIAL**

V. Segura-Jiménez<sup>1,2</sup>, B. Gavilán Carrera<sup>3</sup>, M. Borges Cosic<sup>3</sup>, P. Acosta-Manzano<sup>3</sup>, V. A. Aparicio<sup>4</sup>, I. C. Alvarez-Gallardo<sup>2,5</sup>. <sup>1</sup>Faculty of Education Sciences, Department of Physical Education, Cadiz, Spain; <sup>2</sup>Biomedical Research and Innovation Institute of Cádiz (INIIBICA), Cadiz, Spain; <sup>3</sup>Faculty of Sport Sciences, Department of Physical Education and Sport, Granada, Spain; <sup>4</sup>Faculty of Pharmacy, Department of Physiology, Granada, Spain; <sup>5</sup>Faculty of Education Sciences, Department of Physical Education, Cadiz, Spain

**Background:** Previous evidence has shown physical function (PF) improvements after physical exercise programs in fibromyalgia<sup>1</sup>. However, research comparing the efficacy of land vs. water-based programs is scarce.

**Objectives:** This study aimed at comparing the effects of two exercise interventions (land- and water-based) on PF in patients with fibromyalgia.

**Methods:** A total of 262 women were initially randomized and 152 (age:50.6 ±7.7 years) completed all the assessments with an attendance ≥70% (control n=62, land-based n=48, water-based n=42). The intervention groups trained three non-consecutive days/week (60 min/session) during 24 weeks. Every session consisted of exercises focused on improving cardiorespiratory fitness, muscle strength, and flexibility. Physical function components were assessed with the Functional Senior Fitness Test battery, and a standardized global PF index was calculated. Pre-, post- and re-test (12-week detraining) assessments were conducted. Groups did not differ in sex, sociodemographic characteristics, disease duration, drugs intake, and body mass index. Analysis of covariance was used to test the differences in changes from baseline (post-test vs. pre-test and re-test vs. pre-test) between groups using age, pain sensitivity, and baseline outcomes values as covariates.

**Results:** Land- and water-based exercise groups improved lower body strength (mean difference; 95% confidence interval=2.8; 1.8, 3.8 and 1.7; 0.6, 2.8, respectively), upper body strength (4.8; 2.8, 6.8 and 3.5; 1.4, 5.6, respectively), and agility (-0.8; -1.2, -0.4 and -0.4; -0.8, -0.0, respectively) compared to the control group (all, P≤0.033). Additionally, land-based exercise group improved lower body flexibility and cardiorespiratory fitness compared to both the control (6.4; 2.8, 9.9 and 55.0; 31.0, 79.2, respectively) and water-based (5.4; 1.7, 9.2 and 37.5; 11.4, 63.6, respectively) groups (all, P≤0.002). Global PF improved in the land-based compared to the control group (0.4; 0.2, 0.5, P<0.001) and the water-based group (0.2; 0.0, 0.4, P=0.019). After the detraining period, land- and water-based groups maintained improvements in upper body strength (3.1; 1.2, 5.0 and 2.2; 0.1, 4.2, respectively) compared to the control group (all, P≤0.032). Land-based exercise group maintained improvements in lower body flexibility (5.1; 1.5, 8.8), lower

body strength (1.7; 0.8, 2.6), agility (-0.6; -1.0, -0.3) and cardiorespiratory fitness (31.0; 6.8, 55.2) compared to control group (all, P≤0.007), and agility (-0.5; -0.9, -0.1) and cardiorespiratory fitness (40.2; 11.7, 68.7) compared to the water-based group (all, P≤0.014). The improvements in global PF were maintained in the land-based group compared to the control group (0.1; 0.0, 0.3, P=0.049).

**Conclusion:** Land- and water-based exercise interventions are overall effective to improve PF in patients with fibromyalgia. However, the land-based exercise intervention presented greater effectiveness compared to the water-based exercise intervention. Improvements were overall sustained in the land-based group after a 12-week detraining period.

**References:**

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**VITAMIN D SUPPLEMENTATION; IS IT EFFECTIVE IN FIBROMYALGIA PATIENTS?**

S. A. A. Tabra<sup>1</sup>, M. H. Abu-Zaid<sup>1</sup>, S. Hablas<sup>1</sup>. <sup>1</sup>Faculty of Medicine Tanta University, Rheumatology and Rehabilitation, Tanta, Egypt

**Background:** Fibromyalgia syndrome (FMS) is a chronic pain syndrome which presented by easy fatigability, widespread body pain, anxiety and tenderness points on specific anatomic regions. Fibromyalgia may be risk factor for vitamin D deficiency because of pain, poor mobility, or depression, potentially leading to less time of sun exposure or high rates of adiposity leading to decreased synthesis of vitamin D & there are conflicting results on the role of vitamin D in improving chronic nonspecific musculoskeletal pains<sup>1,2</sup>.

**Objectives:** Assessment of the effectiveness of vitamin D supplements as adjunct therapy in functional status, quality of life and psychological status in fibromyalgia patients with vitamin D insufficiency.

**Methods:** One hundred adult patients of primary FMS (according to the 2010 ACR criteria for FMS) associated with vitamin D insufficiency (21-29ng/mL) were selected to participate in this study. Patients with secondary FMS were excluded; also we excluded patients with any psychiatric disorders and patients who had other chronic diseases interfering with calcium, phosphorus, and vitamin D metabolism. After written consent; the patients were randomly divided into 2 equal groups; group

**Table 1. Summary of SR. P: population; C: comparison; H: High, M: Moderate; L: Low confidence; MA: meta-analysis; SOC: standard of care; PRO: patient reported outcomes; ROM: range of motion; MPA: methylprednisolone acetate; TA/TH: triamcinolone acetate/ hexacetonide; MW: molecular weight; YR: Yttrium synoviorthesis \*Same SR assessed knee arthritis in OA and RA separately**

SR	P	C	AMSTAR2	Efficacy	Safety
Newberry	knee OA	HA vs PBO; HA; Lavage	H	MA. HA better than PBO in function in older patients (small effect).	No diff in AE
Juni		GC vs Sham; PBO; SOC	H	MA. GC better in pain and function until 6w. No diff at 12-24w.	No diff in AE
Pas		MSC vs PBO; PRP; HA	M	No MA. MSC better in pain, PRO, MRI, etc High risk of bias.	No diff in AE
Trojan		HA vs PBO; GC	M	NMA. HA better vs GC or PBO in WOMAC pain, stiffness, function and OARSI criteria.	No diff in AE
Gallagher		HA vs PBO	M	No MA. No diff in joint space width. High risk of bias.	Not reported
Samson		HA vs Glucosamine; Chondroitin; Lavage	M	MA. HA better in pain (small effect), unclear clinical benefit	MA. More AE with HA. SAE in 3/1002 knees with HA (severe swelling, hypersensitivity reaction)
Di		PRP vs HA	L	No MA. PRP better only in WOMAC function.	More AE with PRP (p<0.05) SAE in 2 knees with HA (severe swelling)
Silvinato*		MPA vs TA; TH	L	MA. MPA better vs TA in pain until w6 in pain or function at 12w.	No diff in AE
Trigkilidas		HA vs PBO; GC	L	No MA. HA (small effect) better in mild-moderate OA	No diff in AE
Lo		HA vs PBO	L	No MA. HA (small effect) better in pain. High heterogeneity	No diff in AE
De Souza Figueiredo	TM OA Hip OA	HA vs GC HA vs GC; PBO; PRP; Anaesthetics	M L	HA better in pain at w24 MA. No diff in HA vs comparators in pain and OARSI criteria	Not reported No diff in AE
Lee Heuft	Shoulder capsulitis RA (knee)	HA vs SOC YR vs PBO; GC	M M	No MA. No diff in HA vs SOC. No MA. YR better vs PBO, TH better vs YR in ROM and knee circumference.	No diff in AE Not reported
Silvinato*		MPA vs TA; TH	L	SR inconclusive MA. No diff in pain or function.	No diff in AE
Saito		HA vs PBO	L	MA. HA better in global effectiveness, pain and inflammation.	No diff in AE

I received duloxetine (60 mg once daily for 6 months) plus 50,000 unit oral cholecalciferol weekly for 8 weeks then monthly for 16 weeks. Group II received duloxetine (60 mg once daily for 6 months) plus placebo. The patients were assessed at baseline and after 6 months of treatment by measuring serum levels of 25(OH)D, Fibromyalgia Impact Questionnaire (FIQ), Medical Outcomes Study Questionnaire Short Form 36 Health Survey (SF-36) & Hospital Anxiety and Depression Scale (HADS). **Results:** Eighty six patients completed this study. There was no significant difference between all groups in demographic data, educational status and all baseline variants except serum levels of 25(OH) D. After 6 months; there was significant improvement ( $P<0.05$ ) in group I in serum levels of 25(OH) D. There was significant improvement ( $P<0.05$ ) after 6 months in FIQ, SF-36 and HADS in both groups. There was significant better improvement ( $P<0.05$ ) in group I than in group II in FIQ, SF-36 and HADS. The results of the study are summarized in table 1.

**Table 1. Pre- and post-treatment assessment measures of the patient groups**

assessment measures	Baseline	Baseline	After 6 months	After 6 months
	Group I	Group II	Group I	Group II
25(OH)D	25.3 ± 4.9 ng/ml	26.8 ± 5.3 ng/ml	36.8 ± 3.9 ng/ml	25.6 ± 3.4 ng/ml
FIQ	47.5±5.4	46.7±6.7	27.5±6.1	38.5±7.3
SF-36 (Total score)	47.6±10.4	47.0±9.9	61.0±5.8	54.8±5.3
HAD anxiety	8.2±0.6	8.4±0.3	7.1±0.7	7.5±1.4
HADS depression	8.6±0.3	8.6±0.9	7.3±0.8	7.7±1.4

**Conclusion:** Vitamin D supplement is effective as an adjuvant therapy in improving functional status, quality of life and psychological status in fibromyalgia patients with vitamin D insufficiency.

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THU0472

#### CATHEPSIN S GENE EXPRESSION MEASURED IN THE PERIPHERAL BLOOD OF OSTEOARTHRITIC PATIENTS PRIOR TO SURGERY AS A BIOMARKER OF POST-OPERATIVE PAIN DEVELOPMENT

E. Tchetina<sup>1</sup>, K. Glemba<sup>2</sup>, G. Markova<sup>1</sup>, E. Taskina<sup>3</sup>, M. Makarov<sup>2</sup>, <sup>1</sup>Nasonova Research Institute of Rheumatology, Immunology and Molecular Biology, Moscow, Russian Federation; <sup>2</sup>Nasonova Research Institute of Rheumatology, Orthopedics, Moscow, Russian Federation; <sup>3</sup>Nasonova Research Institute of Rheumatology, Osteoarthritis, Moscow, Russian Federation

**Background:** Osteoarthritis (OA) is a chronic rheumatic disease, which involves pain, limited inflammation, and local destruction of the knee joint. OA pain is a major clinical symptom, which limits working capacity and denotes an important indication for joint replacement in the end-stage OA. In spite of significant number of positive outcomes, chronic postoperative pain represents a major adverse consequence of surgery, which is observed in 10-40% of OA patients. Therefore, identification of patients potentially capable of developing chronic postoperative pain prior to surgery could significantly improve therapy outcome. Recently we hypothesized that genes related to pain sensitization whose expression is upregulated in about 10-40% of the examined end-stage OA patient cohort might be responsible for postoperative pain. Retrospective analysis of gene expression in the peripheral blood of end-stage OA patients before joint replacement surgery revealed that expression of cathepsins S and K, caspase 3, and MMP-9 genes might be associated with postoperative pain development [*Ann Rheum Dis*, 78, suppl 2:A520].

**Objectives:** To examine the validity of our hypothesis in the prospective study.

**Methods:** We examined peripheral blood of 26 healthy volunteers (average age 55±8.3 years old) and 40 end-stage OA patients (average age 56.5±8.9 years old) undergoing joint replacement surgery. Patients were examined before and 6 months after surgery. Pain was assessed prior to surgery using VAS index and neuropathic pain questionnaires DN4 and PainDETECT. Functional activity was evaluated by WOMAC. After surgery pain indices according to VAS of 30% and higher were considered. MMP-9 and caspase 3 protein levels were quantified by ELISA. Total RNA isolated from whole blood was used in expression studies for caspase 3; metalloproteinase (MMP)-9; cathepsins K and S genes. These were performed with quantitative real-time RT-PCR.

**Results:** Out of 40 patients pain complaints were obtained from 9 patients (22,5%) after 6 months' post-surgery. Prior to surgery all the examined genes were significantly upregulated in the patients who developed post-operative pain compared to healthy controls and those subjects who did not develop pain after surgery. However, no difference in the levels of the examined gene-related and functional indices in patients, who developed pain or not, was noted before surgery. ROC curve analyses confirmed significant associations ( $p<0.05$ ) between expressions of the examined genes prior to surgery with the likelihood of pain development after surgery. The cut-off values for the examined gene expressions were 11.34 for cathepsin S (sensitivity of 0.89 and specificity of 0.76), 10.11 for caspase 3 (sensitivity of 0.86 and specificity of 0.65), 10.09 for cathepsin K (sensitivity of 0.86 and specificity of 0.78). Moreover, among the examined genes cathepsin S expression was the most informative predictor of postoperative pain development [AUC= 0.857, 95%CI (0.708-1.000)].

**Conclusion:** High cathepsin S gene expression in the peripheral blood of the end-stage OA patients measured prior to joint replacement surgery could serve an important biomarker of post-operative pain development.

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#### IS PAIN INTENSITY ASSOCIATED WITH EARLY MORTALITY IN PATIENTS WITH PSORIATIC ARTHRITIS?

J. Vela<sup>1,2</sup>, R. Cordtz<sup>1</sup>, S. Kristensen<sup>1,3</sup>, K. Kjær Petersen<sup>4,5</sup>, L. Arent-Nielsen<sup>4</sup>, C. T. Torp-Pedersen<sup>6</sup>, L. Dreyer<sup>1,3,7</sup>. <sup>1</sup>Aalborg University Hospital, Aalborg, Denmark; <sup>2</sup>Clinical Institute, Aalborg University, Aalborg, Denmark; <sup>3</sup>Clinical Institute, Aalborg University, Aalborg, Denmark; <sup>4</sup>Center for Sensory-Motor Interaction, Aalborg University, Aalborg, Denmark; <sup>5</sup>Center for Neuroplasticity and Pain, Aalborg University, 9000, Denmark; <sup>6</sup>Northzealands Hospital - Hillerød, Department of Cardiology, Hillerød, Denmark; <sup>7</sup>DANBIO Registry, Glostrup, Denmark

**Background:** Studies regarding excess mortality among patients with psoriatic arthritis (PsA) are conflicting due to the heterogeneous nature of the disease. Thus, identifying risk factors for mortality is crucial, but few studies have examined these in PsA. Presence of chronic pain can cause excess mortality and since pain is prevalent among patients with PsA this association should be explored.

**Objectives:** To investigate whether higher cumulative pain intensity is associated with an excess mortality ratio in patients with PsA.

**Methods:** A nested case-control study was performed using data from the national Danish healthcare registers and the DANBIO rheumatology register. Cases were patients who died while followed in routine care. Cases were matched on sex, year of birth and calendar period of DANBIO entry with up to five controls. The main exposure of interest was the mean pain intensity (all causes) reported during the time followed in routine rheumatology practice. The pain intensity was measured on a visual analogue scale (VAS) ranging from 0 (no pain) to 100 (worst imaginable pain). Conditional logistic regression was used to calculate the odds of mortality per 5 unit increase in VAS pain while adjusting for inflammatory markers.

**Results:** The Danbio PsA cohort consisted of 8019 patients. In total, 266 cases, i.e. PsA patients who died during the observational period, were identified and matched with 1198 controls (4.5 controls per case). Increasing pain intensity was associated with increased odds of mortality (OR 1.05, 95%CI 1.01 to 1.09) in the crude model, but the association disappeared when adjusting for age, sex, calendar time, socioeconomic status, average c-reactive protein and swollen joint count during the observation period (OR 0.98, 95%CI 0.93-1.03).

Age, average CRP, biological DMARD use, glucocorticoid use, and comorbidities (see table) increased the odds of mortality.

**Table regression estimates from fully adjusted model**

	Odds Ratio	95% CI
Age	2,73	1,60-4,68
C-reactive protein	1,05	1,03-1,07
Swollen joint count	1,08	0,97-1,22
Health assessment questionnaire	1,25	0,84-1,86
bDMARD use	2,62	1,51-4,57
cDMARD use	0,69	0,46-1,03
Glucocorticoid use	3,90	2,51-6,05
Chronic obstructive pulmonary disease	2,19	1,20-4,02
Diabetes mellitus	2,65	1,62-4,31
Cancer	6,15	3,88-9,76
Cardiovascular disease	2,61	1,71-3,97

**Conclusion:** These results indicate that experienced pain in itself is not associated with excess mortality. Age, recent glucocorticoid use, biological DMARD