DOI: http://dx.doi.org/10.1590/1413-785220223001e255939
OSTEOMETABOLIC

SELF-MANAGEMENT PROGRAM (PARQVE) IMPROVES QUALITY OF LIFE IN SEVERE KNEE OSTEOARTHRITIS

PROGRAMA DE AUTOGESTÃO (PARQVE) MELHORA A QUALIDADE DE VIDA NA OSTEOARTRITE GRAVE DO JOELHO

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ABSTRACT

Objective: To evaluate the effects of the self-management program PARQVE in patients with severe knee osteoarthritis (KOA). Methods: Prospective randomized controlled clinical trial with 65 grade IV Kelgren & Lawrence (K&L) KOA patients who were allocated into groups: Control (CG) and Intervention (IG). Both groups received usual care. IG also participated in two days of multi-professional interventions about OA (causes and treatment) and received the program's DVD and book. Standing X-rays were obtained at inclusion and Ahlback's classification was registered. Western Ontario and McMaster Universities Index (WOMAC), Numerical Rating Scale (NRS), Lequesne, weight, and body mass index (BMI) were obtained at inclusion, and after 6, 12 and 24 months. Results: Groups were similar at baseline, despite higher WOMAC stiffness scores and a greater number of Ahlback's grade 4 and 5 in the IG. Only the IG improved WOMAC and total functions ($p<0.001$) during the study period above 12%, but did not reach the minimal clinically important difference of 20%. Best results were in one year. Non-significant improvements were observed without changes in body composition ($P>0.05$). Conclusions: Patients with severe KOA have mild to moderate function and quality of life improvement due to self-management program (PARQVE). ***Level of Evidence I; Therapeutic Studies; Prospective Randomized Controlled Trial.***

Keywords: Osteoarthritis, knee. Education. Clinical trial. Minimal clinically important difference. Quality of life. Patient education as topic. Treatment outcome.

RESUMO

Objetivo: Avaliar os efeitos do programa de autocuidado PARQVE em pacientes com osteoartrite grave de joelho (OAJ). Métodos: Ensaio clínico prospectivo randomizado controlado com 65 pacientes Kelgren & Lawrence (K&L) grau IV que foram alocados nos grupos: Controle (GC) e Intervenção (GI). Ambos os grupos receberam cuidados habituais. O IG também participou de dois dias de intervenções multiprofissionais sobre OA (causas e tratamento) e seus membros receberam o DVD e o livro do programa. Raios-X em pé foram obtidos na inclusão e a classificação de Ahlback foi registrada. Western Ontario e McMaster Universities Index (WOMAC), Escala de classificação numérica (ECN), Lequesne, peso e índice de massa corporal (IMC) foram obtidos na inclusão, e aos 6, 12 e 24 meses. Resultados: Os grupos eram semelhantes no início do estudo, apesar de maiores escores de rigidez WOMAC e um número maior de pacientes de Ahlback grau 4 e 5 no GI. Apenas o GI melhorou em WOMAC e função total ($p <0,001$) acima de 12% durante o período de estudo. Os melhores resultados foram após um ano. Melhorias não significativas foram observadas na composição corporal ($P> 0,05$). Conclusões: Pacientes com OAJ grave apresentam melhora leve a moderada de função e qualidade de vida pelo programa de autogerenciamento (PARQVE). ***Nível de Evidência I; Estudos Terapêuticos; Estudo Clínico Prospectivo e Randomizado.***

Descritores: *Osteoartrite do joelho. Educação. Ensaio clínico. Diferença mínima clinicamente importante. Qualidade de vida. Educação de pacientes como assunto. Resultado do tratamento.*

Citation: Biscaro RC, Ochoa PGG, Ocampos GP, Arouca MM, Camargo OP, Rezende MU. Self-management program (PARQVE) improves quality of life in severe knee osteoarthritis. Acta Ortop Bras. [online]. 2022;30(1)Esp.: Page 1 of 7. Available from URL: http://www.scielo.br/aob.

INTRODUCTION

Osteoarthritis (OA) is considered a serious disease because it affects 240 million people worldwide, limiting mobility, disabling normal activity and increasing risk of cardiovascular disease, diabetes, hypertension and death. OA has no cure and yet, according to experts, all patients should receive education to be active, exercise and manage their weight.[1]

In the Department de Ortopedia e Traumatologia - Hospital das Clínicas - Faculdade de Medicina da Universidade de São Paulo (DOT-HC-FMUSP), a series of studies were made in order to develop

All authors declare no potential conflict of interest related to this article.

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Article received on 09/30/2021, approved in 11/01/2021.

a self-management program for patients with knee OA (KOA) called PARQVE (Project Arthritis Recovering Quality of Life by Education).[2–9] Initially, patients were included with all degrees of knee OA[2,3,8,9] and although not using all coping tools added to the program through the years, the impression of results were bleak since only 10% of patients improved significantly, far away from reported results.[10] In order to verify the effectiveness of two days of self-management-program on OA by a multiprofessional group to patients with KOA, patients with grades I to III Kellgren & Lawrence (K&L)[11] KOA submitted to usual care were compared to patients with the self-management program and usual care finding clinically relevant improvements of function and strength in those who participated in the PARQVE program.[5,6,12] Although we agree that all patients should receive education,[1] K&L grade IV KOA carries a significant diversity of clinical presentations varying from obliteration of the joint space to instability and deformity where diet and exercise will hardly compensate for instability. Ahlback's classification modified by Keyes[13] reflects the anatomic and pathologic progression of medial compartment KOA, and is of value in allowing more accurate comparisons to be made of different methods of treatment. The objective of this study is to verify how much an OA self-management program (PARQVE) can improve quality of life in patients with severe KOA.

MATERIAL AND METHODS

This study is a single-blind, single center, prospective randomized controlled clinical trial that followed the guidelines of the CONSORT statements for randomized controlled trials and nondrug treatments[14] and was performed at the Osteometabolic Group -Department of Orthopedics and Traumatology––Hospital das Clínicas–University of São Paulo. Ethics Committee for Analysis Certificate - CAAE 37436114.6.0000.0068. Clinical Trials registration number: NTC 02335034.

Eligibility criteria included patients 40 years of age or older, with American College of Rheumatology (ACR) clinical and radiological definition of KOA with K&L grade 4, able to understand Western Ontario and McMaster Universities Index (WOMAC)[15] and sign the informed consent. Patients were excluded if missed interventions or if submitted to knee surgery or any other disease or surgery that prevented them from participating in the program.

Randomization

Fifty-four sealed, opaque and non-translucent envelopes containing a card indicating CG or IG were mixed in an urn. The patient retrieved a card from the urn and opened it in front of an assistant of the project. Patients were directed to the subsequent routine.

Interventions

Patients randomized to the intervention group (IG) participated in two saturdays (8:00 to 17:00, two months apart) of interventions including lectures and physical and mental exercises in order to understand the disease and the importance of changing lifestyle and how to accomplish such changes[5] with a group of professionals including orthopedic surgeons, nutritionist, psychologists, physical therapists, physical educators, occupational therapists and social workers. IG participants received written[16] and video (DVD) educational material on the first day of the program, with all material explained in the interventions so they could change lifestyle at home or in community centers and primary and secondary care centers of the city of São Paulo compiled by the social workers of the program.

Usual care/ Follow-up routine

The orthopedic team treated all patients (control - CG and IG) on weekdays for inclusion but on Saturdays for baseline, six, 12- and 24-months evaluations. Interventions were scheduled less than a month after baseline evaluation. At first attendance patients were prescribed analgesics such as paracetamol, codeine and/or dipyrone according to symptoms. Subsidiary exams were requested. If criteria matched, patients were included in a subsequent follow-up. At each visit since the inclusion, the medical team explained the disease and its forms of treatment based on international guidelines[17,18] and prescribed whatever services they considered appropriate including the need to diet and exercise, orthotics, and medications to each patient, including diacerhein. When baseline evaluations were performed all patients were under medications for more than two months.

Outcome Measures

The primary aim of this study was to evaluate the improvement in total WOMAC of the patients at 12 months. Secondarily was to evaluate improvements in WOMAC total at 6 and 24 months, as well as WOMAC pain, stiffness and function, Numerical Rating Scale (NRS), Lequesne algo-functional questionnaire, weight body and mass index (BMI) at six and 12 months, 24 months. At each follow-up evaluation verify if improvement reached minimum clinically important differences (MCID).

Post Hoc Outcomes

Post hoc outcomes at 6, 12 and 24 months were: reduction of at least 5Kg in body weight,[19] NRS pain reduction of 20%,[20] WOMAC pain reduction of 11%,[21] WOMAC function of 20%,[21] WOMAC stiffness of 8%,[21] and WOMAC total improvements of 12% in respect to baseline.[21,22]

Sample Size

The number of patients was calculated to obtain a statistical power of 80% and a significance level of 5%. The standard deviation of a pilot study of 15.8[23] and an expected improvement of 20% estimated a number of 22 per group. Adding 20% per losses a number of 27 per group was selected.

Blinding

Patients were conscious about the group they were randomly assigned. Evaluators were blind to groups.

Statistical analysis

Quantitative personal and clinical characteristics were described according to groups using summary measures (means, standard deviations, medians, minimum and maximum) and compared between groups using the Mann-Whitney test or Student's t-test, the qualitative characteristics were described according to groups and the association with the use of the chi-square test was verified. The WOMAC domains were described according to groups and evaluation moments using summary measures and compared between groups and moments using generalized estimated equations (GEE) with Poisson marginal distribution and identity link function for the other evaluated parameters were assumed normal distribution with identity link function and assumed first order autoregressive correlation matrix between the evaluation moments for all analyses. The analyzes were followed by Bonferroni's multiple comparisons to verify where differences between groups and evaluation moments occurred when significant. The results were illustrated using graphs of mean profiles with the respective 95% confidence intervals. The analyzes were performed using the IBM-SPSS for Windows version 22.0 software and tabulated using the Microsoft-Excel 2010 software, and the tests were performed with a significance level of 5%.

RESULTS

Between January and February 2015, 65 patients met the inclusion criteria and agreed to participate. Randomization with envelopes was programmed for 54 patients. The remaining 11 patients were invited

to participate in the program and invited to come at the evaluation days, after randomization was completed. These extra patients came to all evaluations and their data were included (Figure 1). Groups were similar at inclusion despite a greater number of volunteers in the study group (Table 1, Figure 1).

WOMAC total and function were different between groups ($p<0.001$, Table 2, Figure 2), improving from baseline to all other moments in the IG ($p<0.001$, Table 3). WOMAC Pain varied during the study

Table 1. Description of baseline characteristics according to groups and results of statistical tests.

Variable	Group		p
	Control (N = 27)	Intervention (N = 38)	
Age (years)			0,996
Mean ± SD	67.5 10.3	67.5 11.1	
median (min.; max.)	65.5 (46; 86)	69 (34; 88)	
Gender, n (%)			0.378*
Male	9 (30,8)	8 (21,1)	
Female	18 (69,2)	30 (78,9)	
Weight (Kg)			0.261
Mean ± SD	78.4 14.6	82.8 15.4	
median (min.; max.)	78.7 (48.5; 119.7)	82 (50.7; 124.3)	
BMI			0.386
Mean ± SD	31.6 6.1	32.8 5.3	
median (min.; max.)	33 (21.5; 47.3)	32.3 (23.7; 42.7)	
WOMAC pain			0.662**
Mean ± SD	10.5 3.8	11.1 3.9	
median (min.; max.)	12 (4; 15)	11 (5; 18)	
WOMAC stiffness			0.010**
Mean ± SD	4.3 1.2	5.4 1.9	
median (min.; max.)	4 (2; 6)	6 (0; 8)	
WOMAC function			0.242**
Mean ± SD	36.6 10	42.1 9.7	
median (min.; max.)	40.5 (13; 51)	40 (24; 63)	
WOMAC total			0.233**
Mean ± SD	51.4 13.7	58.5 13.7	
median (min.; max.)	55.5 (22; 70)	54 (33; 89)	
NRS			0.194
Mean ± SD	67.4 17.6	74.4 15.6	
median (min.; max.)	67.5 (25; 100)	80 (40; 100)	
Lequesne			0.315
Mean ± SD	14.2 3.6	15.4 3.9	
median (min.; max.)	14.3 (6; 21)	14 (8.5; 21)	
Ahlback Right			0.993**
1	0 (0)	2 (6,3)	
2	1 (4,3)	0 (0)	
3	4 (17,4)	5 (15,6)	
4	11 (47,8)	15 (46,9)	
5	7 (30,4)	10 (31,3)	
Ahlback Left			0.095**
2	1 (4,5)	2 (6,7)	
3	8 (36,4)	2 (6,7)	
4	8 (36,4)	16 (53,3)	
5	5 (22,7)	10 (33,3)	
Worst Ahlback			0.383**
3	4 (17,4)	1 (3,1)	
4	10 (43,5)	17 (53,1)	
5	9 (39,1)	14 (43,8)	

Student T test; ** Mann-Whitney test; * Chi square test.

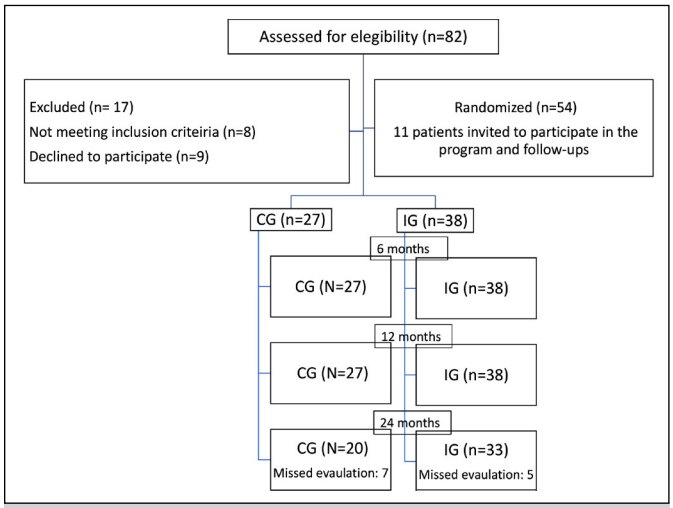

Figure 1. Flowchart.

irrespective of the group ($p=0.049$, Table 2). Despite better IG averages at 12 months, results were not significant ($p>0.05$, Table 3). IG WOMAC pain average results at six and 12 months, reduced 11% and 16%, respectively, reaching MCID of 11%.[21] None of the groups improved function above 20%(MCID).[21] IG stiffness results showed average improvement of 13% in all moments in respect to baseline (MCID of 8%).[21] The sum of WOMAC subsets in the IG led to improvements in WOMAC total above 13% in all moments in respect to baseline (MCID of 12%).[21]

(Table 4) shows that only weight showed a statistically different mean behavior of the groups throughout the evaluation moments (p Interaction = 0.008). In (Table 5 and Figure 3) we can see that the IG weight decreased on average from baseline to the other moments, and in 2 years the weight was on average lower than the other evaluated moments ($p < 0.05$), without significant mean difference between the groups at any time evaluated ($p > 0.05$). One patient in the control group lost more than 5kg whereas eight/38 patients (21%) in the IG lost ≥ 5kg.[19] Among the eight patients they presented grades 3, 4 and 5 of Ahlback. Pain, by NRS, reduced on average 11.4% not reaching the 20% mark.[20] Lequesne results failed to show any difference between groups or during the study period.

DISCUSSION

We were surprised by an actual improvement in patients with grade IV K&L (Grades III to V Ahlback) by the self-sufficiency program (PARQVE).[5] Groups at inclusion were similar with a reasonable amount of grade V Ahlback (with subluxation of the joint). One could say that the intervention group had a higher percentage of grades IV and V Ahlback, and at inclusion average pain and scores were non significantly higher (except for stiffness) in the IG. What we do not know is if they consume less medication and were less willing to be submitted to total knee arthroplasty as has been described.[10]

Yet this group responded with improvements in pain, stiffness, function and quality of life (considering that there is a direct relation between WOMAC total and EQ5D),[24] not as high as those improvements seen in patients with grades I to III K&L,[5] but above minimum clinically important differences (MCID)[21] for total knee replacement. Interestingly almost 20% of the IG reduced at least 5kg. That percentage is superior to those found in the group of patients with K&L I-III submitted to the same program.[5]

Lequesne results were practically unchanged during the study period demonstrating severe commitment of the patients and a

Table 2. Description of the WOMAC domains and the total according to groups and moments of assessment and results of comparative tests.

Variable/Group	Moment				p Group	p Moment	p Interaction
	Baseline	6 months	12 months	24 months			
WOMAC pain					0.505	0.049	0.237
Control							
mean ± SD	10.5 ± 3.8	10.5 ± 3.6	9.9 ± 3.2	11.3 ± 2.7			
median (min.; max.)	12 (4; 15)	11 (2; 15)	10 (2; 17)	12 (5; 16)			
Intervention							
mean ± SD	11.1 ± 3.9	9.8 ± 3.4	9.3 ± 3.3	10.1 ± 3.3			
median (min.; max.)	11 (5; 18)	9.5 (4; 17)	9 (3; 16)	10 (5; 17)			
WOMAC stiffness					0.436	0.51	0.06
Control							
mean ± SD	4.3 ± 1.2	5.1 ± 1.7	4.2 ± 1.5	4.8 ± 1.4			
median (min.; max.)	4 (2; 6)	6 (0; 8)	5 (1; 7)	5 (1; 8)			
Intervention							
mean ± SD	5.4 ± 1.9	4.7 ± 1.5	4.7 ± 1.7	4.7 ± 1.7			
median (min.; max.)	6 (0; 8)	5 (1; 8)	5 (0; 8)	5 (0; 7)			
WOMAC function					0.612	<0.001	<0.001
Control							
mean ± SD	36.6 ± 10	38.2 ± 10.8	35.9 ± 11.1	38.7 ± 10.8			
median (min.; max.)	40.5 (13; 51)	41 (9; 52)	36 (10; 56)	40 (17; 59)			
Intervention							
mean ± SD	42.1 ± 9.7	35.6 ± 12.7	36.5 ± 12.9	36.7 ± 11.9			
median (min.; max.)	40 (24; 63)	38 (7; 62)	36.5 (10; 65)	37 (14; 64)			
WOMAC total					0.687	<0.001	<0.001
Control							
mean ± SD	51.4 ± 13.7	53.8 ± 15.5	50.1 ± 14.9	54.6 ± 14.1			
median (min.; max.)	55.5 (22; 70)	57.5 (15; 73)	49 (14; 79)	57 (26; 81)			
Intervention							
mean ± SD	58.5 ± 13.7	50.1 ± 16.7	50.6 ± 16.6	51.5 ± 16			
median (min.; max.)	54 (33; 89)	52 (12; 85)	50 (21; 89)	53 (22; 86)			

Generalized Estimated Equations with Poisson distribution and identity function.

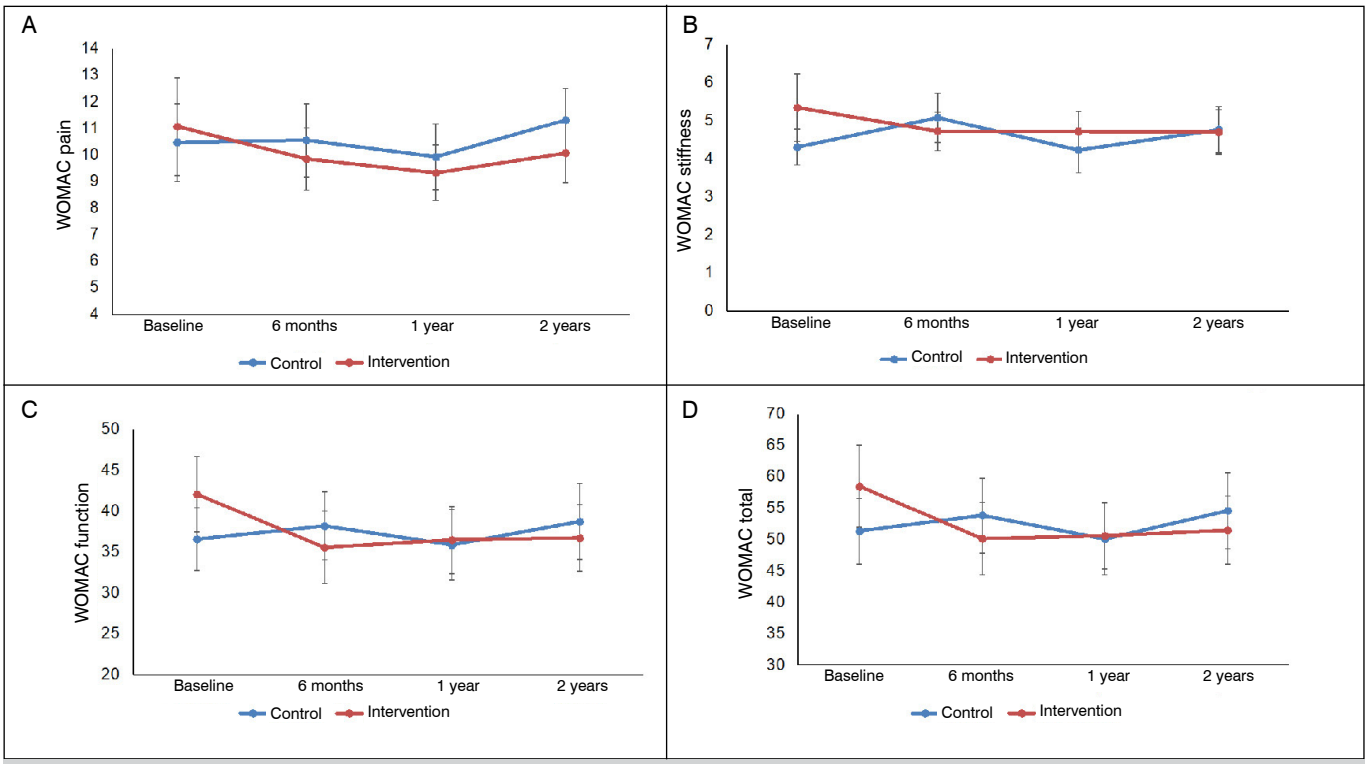

Figure 2. WOMAC pain (A), stiffness (B), function (C) and Total (D) results from control and intervention groups.

Table 3. Result of the comparisons of the WOMAC domains and total between groups or evaluated moments.

Variable	Group/ Moment	Comparisson		Average difference	Standard error	freedom degree	p	CI (95%)	
								Inferior	Superior
WOMAC pain		Baseline -	6 months	0.80	0.48	1	0.603	-0.48	2.07
		Baseline -	12 months	1.33	0.55	1	0.097	-0.13	2.79
		Baseline -	24 months	0.52	0.63	1	>0.999	-1.13	2.17
		6 months -	12 months	0.53	0.40	1	>0.999	-0.51	1.58
		6 months -	24 months	-0.28	0.53	1	>0.999	-1.66	1.11
		12 months -	24 months	-0.81	0.43	1	0.343	-1.93	0.31
WOMAC function	Control	Baseline -	6 months	-1.62	1.03	1	>0.999	-4.85	1.62
		Baseline -	12 months	0.69	1.30	1	>0.999	-3.37	4.75
		Baseline -	24 months	-1.72	1.54	1	>0.999	-6.54	3.10
		6 months -	12 months	2.31	1.03	1	0.701	-0.91	5.52
		6 months -	24 months	-0.11	1.41	1	>0.999	-4.52	4.30
		12 months -	24 months	-2.41	1.13	1	0.908	-5.94	1.11
	Intervention	Baseline -	6 months	9.99	1.34	1	<0.001	5.82	14.17
		Baseline -	12 months	7.95	1.49	1	<0.001	3.30	12.60
		Baseline -	24 months	8.25	1.62	1	<0.001	3.21	13.29
		6 months -	12 months	-2.04	0.89	1	0.583	-4.81	0.72
		6 months -	24 months	-1.74	1.14	1	>0.999	-5.30	1.82
		12 months-	24 months	0.30	0.89	1	>0.999	-2.49	3.09
	Baseline	Control -	Intervention	-7.84	1.87	1	0.001	-13.69	-2.00
	6 months	Control -	Intervention	3.76	1.57	1	0.462	-1.14	8.67
	12 months	Control -	Intervention	-0.59	1.53	1	>0.999	-5.37	4.19
	24 months	Control -	Intervention	2.13	1.65	1	>0.999	-3.03	7.29
WOMAC total	Control	Baseline -	6 months	-2.46	1.21	1	>0.999	-6.25	1.33
		Baseline -	12 months	1.27	1.52	1	>0.999	-3.49	6.03
		Baseline -	24 months	-2.58	1.82	1	>0.999	-8.26	3.09
		6 months -	12 months	3.73	1.21	1	0.055	-0.03	7.50
		6 months -	24 months	-0.12	1.66	1	>0.999	-5.31	5.06
		12 months-	24 months	-3.85	1.32	1	0.100	-7.98	0.28
	Intervention	Baseline -	6 months	12.84	1.56	1	<0.001	7.96	17.72
		Baseline -	12 months	11.01	1.74	1	<0.001	5.58	16.43
		Baseline -	24 months	11.03	1.89	1	<0.001	5.13	16.94
		6 months -	12 months	-1.83	1.04	1	>0.999	-5.07	1.40
		6 months -	24 months	-1,81	1.34	1	>0.999	-5.99	2.38
		12 months-	24 months	0.03	1.04	1	>0.999	-3.23	3.28
	Baseline	Control -	Intervention	-10.26	2.20	1	<0.001	-17.15	-3.38
	6 months	Control -	Intervention	5.04	1.86	1	0.193	-0.79	10.86
	12 months	Control -	Intervention	-0.53	1.81	1	>0.999	-6.17	5.11
	24 months	Control -	Intervention	3.35	1.95	1	>0.999	-2.75	9.46

Bonferroni's multiple comparissons.

Table 4. Description of anthropometric measures (weight and BMI), Numerical Rating Scale (NRS) and Lequesne (algofunctional questionnaires) results according to groups and evaluation moments and results of comparative tests.

Variable/Group	Moment				p_{Group}	p_{Moment}	$p_{Interaction}$
	Baseline	6 months	12 months	24 months			
Weight (Kg)					0.383	0.001	0.008
Control							
mean ± SD	78.4 ± 14.6	78.3 ± 14.6	76.7 ± 12.3	78.5 ± 15.8			
median (min.; max.)	78.7 (48.5; 119.7)	79.4 (50.6; 120.5)	79.1 (51.3; 105.1)	78.3 (57.4; 104.3)			
Intervention							
mean ± SD	82.8 ± 15.4	81.6 ± 15.7	81.6 ± 15	80.9 ± 12.9			
median (min.; max.)	82 (50.7; 124.3)	81.7 (45.7; 120.6)	80.6 (46.3; 119.8)	77.1 (60.1; 111)			
IMC					0.708	0.668	0.717
Control							
mean ± SD	31.6 ± 6.1	31.6 ± 6.3	30.9 ± 5.5	31.5 ± 5.2			
median (min.; max.)	33 (21.5; 47.3)	33.8 (21; 47.7)	33.4 (22; 40.1)	32.6 (24.4; 39.9)			
Intervention							
mean ± SD	32.8 ± 5.3	32.3 ± 5.4	32.4 ± 5.3	32.5 ± 5			
median (min.; max.)	32.3 (23.7; 42.7)	31.6 (22.4; 43.6)	32.4 (22.1; 43.8)	31 (25.8; 44.6)			
NRS					0.393	0.225	0.341
Control							
mean ± SD	67.4 ± 17.6	69.5 ± 20.6	63.9 ± 17.2	65.1 ± 16.1			
median (min.; max.)	67.5 (25; 100)	75.5 (25; 100)	60 (24; 95)	68 (22; 92)			
Intervention							
mean ± SD	74.4 ± 15.6	67.3 ± 20.8	65.9 ± 18.4	67.7 ± 18.8			
median (min.; max.)	80 (40; 100)	68 (10; 96)	62 (20; 97)	74 (22; 97)			
Lequesne					0.627	0.158	0.544
Control							
mean ± SD	14.2 ± 3.6	13.8 ± 3.4	14.3 ± 3.5	14 ± 4.1			
median (min.; max.)	14.3 (6; 21)	15 (5.5; 19)	14.3 (4; 20.5)	14.5 (6; 20)			
Intervention							
mean ± SD	15.4 ± 3.9	13.8 ± 4.2	14.3 ± 3.8	14.3 ± 3.5			
median (min.; max.)	14 (8.5; 21)	13.5 (5.5; 22.5)	14.8 (4.5; 21.5)	14.5 (6.5; 21.5)			

Generalized Estimated Equations with Poisson distribution and identity function.

Table 5. Results of comparisons of Weight (kg) between groups or evaluated moments.

Variable	Group/ Moment	Comparisson		Average difference	Standard error	freedom degree	p	CI (95%)	
								Inferior	Superior
weight	Control	Baseline -	6 months	0.07	0.30	1	>0.999	-0.86	1.01
		Baseline -	12 months	0.01	0.43	1	>0.999	-1.32	1.35
		Baseline -	24 months	0.19	0.66	1	>0.999	-1.89	2.26
		6 months -	12 months	-0.06	0.31	1	>0.999	-1.01	0.90
		6 months -	24 months	0.11	0.59	1	>0.999	-1.74	1.97
		12 months-	24 months	0.17	0.51	1	>0.999	-1.42	1.76
	Intervention	Baseline -	6 months	1.20	0.25	1	<0.001	0.42	1.99
		Baseline -	12 months	1.14	0.35	1	0.031	0.05	2.24
		Baseline -	24 months	2.39	0.44	1	<0.001	1.00	3.78
		6 months -	12 months	-0.06	0.25	1	>0.999	-0.84	0.73
		6 months -	24 months	1.19	0.37	1	0.040	0.02	2.35
		12 months-	24 months	1.25	0.27	1	<0.001	0.39	2.10
	Baseline	Control -	Intervention	-4.34	3.71	1	>0.999	-15.94	7.25
	6 months	Control -	Intervention	-3.22	3.71	1	>0.999	-14.81	8.38
	12 months	Control -	Intervention	-3.21	3.71	1	>0.999	-14.81	8.38
	24 months	Control -	Intervention	-2.14	3.74	1	>0.999	-13.82	9.54

Bonferroni's multiple comparissons.

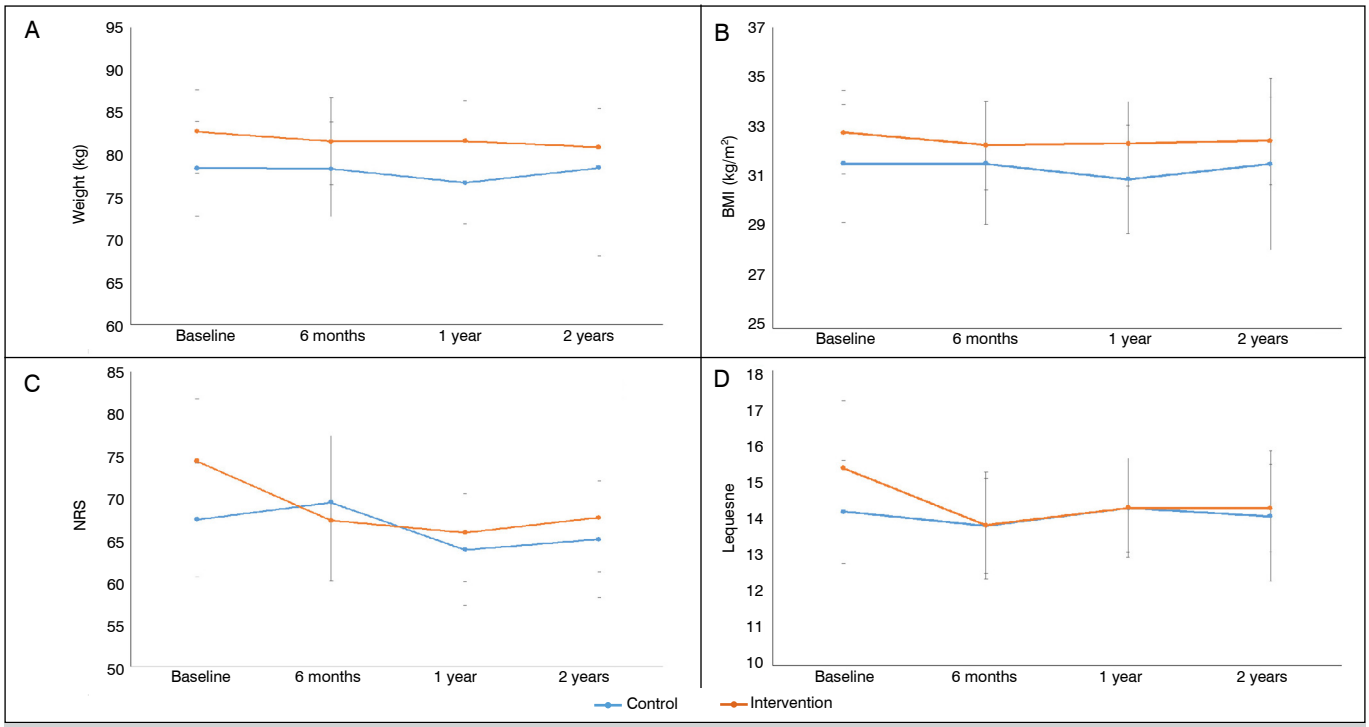

Figure 3. Weight, Body mass index (BMI), numerical rating scale (NRS) and Lequesne results.

lack of sensibility of the scale to show improvements in quality of life in such cases.

There are several limitations to this study: Joining different degrees of OA severity in K&L grades IV; not controlling hours and intensity of exercises performed by the patients; not controlling medications taken by patients; lack of control of satisfaction, diet and if patients were less willing to undergo surgery.[10] Among the strengths are the prospective nature of the study. We do believe that a study separating Ahlback 3 from 4 and from 5 should be performed since the severity of the disease is markedly different.

CONCLUSION

Patients with severe KOA have mild to moderate functional and quality of life improvement by self-management program (PARQVE).

ACKNOWLEDGMENTS

We thank the secretaries (especially Suellen Lima, Livia Abreu, Flavia Rondon Alves and Natalia Borges), the entire PARVE team (Nadia L.R. Brito, Fabiane E.S. Farias, Cleidneia A.C. Silva, Claudia H.A. Cernigoy, José M. Rodrigues da Silva, Marilu M. Moreira, Olga F.N. Santana, Marcelo I. Hissadomi, Renato Frucchi, Thiago Pasqualin, Gustavo C. Campos Alexandre F. Pailo), and the staff and patients of the Hospital das Clínicas, Department of Orthopaedics, Faculdade de Medicina Universidade de São Paulo for all the efforts for this achievement.

Funding

This study was partially supported by TRB Pharma Brasil and by the Universidade de São Paulo, Faculty of Medicine, Hospital das Clínicas, Institute of Orthopedics and Traumatology, Department of Orthopedics and Traumatology, HC-DOT/FMUSP, São Paulo, SP, Brazil.

AUTHORS' CONTRIBUTION: Each author contributed individually and significantly to the development of this article. RCB and PGGO: acquisition, interpretation, writing and final approvement of the manuscript. GPO and MMA: data analysis, revision and final approvement of the manuscript. OPC: revision and final approvement of the manuscript. MUR: study design, data interpretation, writing and final approvement of the manuscript.

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