ARD Online First, published on September 16, 2011 as 10.1136/ard.2010.148577

Tailored cognitive–behavioural therapy and exercise training improves the physical fitness of patients with fibromyalgia

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Accepted 5 July 2011

ABSTRACT

Objectives Patients with fibromyalgia have diminished levels of physical fitness, which may lead to functional disability and exacerbating complaints. Multidisciplinary treatment comprising cognitive–behavioural therapy (CBT) and exercise training has been shown to be effective in improving physical fitness. However, due to the high drop-out rates and large variability in patients' functioning, it was proposed that a tailored treatment approach might yield more promising treatment outcomes.

Methods High-risk fibromyalgia patients were randomly assigned to a waiting list control group (WLC) or a treatment condition (TC), with the treatment consisting of 16 twice-weekly sessions of CBT and exercise training tailored to the patient's cognitive–behavioural pattern. Physical fitness was assessed with two physical tests before and 3 months after treatment and at corresponding intervals in the WLC. Treatment effects were evaluated using linear mixed models.

Results The level of physical fitness had improved significantly in the TC compared with the WLC. Attrition rates were low, effect sizes large and reliable change indices indicated a clinically relevant improvement among the TC.

Conclusions A tailored multidisciplinary treatment approach for fibromyalgia consisting of CBT and exercise training is well tolerated, yields clinically relevant changes, and appears a promising approach to improve patients' physical fitness.

ClinicalTrials.gov ID NCT00268606

Fibromyalgia is a high-prevalence rheumatological condition characterised by widespread pain without clear pathophysiological mechanisms. Patients have difficulty remaining active or show an imbalance in activity and inactivity, which may eventually lead to deconditioning, functional disabilities and exacerbating complaints.[1] Physical exercise training aimed at increasing their levels of physical functioning and diminishing their complaints is one of the key components in the treatment. Several meta-analyses have shown the benefits of this approach both in fibromyalgia and other chronic pain conditions, especially in combination with cognitive–behavioural therapy (CBT).[2–4] However, the limited effects, high drop-out rates and large variability in the patients' level of functioning suggest that a tailored approach might be more beneficial.[5] We previously showed that a multidisciplinary treatment for high-risk fibromyalgia patients consisting of CBT and exercise training tailored to pain-avoidance (PA) and pain-persistence (PP) patterns was effective in improving self-reported physical and psychological functioning.[6] The aim of the present study was to investigate the additional effects of this approach exploratively at the level of physical fitness.

METHODS

Participants and procedure

The current study was conducted using the same sample we described in our previous study,[6] patients with a relatively recent diagnosis of fibromyalgia (diagnosis <5 years; American College of Rheumatology)[7] all referred to our outpatient clinic by their rheumatologists. Only patients who showed a risk profile of self-reported heightened psychological distress were included. Subsequently, patients were assigned to a PA or a PP group based on a previously validated procedure, consisting of the judgement of a trained therapist based on a semistructured interview and a screening instrument of PA behaviour.[8] Consistent with our previous study,[8] the baseline assessment showed that the patients with a PA pattern had significantly lower levels of physical fitness (both $p<0.01$), compared with the PP group. The total sample of 158 patients was randomly assigned in clusters to the treatment condition (TC), patients who received the treatment, or the waiting list control condition (WLC) separate for the PA and PP group. For the complete inclusion procedure see van Koulil *et al*.[6] The majority of the sample of 158 patients (PA TC n=29; PP TC n=39; PA WLC n=45; PP WLC n=45) were women (94%) with a mean age of 40.8 years (SD 10.5; see table 1). Physical test data were available at baseline for 120 patients and at follow-up for 113 patients, due to 16 patients who dropped out during the trial and 29 patients who had missing data. Physical fitness was assessed before and 3 months after treatment for the TC and at corresponding intervals for the WLC. The trial was registered in a clinical trial register (ClinicalTrials.gov ID NCT00268606).

Tailored treatment

The tailored outpatient group treatment consisted of 16 twice-weekly sessions of CBT and exercise training each lasting 2 h and one booster session 3 months after treatment conclusion. CBT was aimed at diminishing the daily perceived cognitive, behavioural, emotional and social consequences of pain and accompanying complaints.

The exercise training was aimed at increasing endurance and flexibility based on graded activity, and comprised exercises (eg, cycling, gymnastic exercises, strength and flexibility exercises, functional walking training), hydrotherapy and relaxation therapy. Throughout, the patients received consolidating homework assignments. The PA treatment aimed at increasing the patients' level of daily activities and diminishing their PA behaviours by stimulating them gradually and systematically to increase their daily activities with individual goals and exposure to fear-related situations as the guiding principle. The PP treatment first focused on regulating and diminishing their PP behaviours by teaching the participants to pace their activities and to alternate between activity and inactivity, followed by gradually increasing their daily activities (see van Koulil *et al*[9] and supplementary text (S1), available online only, for a more detailed treatment description).

Measures

Physical fitness was assessed by physical therapist examination. The shuttle walking test (SWT) is a standardised maximal test assessing walking speed and endurance in terms of the total distance walked at a progressive pace set by audio signals until the patient reaches exhaustion.[10] The cycling test is a submaximal test starting at 25 W and based on stepwise resistance increase of 5 W every minute and measures the total minutes cycled with a progressive resistance until the patient reaches exhaustion.[11] For both tests perceived exertion after test completion was assessed using the Borg scale ranging from 0 (no perceived exertion) to 10 (maximum perceived exertion).[12] The measures described have all been used in previous studies of chronic physical symptoms and have shown good validity and reliability.[10 11 13]

Statistical analyses

Treatment effects were evaluated using a linear mixed model taking into account the specific design features of this trial. For each of the outcomes the post-assessment was used as dependent variables, and treatment, baseline measurement and patient pattern (PA or PP) were used as independent variables in the primary analyses. Random effects were added for randomisation groups. Secondary analyses contained pattern by treatment interactions—to test for a homogeneous treatment effect in both patterns. All analyses were performed using the intention-to-treat principle. We also performed an analysis using last observation carried forward as a sensitivity analysis. Effect sizes were calculated for the PA and PP and the TC and WLC separately by computing the difference between the means of the assessment points divided by the pooled SD at baseline.[14] In addition, we calculated a reliable change (RC) index for the PA and PP separately

Table 1 Baseline sociodemographic characteristics of the participants for each of the study conditions

	PA		PP	
	TC (n=29)	WLC (n=45)	TC (n=39)	WLC (n=45)
Sex (% female)	93	96	97	89
Married/cohabiting (%)	72	76	82	77
Age, years	42.3 (12.4)	39.4 (10.4)	41.1 (9.4)	40.9 (10.4)
Educational level*				
Primary (%)	4	2	9	5
Secondary (%)	81	93	77	71
Tertiary (%)	15	5	14	24

*Primary, secondary and tertiary education represents an average of 7, 12 and 17 years of formal education, respectively.
PA, pain-avoidance group; PP, pain-persistence group; TC, treatment condition; WLC, waiting list control.

Table 2 Mean (SD), number of patients and effect sizes for the outcomes of the physical tests and the perceived exertion after test completion at baseline and 3-month follow-up for the TC and the WLC of the PA and PP groups

			Baseline	Follow-up	ES
Walking test					
Distance walked (m)	PA	TC	259.6 (156.7) n=28	438.7 (128.9) n=23	1.23
		WLC	245.5 (133.4) n=31	250.3 (136.9) n=30	0.03
	PP	TC	305.7 (122.8) n=37	496.9 (149.9) n=36	1.49
		WLC	339.2 (133.7) n=24	381.7 (150.8) n=24	0.33
		TC*			1.36
		WLC†			0.18
Perceived exertion (scale 0–10)	PA	TC	3.8 (1.5) n=28	2.9 (1.3) n=23	0.64
		WLC	4.8 (1.5) n=30	5.3 (1.9) n=29	−0.29
	PP	TC	3.9 (1.8) n=37	2.8 (1.4) n=36	0.68
		WLC	4.6 (1.9) n=24	4.5 (1.5) n=24	0.06
		TC*			0.66
		WLC†			−0.12
Cycle test					
Time cycled (min)	PA	TC	7.8 (4.6) n=28	12.5 (4.5) n=23	1.13
		WLC	6.9 (3.7) n=30	7.1 (3.9) n=30	0.05
	PP	TC	8.9 (3.8) n=37	12.4 (3.8) n=36	0.80
		WLC	12.3 (5.0) n=24	12.0 (4.8) n=24	−0.11
		TC*			0.97
		WLC†			−0.03
Perceived exertion (scale 0–10)	PA	TC	4.9 (2.1) n=27	3.8 (1.5) n=23	0.28
		WLC	5.2 (2.0) n=30	5.6 (1.7) n=28	−0.22
	PP	TC	4.8 (1.5) n=36	4.0 (1.7) n=36	0.50
		WLC	5.0 (1.6) n=24	4.9 (1.5) n=22	0.06
		TC*			0.39
		WLC†			−0.08

*Mean effect size (ES) for the treatment condition (TC) pain-avoidance (PA) and pain-persistence (PP) groups.
†Mean ES for the waiting list control (WLC) PA and PP groups.

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Table 3 Number of patients with clinically significant improvements in the TC and WLC conditions at 3-months follow-up for the outcomes of the physical tests

		No of patients with improvement/total	
		TC	WLC
Walking test	PA	17/23 (74%)	2/30 (7%)
	PP	27/36 (75%)	5/24 (21%)
		75%	14%
Cycle test	PA	13/23 (57%)	3/29 (10%)
	PP	17/36 (47%)	3/24 (13%)
		52%	12%

PA, pain-avoidance; PP, pain-persistence; TC, treatment condition; WLC, waiting list control.

as $RC=X_2–X_1/S_1\sqrt{1-R_{xx}}$ where X_2 is post-assessment, X_1 is baseline assessment, S_1 is SD and R_{xx} is test–retest reliability. The RC index is a conservative measure used to determine the clinical meaningfulness of change as the basis for determining the percentage of patients showing a clinically relevant improvement (reliable change >1.64, 95% CI one-tailed, p<0.05).[15 16] As the test–retest reliability of the measures used was not available, the association between the baseline and follow-up assessment of the WLC was used as an indicator for test–retest reliability.

RESULTS

With regard to the level of physical fitness, a significant condition effect was found for the total metres walked; the TC walked 163.10 m (95% CI 207.71 to 118.48, p<0.001) longer at post-assessment compared with the WLC; and for the total minutes cycled, the TC cycled 3.49 min (95% CI 5.05 to 1.94, p<0.001) longer at post-assessment compared with the WLC. With regard to the level of perceived exertion, a significant condition effect was found for the SWT; the TC showed a 1.88 points (95% CI 1.00 to 2.76, p<0.001) lower post-assessment score compared with the WLC; and for the cycling test the TC showed a 1.24 point (95% CI 0.45 to 2.03, p<0.01) lower post-assessment score compared with the WLC. See table 2 for the mean scores of the TC and WLC for the PA and PP separately. The pattern × condition interaction effects were not significant, showing no significant differences between both groups. The sensitivity analysis showed that the results after using last observation carried forward were comparable with results presented above. Effect sizes indicated large effects for the TC (SWT 1.36; cycling test 0.97) and small effect sizes for the WLC (SWT 0.18; cycling test –0.03; see table 2). In addition, the RC index indicated a higher proportion of patients with clinically significant improvements with regard to the level of physical fitness in the TC, relative to the WLC at post-assessment (see table 3).[15 16]

DISCUSSION

Examining the effects of tailored multidisciplinary treatment for fibromyalgia on the patients' level of physical fitness, we found that physical fitness had significantly improved in the treated patients compared with the control condition, which also held for perceived exertion after physical activity. The treated patients thus cycled longer and walked further while reporting less exertion than the controls. Effect sizes for the physical tests were large (>0.80), suggesting a clinically relevant change.[14] No differences were found between the PA and PP groups. Several factors could have contributed to these results. As the inclusion of a psychological component aimed at cognitive–behavioural change is presumed to improve treatment adherence and the motivation and maintenance of the reached behavioural goals,[5 17] our intervention comprised both exercise training and CBT. We also tailored the exercise programme to the individual patient's baseline condition and his/her specific PA or PP pattern.[6 8 9] Preliminary evidence for the validity of these patterns was shown previously.[6 8 9] Furthermore, relapse prevention and maintaining long-term goals, components that are supposed to contribute to treatment adherence and relatively stable longer-term treatment results, were systematically addressed throughout the treatment and during the booster session. However, the physical tests were carried out by the physiotherapists who were also involved in the treatment, and longer-term effects and norms merit further investigation. Furthermore, future research is needed to clarify further the PA and PP patterns, for example with behavioural methods such as self-observation lists or measures of activity levels (actometer). Nonetheless, these results indicate that a tailored multidisciplinary treatment approach for fibromyalgia is well tolerated, yields clinically relevant changes, and accordingly appears a promising approach to improve patients' physical fitness.

Acknowledgements The authors acknowledge the contributions and support of the patients, rheumatologists and rheumatology nurse consultants of all the participating study sites. The authors would further like to thank M Effting, M Limborgh, M Font Freide, C Barends, R Speulman, AJL de Jong, AJL Verborg, JF Haverman and KJ Korff for their help in collecting the data.

Funding This study was partly supported by grants from the Dutch Arthritis Association ('Reumafonds') and the Netherlands Organization for Health Research and Development ('ZONMW').

Competing interests None.

Ethics approval This study was conducted with the approval of the Commissie Mensgebonden Onderzoek (CMO) Regio Arnhem, Nijmegen.

Provenance and peer review Not commissioned; externally peer reviewed.

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Ann Rheum Dis published online September 16, 2011
doi: 10.1136/ard.2010.148577