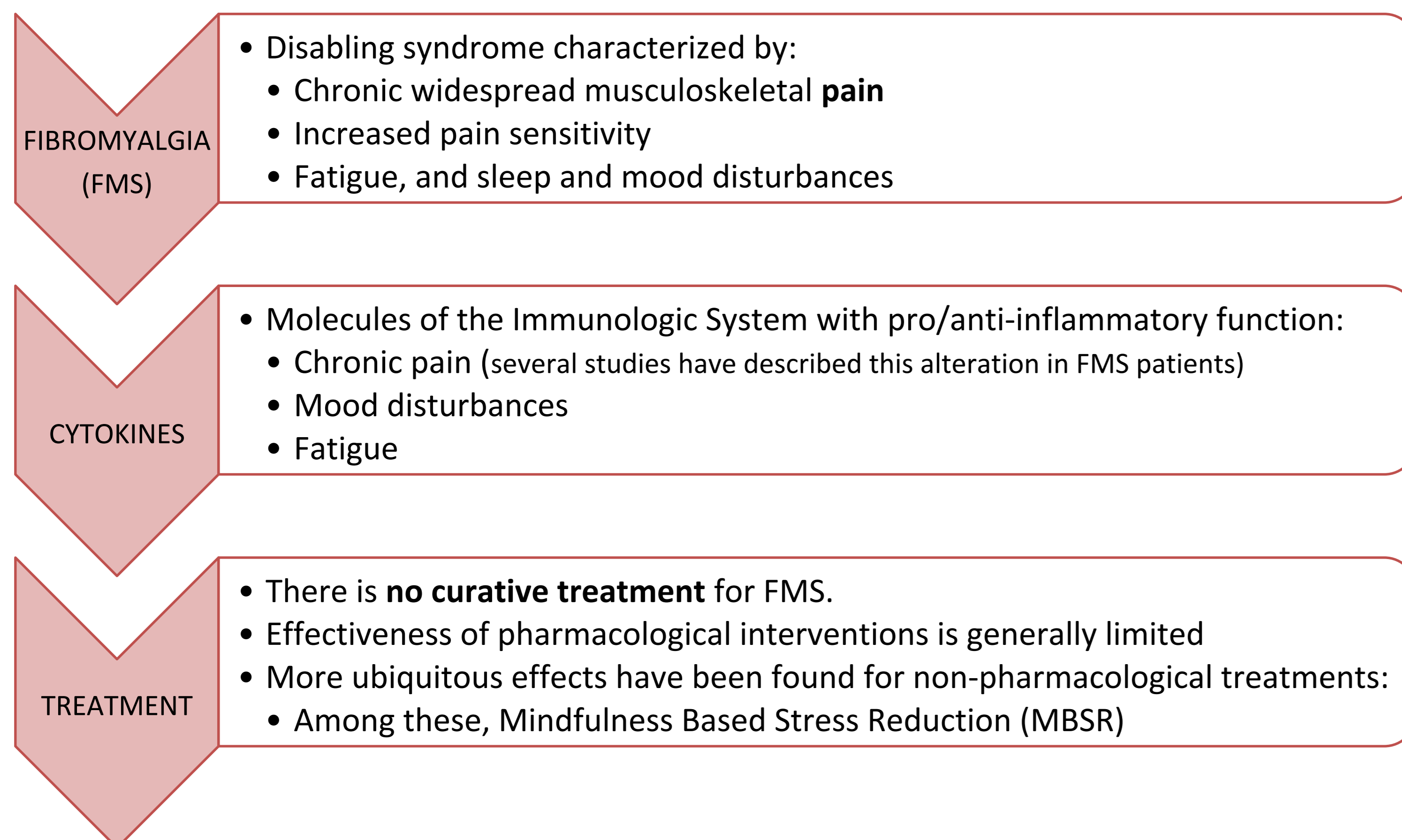


EFFECTS OF A MINDFULNESS-BASED STRESS REDUCTION PROGRAM (MBSR) ON CLINICAL SEVERITY AND INFLAMMATORY BIOMARKERS IN PATIENTS WITH FIBROMYALGIA

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Introduction



Objectives

- O1:** To explore the relationship between mindfulness, inflammatory biomarkers and FMS clinical symptomatology.
O2: To examine the impact of MBSR on FMS and inflammatory biomarkers levels in serum.

Methods

- ✓ Randomized controlled trial with two parallel groups: Treatment as usual (TAU) and TAU + MBSR.
- ✓ Pre-post design.

n=17; TAU+MBSR n=10, TAU n=7

Mini-Mental State Examination (MMSE); Structured Clinical Interview for DSM Axis I Disorders (SCID-I); Revised Fibromyalgia Impact Questionnaire (FIQ-R) Hospital Anxiety and Depression Scale (HADS); Perceived Stress Scale-10 (PSS-10); Five Facet Mindfulness Questionnaire (FFMQ)

Pro- (IL-6 and IL-8) and anti-inflammatory cytokines (IL-10) in serum; levels of high-sensitivity C-reactive protein.

Table 1. Inclusion and exclusion criteria of the study

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> ✓ Woman, between the ages of 18 and 65. ✓ FMS diagnosis according to ACR 1990. ✓ Understanding of Spanish language. ✓ Written informed consent. ✓ Since the study is performed on a sample of patients in which neuroimaging tests will also be held, all participants of this study are right-handed. 	<ul style="list-style-type: none"> ✓ Score ≤ 27 in the MMSE. ✓ Psychological treatment received during the last year. ✓ Prior experience with meditation techniques. ✓ Comorbid mental disorder or severe medical condition. ✓ Inflammatory situation previous to extraction. ✓ BMI ≥ 36 kg/m² or weight ≥ 110 kg. ✓ ≥ 8 caffeine/units per day and ≥ 5 cigarettes/day. ✓ Pregnancy or breastfeeding. ✓ Use of local or oral corticosteroids, anti-cytokine drugs or oral contraceptives.

Table 2. Sociodemographic and clinical data for TAU and TAU+MBSR groups

	TAU	TAU + MBSR	p
Age (years): M (SD)	56.70 (7.10)	54.40 (6.00)	n.s.
Severity FMS			
FIQ-R baseline (mean (SD))	40.63 (23.122)	57.61 (21.72)	n.s.
(range 0-90)			
Years with FMS	17 (11.77)	8.67 (7.71)	n.s.

Note: n.s. is no significant

References

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Results

Table 3. Correlations between clinical and mindfulness scales with levels of inflammatory biomarkers at baseline

	IL-6	IL-8	IL-10	hs-CRP
FIQ-R	r = .24	r = -.12	r = .05	r = -.02
PSS-10	r = .17	r = .17	r = -.33	r = .19
HADS-A	r = .46*	r = -.06	r = -.01	r = -.06
HADS-D	r = .36	r = .09	r = -.22	r = -.22*
FFMQ-Observe	r = .39	r = -.15	r = .03	r = .42*
FFMQ-Describe	r = .08	r = .10	r = -.11	r = -.06
FFMQ-ActAwareness	r = -.04	r = -.01	r = -.15	r = -.05
FFMQ-Nonjudge	r = -.23	r = -.38	r = .11	r = -.13
FFMQ-Nonreact	r = .17	r = -.51*	r = .18	r = .13

*p ≤ .10; **p ≤ .05

Table 4. Correlations between clinical scores and mindfulness skills

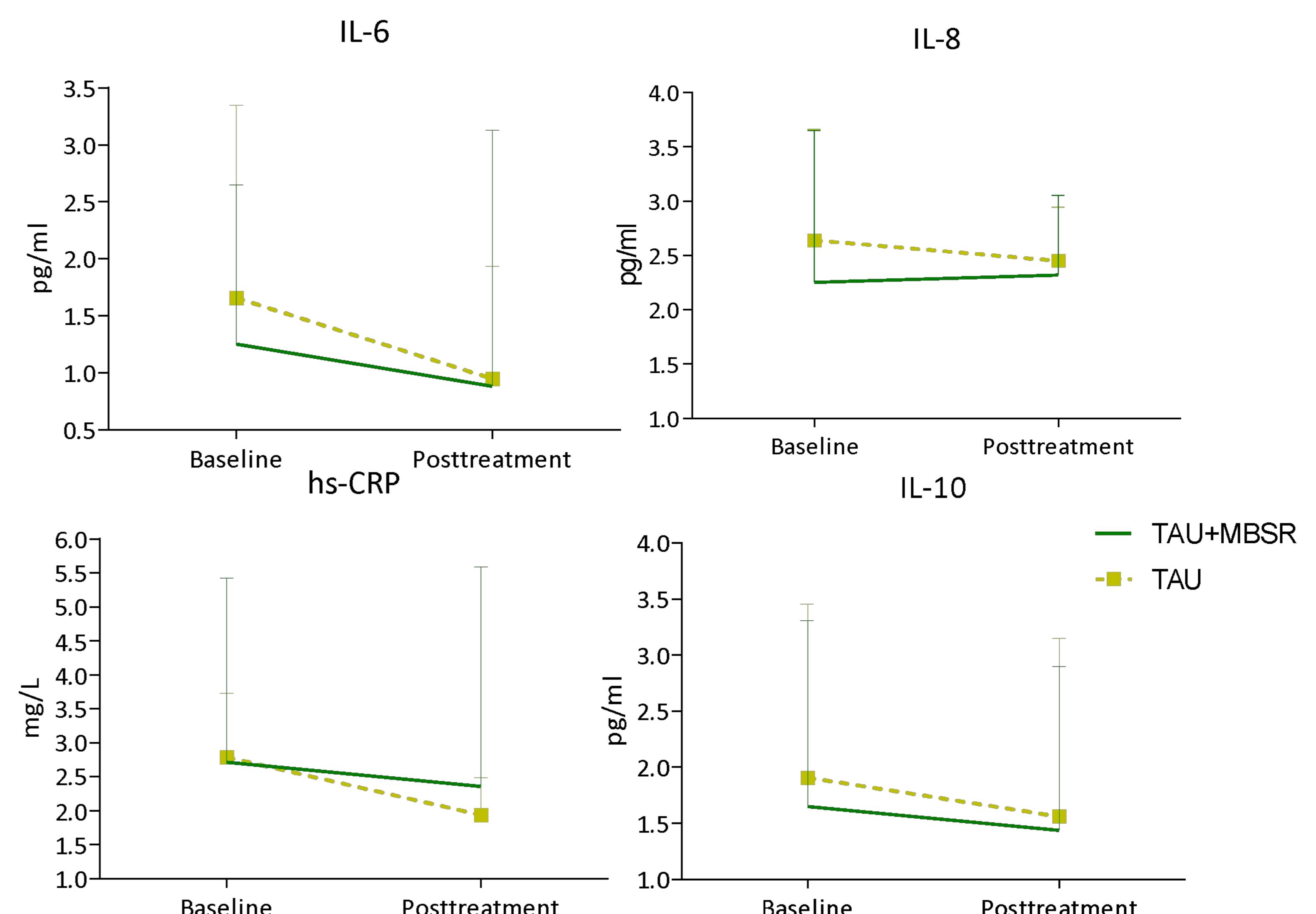
	FFMQ_Observe	FFMQ_Describe	FFMQ_ActAware	FFMQ_Nonjudge	FFMQ_Nonreact
FIQ-R	r = .22	r = -.58**	r = -.68**	r = -.46*	r = .27
PSS-10	r = .81	r = -.38	r = -.42	r = -.82**	r = -.02
HADS-A	r = .26	r = -.16	r = -.55**	r = -.41	r = .25
HADS-D	r = -.12	r = -.20	r = -.53	r = -.40	r = .12

Table 5. Study variables pre and post for both groups

	TAU+MBSR				TAU				ANOVA	η ²
	Pre	Post	t-value (df)	p Cohen's d	Pre	Post	t-value (df)	p Cohen's d		
FIQ-R	60.27 (22.19)	40.67 (23.12)	2.68 (9)	p = .03** d = .21	55.31 (2.26)	57.61 (21.71)	-1.50 (5)	p = .19 d = -.12	F (1) = 5.93 p = .03**	.30
PSS-10	19.20 (8.33)	13.90 (8.34)	2.24 (9)	p = .05* d = .33	19.33 (9.37)	17.33 (9.83)	< 1 (5)	p = .44 d = .12	F (1) ≤ 1 p = .37	.06
HADS-D	8.60 (5.40)	4.80 (4.16)	2.77 (9)	p = .02** d = .59	7.17 (4.62)	8.17 (4.16)	-1.22 (5)	p = .26 d = .14	F (1) = 6.38 p = .02**	.31
HADS-A	10.80 (4.02)	7.80 (4.52)	1.89 (9)	p = .09* d = -.54	8.67 (3.62)	9.67 (4.67)	-1.12 (5)	p = .31 d = .13	F (1) = 3.33 p = .10*	.19
FFMQ-Observe	22.40 (7.41)	28.50 (7.05)	-3.47 (9)	p = .01** d = .67	22.83 (7.13)	22.16 (5.98)	< 1 (5)	p = .77 d = .06	F (1) = 5.72 p = .03**	.29
FFMQ-Nonreact	21.66 (2.33)	26.10 (4.48)	-2.45 (9)	p = .04** d = -.73	22.50 (6.47)	21.66 (2.33)	< 1 (5)	p = .72 d = .11	F (1) = 3.20 p = .10*	.17
IL-6 (pg/ml)	2.25 (1.40)	.88 (1.04)	2.25 (9)	p = .05** d = .16	1.66 (1.69)	.95 (.99)	1.61 (6)	p = .16 d = .28	F (1) ≤ 1 p = .42	.04
IL-10 (pg/ml)	1.65 (1.55)	1.44 (1.46)	2.44 (9)	p = .04** d = .10	1.91 (1.55)	1.56 (1.59)	5.42 (6)	p = .00** d = .13	F (1) = 1.31 p = .27	.08

Note: Normal range for serum biomarkers: IL-6: 1-2 pg/ml; IL-8: 1-157 pg/ml; IL-10: 4-17 pg/ml. Note: in this table we only reflected those variables with significance (p ≤ .05) or with a tendency (p ≤ .10).

Figure 1. Effect of MBSR on serum inflammatory biomarkers



Conclusions

Consistent with **objective 1**, mindfulness has a pro-salutary effect on FMS patients, as shown by the association between FFMQ facets “describe” and “act with awareness” and clinical severity. Anxiety, along with mindfulness facets “observe” and “non react” appears to play a role on inflammatory state of FMS patients.

Supporting **objective 2**, MBSR training improves clinical severity, anxiety, stress and depressive symptomatology. We have not detected a regulatory function of MBSR on immunological function in patients with FMS.

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