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Citation for published version (APA):

Carleton, R. N., Asmundson, G. J. G., Korol, S. L., LeBouthillier, D. M., Hozempa, K., Katz, J. D., Vlaeyen, J. W. S., & Crombez, G. (2020). Evaluating the efficacy of an attention modification program for patients with fibromyalgia: a randomized controlled trial. Pain, 161(3), 584-594. https://doi.org/10.1097/j.pain.0000000000001746

Document status and date: Published: 01/03/2020

DOI: 10.1097/j.pain.0000000000001746

Document Version: Publisher's PDF, also known as Version of record

Document license: Taverne

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PAIN



Evaluating the efficacy of an attention modification program for patients with fibromyalgia: a randomized controlled trial

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Abstract

Persons with chronic musculoskeletal pain may be hypervigilant for pain-related cues which, paradoxically, may be maintaining their pain. Several randomized controlled trials have assessed whether a modified dot-probe protocol (ie, attention bias modification [ABM]) reduces chronic pain- and pain-related symptoms in persons with several diagnoses, including fibromyalgia. Scalability and economic efficiency potentiates the appeal of ABM protocols; however, research results have been mixed, with only some studies evidencing significant symptom gains from ABM and some evidencing gains for the control group. The current randomized controlled trial sought to replicate and extend previous ABM research using idiosyncratic word stimuli and a 1-month follow-up. Participants included treatment-seeking adult women (n = 117) with fibromyalgia who were randomly assigned to a standard (ie, control) or active (ie, ABM) condition. The protocol was delivered online and involved twice-weekly 15-minute sessions, for 4 weeks, with questionnaires completed at baseline, posttreatment, and 1-month follow-up. Symptom reports were analysed with mixed hierarchical modelling. There was no evidence of differences between the control and ABM groups. Both groups had small significant (Ps < 0.05) improvements in pain experiences at posttreatment, but not at follow-up (Ps > 0.05). There were no significant changes for either group on measures of anxiety sensitivity, illness/injury sensitivity, pain-related fear, pain-related anxiety, or attentional biases (Ps > 0.05). The current findings add to the emerging and mixed literature regarding ABM for pain by demonstrating that ABM produces no substantive improvements in pain or pain-related constructs in a large sample of patients with fibromyalgia.

Keywords: Chronic musculoskeletal pain, Fibromyalgia, Attention modification, Anxiety, Fear

1. Introduction

Attentional biases—automatic tendencies to shift attention towards a specific stimulus or set of stimuli—may exacerbate disabling symptoms of chronic musculoskeletal pain.^{9,10,16,32,57,65,70} Several psychological models of chronic musculoskeletal pain highlight the role of attentional processes wherein heightened attention and vigilance for threat cues is critical to the development and maintenance of chronic pain problems.^{11,26,27,66} Consistent with such models, recent meta-analyses have evidenced that persons with chronic pain, but not healthy controls, demonstrate an attentional bias towards sensory pain words (eg, sharp, tender, and aching) when using the dot-probe paradigm^{24,67}; accordingly,

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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PAIN 161 (2020) 584-594

© 2019 International Association for the Study of Pain http://dx.doi.org/10.1097/j.pain.000000000001746 the attentional bias may be associated with perceiving pain as threatening, inducing fear or anxiety, and something to be avoided, all of which can facilitate maladaptive coping strategies (eg, avoidance), exacerbating disability and pain.⁶⁹

Evidence from the anxiety disorder literature suggests that attentional biases for threatening stimuli can be modified, arguably corrected, using variations of the paradigms used to identify those biases.³⁸ The process of modifying the attentional biases is referred to as attention bias modification (ABM) and such modifications may produce substantial (ie, Ps < 0.01; ds > 0.50) and sustained symptom reductions.^{2,47,55} Researchers have demonstrated that ABM can reduce pain experiences in healthy persons^{43,59,60} and persons with acute pain⁵⁸; however, research trials with chronic musculoskeletal pain patients have often used small sample sizes and produced mixed results. Participants with diverse noncancer chronic pain (n = 8) in an uncontrolled study⁵⁶ reported reductions in pain ($r^2 = 0.16$), anxiety ($r^2 = 0.20$), and depression ($r^2 = 0.18$) after 4 weeks of twice-weekly sessions. Similarly, in a placebo-controlled study,¹⁹ participants with fibromyalgia in the active condition (n = 9) selfreported larger reductions than the placebo condition (n = 8) in pain ($r^2 = 0.29$ vs $r^2 = 0.07$), anxiety sensitivity ($r^2 = 0.39$ vs $r^2 =$ 0.07), and pain-related fear ($r^2 = 0.25$ vs $r^2 = 0.04$) after 4 weeks of twice-weekly sessions. By contrast, a second placebocontrolled study⁵⁸ with chronic low back pain participants (n = 22) did not produce significant reductions in pain after 4 sessions of the active condition. A third placebo-controlled study with

adolescents reporting diverse noncancer chronic pain (n = 23) also reported no significant differences in pain, anxiety, depression, or disability after or at a 3-month follow-up.³³

The limited prior research on the utility of ABM for chronic musculoskeletal pain evidences discrepant results based on small heterogeneous samples with limited follow-up data. The current study aims to extend previous work assessing ABM for fibromyalgia. We conducted a randomized, placebo-controlled trial consisting of 8 sessions of ABM delivered through the Internet to a large sample of patients with fibromyalgia, with self-report assessments at preintervention, postintervention, and 1-month follow-up. We expected participants in the ABM group to report significant reductions in self-reported symptoms of pain and painrelated pathology (ie, self-reported disability, pain-related fear, and pain-related anxiety) that would be sustained at follow-up. No differences were expected for the control group. We also expected participants in the ABM group, but not those in the control group, to demonstrate reductions in pain-specific attentional biases.

2. Method

2.1. Participants

Women with fibromyalgia outnumber men, with ratios as high as 10:1.8,40,74,75 Accordingly, men were not recruited for the current investigation. Participants were recruited through poster advertising in local rheumatology clinics, as well as through word of mouth from local rheumatologists, and through participant referrals. Women participants were interviewed by phone to determine eligibility and assess for related fibromyalgia symptoms. Inclusion criteria were a self-reported primary diagnosed complaint of fibromyalgia consistent with contemporary criteria,⁷⁶ 18 to 65 years of age, able to read English at a grade 8 level, and normal/corrected-to-normal vision. Exclusion criteria were impediments to typing, suicidal intent, recent substance abuse, current or past schizophrenia, bipolar disorder, psychotic symptoms, and being engaged in or awaiting legal proceedings associated with their pain. Comorbid pain-related pathologyspecific diagnoses (eg, arthritis), or clinically significant symptoms of depression or anxiety were not exclusionary, so long as fibromyalgia was the primary complaint. In addition, use of cognitive behaviour therapy, formal rehabilitation programs, exercise, psychoactive medications, and pain medications (eg, pharmaceutical, analgesic creams, and herbal remedies) were not exclusionary, so long as participants reported no change in status for 3 months before participation and agreed not to change their status (eg, add new medications) during participation. Pain coping strategies (eg, the use of heat/cold, electricity, and mechanical support) did not serve as exclusionary criteria, and were recorded.

There were 578 participants who screened positive for participation in this study (see CONSORT diagram, **Fig. 1**, for details). A subset of 386 participants completed the pretreatment attention task (66.8% of those recruited) and were randomized to either group. Participants were randomly assigned at recruitment using a sequential list generated a priori by an independent statistician. A total of 54 participants in the control group and 63 in the ABM group completed the pretreatment and posttreatment surveys as well as the attention tasks. There were 29 participants in the control group and 26 in the ABM group who completed the attention tasks at all 3 time points (pretreatment, posttreatment, and follow-up). Sample size analyses were conducted using G*Power 3.1.9.2 and imputed parameters (f = 0.57; α = 0.05;

 $1 - \beta = 0.80$) based on previous research examining efficacy of attention modification paradigms, with a multilevel modelling approach,^{3,55} and the results suggest using a sample size of 26 per group.

For those who completed the study, the mean age of participants in the control group was 47.98 (SD = 11.89) and 47.92 (SD = 10.75) for the ABM group. Most participants reported graduating with a college degree (control at 37.0%; ABM at 39.7%), completing high school (control at 24.1%; ABM at 22.2%), or obtaining a partial college degree (control at 20.4%; ABM at 17.5%). Most participants reported being a homemaker (control at 20.4%; ABM at 28.6%) or being employed full-time (control at 18.9%; ABM at 30.2%), followed by those who were retired (control at 11.1%; ABM at 17.5%) or on disability leave (control at 14.8%; ABM at 4.8%). Most participants in both groups reported being married (control at 57.4%; ABM at 65.1%) and Caucasian (control at 83.3%; ABM at 90.4%).

2.2. Self-report measures

2.2.1. Anxiety Sensitivity Index-3

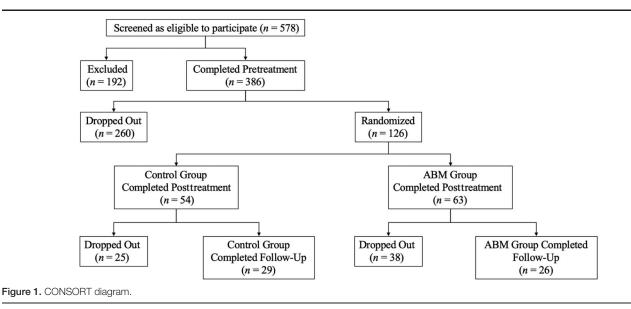
The Anxiety Sensitivity Index-3 (ASI-3⁶⁴) is a self-report measure assessing for tendencies to fear anxiety symptoms, including somatic symptoms associated with pain (eg, "When I feel pain in my chest, I worry that I'm going to have a heart attack"); indeed, anxiety sensitivity seems robustly associated with fearful appraisals of pain experiences.⁴⁸ The ASI-3 consists of 18 items rated on a 5-point Likert scale ranging from 0 (agree very little) to 4 (agree very much). The ASI-3 has demonstrated improvements in internal consistency compared with the original ASI,⁵² as well as good convergent, criterion, and discriminant validity.^{64,73} This measure was administered at pretreatment, posttreatment, and follow-up.

2.2.2. Depression Anxiety and Stress Scale 21-item

The Depression Anxiety and Stress Scale 21-item (DASS-21⁷) is self-report questionnaire revised from the original 42-item questionnaire,40 measuring feelings of depression, anxiety, and stress. The Depression scale assesses hopelessness, low selfesteem, lack of interest, and other associated states. The Anxiety scale assesses physiological arousal, autonomic arousal, subjective anxiety, and other anxiety-related states. The Stress scale assesses tension, negative affect, agitation, and other forms of nonspecific arousal. The 7 items of each scale assess levels of the associated negative emotional state over the past week with a 4point scale, ranging from 0 (did not apply to me at all) to 3 (applied to me very much, or most of the time). The DASS-21 has demonstrated very good convergent validity, acceptable discriminative validity, and good-to-excellent internal consistency.7,22,30 The DASS-21 measure was administered at pretreatment, posttreatment, and follow-up.

2.2.3. Illness/Injury Sensitivity Index-revised

The Illness/Injury Sensitivity Index-Revised (ISI-R¹⁷) is a revised version of the original Illness/Injury Sensitivity Index⁶³ designed to measure fears of illness and injury. The ISI-R consists of 9 items, rated on a 5-point Likert scale, ranging from 0 (agree very little) to 4 (agree very much). Fear of Illness (eg, I worry about becoming physically ill) and Fear of Injury (eg, I am frightened of being injured) factors are represented within the ISI-R¹⁷ but the total summed score was used for this study. The ISI-R correlates highly with the



original index (r = 0.96), has excellent internal consistency ($\alpha = 0.86$), and has convergent validity (r > 0.65).¹⁸ This measure was administered at pretreatment, posttreatment, and follow-up.

2.2.4. McGill Pain Questionnaire—Short Form

The McGill Pain Questionnaire—Short Form (SF-MPQ⁴⁴) was used to measure pain experience. The SF-MPQ includes a pain rating index of 15 commonly used adjectives that describe affective and sensory aspects of pain.⁷⁷ Adjectives are rated on a 4-point intensity scale from 0 to 3. The SF-MPQ also includes a visual analogue scale (VAS) to help assess pain intensity. The SF-MPQ has demonstrated high correlations with the original MPQ,³⁷ as well as good factorial validity for both affective and sensory components of pain (0.78 and 0.76, respectively).⁷⁷ The SF-MPQ was administered at pretreatment, posttreatment, and follow-up.

2.2.5. Pain Anxiety Symptoms Scale-20

The Pain Anxiety Symptoms Scale-20 (PASS-20⁴¹) is a 20-item form of the original PASS⁴², used to measure pain-related anxiety. Items are rated on a 6-point Likert scale ranging from 0 (never) to 5 (always). Four subscales (ie, Cognitive [eg, I can't think straight when in pain], Fear [eg, Pain sensations are terrifying], Escape/Avoidance [eg, I will stop any activity as soon as I sense pain coming on], and Physiological [eg, Pain makes me nauseous]) provide a general measure of pain-related anxiety. Factorial validity has been demonstrated for clinical and non-clinical samples.^{1,23} The PASS-20 was administered at pre-treatment, posttreatment, and follow-up.

2.2.6. Revised Fibromyalgia Impact Questionnaire

The Revised Fibromyalgia Impact Questionnaire (FIQR¹⁴) is an updated version of the FIQ¹⁵ consisting of the same 3 domains as the FIQ (ie, function, overall impact, and symptoms), including questions on memory, tenderness, balance, and environmental sensitivity. For the 9 items rating functional impact, participants are asked to rate on a 0 (no difficulty) to 10 (very difficult) scale how much fibromyalgia made daily activities difficult over the past week (eg, brush or comb your hair, lift and carry a bag full of

groceries). There are also 2 questions (ie, fibromyalgia prevented me from accomplishing goals for the week, I was completely overwhelmed by my fibromyalgia symptoms) asking participants to rate the overall impact of fibromyalgia over the past week, on a 0 (never) to 10 (always) scale and 10 questions rating participant symptom severity on a 0-to-10 scale (eg, pain, energy, sleep, and stiffness). The FIQR correlates with the 3 related FIQ domains (ie, function, overall impact, and symptoms) and has demonstrated good discriminant ability between participants with fibromyalgia from participants with rheumatoid arthritis, systemic lupus erythematosus, major depressive disorder, and healthy controls.¹⁴ The RFIQ was administered at pretreatment, posttreatment, and follow-up.

2.3. Procedure

This study used a randomized, controlled, double-blind protocol (ie, the study researchers and participants were unaware of participant condition assignment), not preregistered, with symptom assessments at pretreatment, posttreatment, and 1-month follow-up. Participants were required to self-report being diagnosed with fibromyalgia by a rheumatologist using contemporary criteria.⁷⁶ Eligible participants were randomly assigned to the control or ABM group and scheduled for a total of 10 sessions over a 6-week period. Random assignment was based on a sequential list generated a priori by an independent statistician (see CONSORT diagram, Fig. 1). The pretreatment and posttreatment sessions took approximately 45 minutes, as participants completed the symptom measures at these sessions, whereas the 8 sessions in between the pretreatment and posttreatment sessions only took 15 minutes, as participants only completed the attention protocol tasks at these sessions. One month after the posttreatment session, participants were invited to complete the same symptom measures that were completed at the pretreatment and posttreatment sessions, and participants in the control group were offered the ABM protocol task.

Inquisit 3 Web Edition from Millisecond Software was used to administer the attention tasks to all participants, allowing the tasks to be conducted simply by clicking on a web link provided to each participant. The tasks used in the current study were modelled after protocols from previous studies.^{2,4,19–21,55} The

interventions were based on the ABM established by Amir et al.² and moved online by subsequent researchers.^{20,21} Word stimuli were used, instead of pictures, because recent evidence suggest that words may produce larger effect sizes than pictures.^{24,46,67} The words used for each session for each participant were derived from a set of 48 pain-specific threat words established as relevant to pain-specific attentional biases (eg, burning, throbbing) and matched to neutral words of comparable length (eq. counting) derived from neutral words used in previous studies.^{6,12,25,51-54} At each treatment session, participants were required to rate their emotional intensity associated with each of the 48 pain-specific threat words from "not at all bothersome" (-3) to "very bothersome" (+3). The 20 words rated as most negative by each participant were then used by the computer as the threat words for that session, which should have facilitated personal relevance (ie. idiosyncratic threat words for each participant). After the threat word rating task, participants were exposed to 240 ABM trials for each session.

Each trial began with a fixation cue ("+") presented in the center of a screen, positioned approximately 40 cm from the participant. Immediately after termination of the fixation cue, the software program (Millisecond Software, Seattle, WA) presented a pair of words in 16 pt Arial font for 500 ms, with one word 1.5 cm above the other. The words in each pair were either both neutral or mismatched, with one neutral and one threat word. Word pairs were presented in random order for each participant. After the word pair was presented for 500 ms, one word was replaced by a probe (either an "E" or "F"). Participants were instructed to determine whether an "E" or an "F" appeared and to respond as quickly as possible by pressing the corresponding key. The key stroke ended the trial and the fixation cue reappeared indicating the start of the next trial. Incorrect responses were recorded, and participants still advanced to the subsequent trial. The trials included various combinations of probe type ("E" or "F"), probe position (top or bottom), and word type (neutral or threat). Dotprobe task reaction times were recorded every session, but only the pretreatment and posttreatment reaction times for both groups were used to assess changes in reaction time.

2.3.1. Attention bias modification group

The ABM consisted of (1) 80 trials with neutral words only; specifically, a 2 (probe type) \times 2 (probe position) \times 20 (word pair presentations) format, and (2) 160 trials wherein the word pair presentations each included one neutral word and one threat word; specifically, a 2 (probe type) \times 2 (probe position) \times 2 (threat word position) \times 20 (word pair presentations) format. For trials with one neutral word and one threat word (ie, 66% of the trials), the probe always appeared in the location where the neutral word had been presented. As such, participants had their attention directed away from the threat word to detect and respond to the probe without being explicitly informed by the experimenter about the contingency between the type of word (ie, threat word) and probe placement. Deployment of attention toward neutral words and away from threat words is hypothesized to modify the attentional bias and thereby remove excitatory inputs (threat words) that maintain the activity in cognitive schemas for pain.

2.3.2. Control group

The control group was similar to the ABM procedure except that for trials with one neutral word and one threat word (ie, 66% of the trials), the probe appeared with equal frequency in the position of the threat and neutral word.

2.4. Analyses

2.4.1. Data preparation

Descriptive statistics were calculated for reaction time at pretreatment, posttreatment, and follow-up after treatment, for Group (ABM and control), and Stimulus Congruency (ie, neutral, threat congruent, and threat incongruent). Stimulus Congruency occurred in 3 categories: (1) neutral (ie, both words neutral and the probe appeared with equal frequency at either position); (2) threat congruent (ie, the probe replaced the threatening stimulus); and (3) threat incongruent (ie, the probe replaced the neutral stimulus).

2.4.2. Idiosyncratic word ratings

Baseline and posttreatment idiosyncratic threat word ratings were compared between groups (ABM vs control) and over time using analysis of variance. In addition, correlational analyses were used to assess relationships between reductions in threat word ratings and symptom measures.

2.4.3. Primary symptom change analyses

Multilevel modelling analyses were conducted for each symptom measure. For each model, time point (level 1) was nested within participants (level 2). Time was coded into 3 time points including, (1) pretreatment, (2) posttreatment, and (3) follow-up, for each symptom measure, with pretreatment as the reference point. For comparisons between groups over time, the control group served as the reference group. Differences in participant pretreatment scores were accounted for by using both a fixed and random intercept in the model. Each final model included the fixed effect of Time and Group to test for main effects and interactions of the variables. There was no evidence indicating participant attrition was nonrandom. All models were computed using the maximumlikelihood estimation, and hypothesis testing was conducted at an α level of 0.05 using 2-tailed tests. Analyses were bootstrapped (BCa) using 1000 samples to provide robust probability values and confidence intervals.

2.4.4. Reaction time analyses

Multilevel modelling analyses were conducted for reaction times of each Stimulus Congruency type. For each model, time point (level 1) was nested within participants (level 2). Time was coded into 3 time points including, (1) pretreatment, (2) posttreatment, and (3) follow-up, for each Stimulus Congruency type (ie, neutral, threat congruent, and threat incongruent), with pretreatment as the reference point. The control group served as the reference for comparisons between groups over time. Differences in pretreatment reaction times were accounted for by using both a fixed and random intercept in the model. Final models included the fixed effect of Time and Group to test for interactions and main effects of the variables. All 3 models used the maximumlikelihood estimation, and hypothesis testing was conducted at an α level of 0.05 using 2-tailed tests. Analyses were also bootstrapped (BCa) using 1000 samples to provide robust probability values and confidence intervals. In addition, Pearson correlations were used to assess relationships between change in attentional bias magnitude from pretreatment to posttreatment and each symptom measure (ie, SF-MPQ, SF-MPQ VAS, ASI-3, ISI-R, PASS-20, DASS-21 subscales, RFIQ), which would identify whether a reduction in self-reported symptoms reflected a relationship with attentional modification.

3. Results

3.1. Descriptive statistics

Descriptive statistics for reaction times are presented in **Table 1**. At pretreatment, the mean differences in response times between neutral, congruent, and incongruent trials were less than 4 ms with standard deviations greater than 170 ms; as such, there was no evidence of a reliable attentional bias at baseline. Descriptive statistics for self-report symptom data are presented in **Table 2**.

Independent t test analyses were used to compare the 386 participants who completed the pretreatment attention task with the 117 participants who completed the posttreatment attention task. The results indicated no statistically significant differences in symptom measures between the groups at pretreatment ($P \ge$ 0.201) and no statistically significant demographic differences. Independent t test analyses were also used to compare the 117 participants who completed the posttreatment survey with the 55 participants who completed the follow-up survey. The results indicated almost no statistically significant differences in symptom measures between the groups at posttreatment ($P \ge 0.074$). The exception was for the DASS-21 subscales wherein participants who did not complete the follow-up survey had significantly higher scores for depression, t(115) = 2.66, P = $0.012, r^2 = 0.06$, anxiety, $t(115) = 2.26, P = 0.026, r^2 = 0.04$, and stress, t(115) = 2.18, P = 0.032, $r^2 = 0.04$, but the effect sizes were all small. The only significant demographic difference was that the group who completed the follow-up survey had more retired participants (n = 15) than the group who did not (n = 2).

3.2. Idiosyncratic word ratings

There were no significant differences between participants who discontinued and those who completed the follow-up questionnaire for baseline average threat word ratings (P = 0.495). For those who completed the final and follow-up questionnaires, there were no significant differences in average threat word ratings (P = 0.885, $\eta_p^2 = 0.002$), nor were there interactions of condition and time (P = 0.526, $\eta_p^2 = 0.012$). Furthermore, there were no significant differences in average threat word ratings between those in the control or ABM treatment group (P = 0.526, $\eta_p^2 = 0.006$).

For the control condition, there were significant correlations for threat word rating changes from baseline to posttreatment with symptom change scores for the following measures; specifically, the SF-MPQ, r(29) = 0.45, P = 0.015, the SF-MPQ VAS, r(29) = 0.71, P < 0.001, the ASI-3, r(29) = 0.56, P = 0.002, the ISI-R, r(29) = 0.59, P = 0.001, the PASS-20, r(29) = 0.47, P = 0.011, and the DASS-21 depression, r(29) = 0.41, P = 0.026. For the ABM treatment condition, there also were significant correlations for threat word rating change from baseline to posttreatment with symptom change scores; specifically, the SF-MPQ VAS, r(26) = 0.76, P < 0.001, the ISI-R, r(26) = 0.45, P = 0.021, and the DASS-21 stress, r(26) = 0.54, P = 0.004.

3.3. Multilevel models

The multilevel model results for each symptom measure (ie, SF-MPQ, SF-MPQ VAS, ASI-3, ISI-R, PASS-20, DASS-21 depression, DASS-21 anxiety, DASS-21 stress, and RFIQ), across each time point (ie, post, follow-up), are presented in **Table 3**. Overall, there were no significant interactions of group and time for changes in any symptom measures for the ABM when compared with the control (all $Ps \ge 0.092$). The control and ABM groups both produced significant decreases in SF-MPQ scores from pretreatment to posttreatment (P = 0.017; P = 0.033,

Table 1					
Reaction	time descri	ptive stati	stics by gr	oup variable	e.

Time	Stimulus congruency	Group	n	М	SD
Pre	Neutral	Control	29	659.66	161.43
		ABM	26	683.89	206.44
		Total	55	671.11	182.73
	Threat congruent	Control	29	660.05	150.34
		ABM	26	678.73	200.18
		Total	55	668.88	174.24
	Threat incongruent	Control	29	660.91	159.46
		ABM	26	684.41	202.37
		Total	55	672.02	179.68
Post	Neutral	Control	29	576.87	102.94
		ABM	26	590.65	88.76
		Total	55	583.38	95.86
	Threat congruent	Control	29	574.10	89.20
		ABM	26	602.67	118.68
		Total	55	587.61	104.18
	Threat incongruent	Control	29	577.16	89.07
		ABM	26	588.14	102.96
		Total	55	582.35	95.14
Follow-up	Neutral	Control	29	676.85	274.47
		ABM	26	660.98	194.09
		Total	55	669.35	237.84
	Threat congruent	Control	29	692.38	343.04
		ABM	26	653.20	148.25
		Total	55	673.86	267.55
	Threat incongruent	Control	29	686.57	229.48
		ABM	26	804.09	869.68
		Total	55	742.13	617.23

ABM, attention bias modification.

respectively), but not from pretreatment to follow-up ($Ps \ge 0.157$). The ABM group did not demonstrate significant changes from pretreatment to posttreatment (P = 0.826), or pretreatment to follow-up, for the SF-MPQ VAS (all P = 0.947). The control group produced significant decreases in SF-MPQ VAS scores from pretreatment to posttreatment (P = 0.022), but not from pretreatment to follow-up (P = 0.098). The ABM group did not demonstrate significant changes from pretreatment to posttreatment (P = 0.107), or pretreatment to follow-up, for the RFIQ scores (P = 0.634). The control group demonstrated significant changes from pretreatment to posttreatment for the RFIQ scores (P = 0.017), but not from pretreatment to follow-up (P = 0.737).

Neither the control nor the ABM group produced significant changes from pretreatment to posttreatment, or pretreatment to follow-up, for the ASI-3, ISI-R, or PASS-20 scores (all $Ps \ge 0.097$). There were also no statistically significant differences from pretreatment to posttreatment in DASS-21 depression scores ($Ps \ge 0.541$), anxiety scores ($Ps \ge 0.277$), or stress scores ($Ps \ge 0.079$); however, from pretreatment to follow-up, the control and ABM groups both produced significant decreases in DASS-21 depression scores (Ps = 0.001), anxiety scores (Ps = 0.001), and stress scores (Ps = 0.001).

3.4. Reaction time analyses

The multilevel model reaction time results for each stimulus congruency type (ie, neutral, threat congruent, and threat incongruent), across each time point (ie, post, follow-up), are presented in **Table 4**. Overall, there were no significant interactions of group and time for changes in reactions time for any of the stimulus congruency types when comparing the ABM group with the control group (all $P_s \ge 0.380$). There were

П	а	b	e	2
				_

Symptom measure descriptive statistics by group variable.

Time	Measure	Contr	ol				ABM				
		n	М	SD	Skew	Kurtosis	n	М	SD	Skew	Kurtosis
Pre	SF-MPQ	54	22.93	10.41	0.10	-0.89	63	21.18	7.34	0.24	0.21
	SF-MPQ VAS	54	62.52	18.53	-0.26	-0.57	63	58.57	18.99	-0.64	0.29
	ASI-3	54	23.98	16.70	0.36	-1.04	63	24.94	18.89	0.65	-0.69
	ISI-R	54	13.24	10.00	0.34	-1.12	63	14.40	11.07	0.56	-1.02
	PASS-20	54	49.89	22.80	0.07	-0.46	63	46.19	26.54	0.36	-0.92
	DASS-21 depression	54	11.67	4.90	-0.21	-0.68	63	12.19	5.76	0.06	-0.39
	DASS-21 anxiety	54	12.98	5.32	0.46	0.00	63	12.75	6.24	-0.01	0.02
	DASS-21 stress	54	13.37	5.20	0.16	-0.16	63	13.08	6.24	-0.25	-0.26
	RFIQ	54	51.15	16.24	-0.26	-0.37	63	48.53	14.74	0.06	-0.93
Post	SF-MPQ	54	19.09	10.72	0.38	-0.48	62	18.44	9.93	0.62	-0.18
	SF-MPQ VAS	54	54.94	26.29	0-0.12	-1.14	62	59.45	23.85	-0.26	-1.07
	ASI-3	54	24.37	18.66	0.47	-0.98	62	21.97	16.36	0.78	-0.37
	ISI-R	54	13.78	10.62	0.45	-0.99	62	13.47	11.21	0.63	-0.87
	PASS-20	54	47.48	25.39	0.31	-0.79	62	45.86	25.44	0.31	-0.82
	DASS-21 depression	54	11.54	4.52	0.37	-0.56	62	11.82	5.64	0.00	-0.15
	DASS-21 anxiety	54	12.50	5.07	0.67	0.49	62	12.10	5.71	0.19	0.27
	DASS-21 stress	54	14.48	5.77	0.03	-0.11	62	13.44	6.28	-0.40	0.02
	RFIQ	54	43.14	22.58	-0.16	-0.90	62	44.75	20.01	-0.35	-0.12
Follow-up	SF-MPQ	29	21.10	11.98	-0.21	-1.25	26	17.50	9.166	0.33	-0.23
	SF-MPQ VAS	29	55.93	25.56	-0.59	-0.93	26	59.27	23.17	-0.14	-1.15
	ASI-3	29	23.21	17.98	0.41	-1.32	25	16.96	16.64	1.18	0.69
	ISI-R	29	15.59	10.77	0.34	-0.83	25	10.48	10.45	1.07	0.16
	PASS-20	29	49.69	29.49	-0.08	-1.05	25	33.80	23.95	0.76	0.73
	DASS-21 depression	29	6.07	5.16	0.63	-0.78	25	3.80	3.21	0.52	-0.67
	DASS-21 anxiety	29	6.04	5.21	0.58	-0.66	25	3.36	3.65	1.45	1.97
	DASS-21 stress	29	8.66	5.95	0.37	-1.16	25	5.16	4.09	0.62	-0.44
	RFIQ	29	49.86	22.91	-0.41	-1.27	25	47.50	16.69	0.15	-1.22

ABM, attention bias modification group; ASI-3, Anxiety Sensitivity Index Third Version; DASS-21, Depression Anxiety Stress Scale 21-item; ISI-R, Illness-Injury Sensitivity Index Revised; PASS-20, Pain Anxiety Symptoms Scale 20-item; SF-MPQ, the McGill Pain Questionnaire—Short Form; SF-MPQ VAS, the McGill Pain Questionnaire—short Form visual analogue scale of pain; RFIQ, The Revised Fibromyalgia Questionnaire.

significant decreases overall in reaction time from pretreatment to posttreatment for the neutral (P = 0.001) and threat congruent (P = 0.003) stimulus types, and a marginally significant decrease for the threat incongruent (P = 0.054) stimulus type. There were no significant changes in reaction time from pretreatment to follow-up for each stimulus congruency type (all $Ps \ge 0.490$).

There were small nonsignificant correlations between changes in attentional bias magnitude (from pretreatment to posttreatment) and changes in scores on the SF-MPQ (r = -0.02, P 0.900), SF-MPQ VAS (r = -0.02, P = 0.877), ASI-3 (r = -0.03, P = 0.819), ISI-R (r = 0.05, P = 0.733), PASS (r = -0.00, P = 0.979), DASS-21 depression (r = -0.02, P = 0.906), DASS-21 anxiety (r = 0.09, P = 0.530), DASS-21 stress (r = 0.14, P = 0.322), and RFIQ (r =0.05, P = 0.737) for the control group. Similarly, for the ABM group, there were small nonsignificant correlations between changes in attentional bias magnitude (from pretreatment to posttreatment) and changes in scores on the SF-MPQ (r = 0.03, P = 0.831), SF-MPQ VAS (r = -0.05, P = 0.688), ASI-3 (r = -0.14, P = 0.283), ISI-R (r = -0.19, P = 0.142), PASS (r = 0.03, P = 0.817), DASS-21 depression (r = -0.13, P = 0.303), DASS-21 anxiety (r =-0.14, P = 0.290), DASS-21 stress (r = -0.22, P = 0.093), and RFIQ (r = -0.12, P = 0.363). In addition, correlating changes in symptom scores with pretreatment biases produced no statistically significant correlations in either group (rs < 0.19, Ps > 0.142), nor for posttreatment biases (rs < 0.24, Ps > 0.066).

4. Discussion

In line with recent general⁴⁹ and specific^{35,46} recommendations for ABM research with chronic pain, the current study was

designed to extend and clarify previous results assessing the impact of ABM on chronic pain^{43,59,60}; specifically, the current research was designed to extend prior research¹⁹ by further investigating the efficacy of ABM with idiosyncratic stimuli to reduce pain and related symptoms experienced by persons with fibromyalgia. We conducted a randomized, placebo-controlled trial assessing 8 sessions of ABM delivered through the Internet to a sample of patients with fibromyalgia, with self-report assessments at pretreatment, posttreatment, and 1-month follow-up. We expected that participants receiving ABM would report significant reductions in self-reported symptoms of pain and pain-related pathology (ie, self-reported disability, pain-related fear, and pain-related anxiety) that would be sustained at follow-up.

The large sample and use of idiosyncratic stimuli for the current study produced results partially consistent with some,³³ but not all,¹⁹ previous research. In contrast to our hypotheses, based on the confidence intervals, there were no interaction effects that would indicate a significant difference between the ABM and control groups. In contrast to our hypotheses, participants in the control group, but not in the ABM, reported small, but statistically significant, decreases in pain intensity from pretreatment to posttreatment, that were no longer statistically significant at follow-up. The study extends previous work¹⁹ by including a fibromyalgia-specific measure of function, overall impact, and symptoms. In contrast to our hypotheses, participants in the control group, but not in the ABM, reported small, but statistically significant, decreases in fibromyalgia-specific function, overall impact, and symptoms from pretreatment to posttreatment, which were no longer statistically significant at follow-up. In line with our hypotheses, participants in the ABM group reported

Table 3

Multilevel Models for Dependent Measures from Pretest to Follow-up.

	Group	Fixed effe	cts		Cohen's d	Random eff	ects			
		b	95% CI	Р		Variance	95% CI	Р		
SF-MPQ										
Intercept	Control	22.93	20.99 to 24.76	0.001†		61.10	44.41-84.06	0.001†		
	ABM	21.17	19.58 to 22.66	0.001†						
Post	Control	-3.83	-7.05 to -0.61	0.017*	0.363					
	ABM	-2.74	-5.19 to -0.33	0.033*	0.314					
Follow-up	Control	-1.98	-5.50 to 1.49	0.275	0.163					
	ABM	-2.18	-5.11 to 0.88	0.157	0.443					
Group		-1.75	-4.25 to 0.60	0.111						
Group imes post		1.09	-2.41 to 4.55	0.585						
Group $ imes$ follow-up		-0.21	-4.36 to 4.35	0.937						
SF-MPQ VAS										
Intercept	Control	62.52	58.74 to 65.96	0.001†		298.17	212.85-417.68	0.001†		
Intercept	ABM	62.52 58.57	54.25 to 63.13	0.0011		290.17	212.00-417.00	0.001]		
Post	Control	-7.57	-13.30 to -1.77	0.0011	0.333					
POSI										
Fallow up	ABM	0.70	-6.38 to 7.49	0.826	0.041					
Follow-up	Control	-6.51	-13.95 to 1.11	0.098	0.361					
Crown	ABM	-0.32	-8.38 to 7.38	0.947	0.033					
Group		-3.95	-9.44 to 1.76	0.141						
Group \times post		8.28	-0.53 to 17.79	0.092						
Group imes follow-up		6.19	-3.98 to 15.88	0.307						
ASI-3										
Intercept	Control	23.98	20.26 to 27.62	0.001†		226.80	[168.36-305.53]	0.001†		
	ABM	24.94	22.57 to 26.65	0.001†						
Post	Control	0.39	-3.90 to 5.06	0.872	0.022					
	ABM	-2.85	-6.86 to 1.37	0.171	0.168					
Follow-up	Control	-2.56	-7.98 to 2.73	0.395	0.042					
	ABM	-3.04	-8.12 to 1.90	0.192	0.448					
Group		0.96	-2.84 to 4.30	0.662						
$\dot{\text{Group}} \times \text{post}$		-3.24	-8.92 to 2.68	0.319						
$\operatorname{Group} imes \operatorname{follow-up}$		-0.48	-8.51 to 8.02	0.888						
ISI-R										
Intercept	Control	13.24	11.22 to 15.33	0.001†		88.55	66.11-118.60	0.001†		
intoroopt	ABM	14.40	12.93 to 15.61	0.001†		00.00	00.11 110.00	0.0011		
Post	Control	0.54	-2.04 to 2.85	0.691	0.052					
1 031	ABM	-0.82	-0.2,94 to 1.47	0.445	0.083					
Follow-up	Control	0.84	-2.00 to 3.31	0.647	0.226					
i oliow-up	ABM	-1.49	-4.97 to 1.64	0.381	0.364					
Group	ADIM	1.16	-0.88 to 2.75	0.325	0.304					
Group $ imes$ post		-1.36	-4.65 to 1.95	0.452						
Group \times follow-up		-2.33	-7.09 to 3.08	0.325						
		2.00	7.03 10 3.00	0.020						
PASS-20										
Intercept	Control	49.89	46.15 to 54.07	0.001†		546.86	413.56-723.13	0.001†		
	ABM	46.19	43.51 to 47.91	0.001†						
Post	Control	-2.41	-6.90 to 1.71	0.348	0.099					
	ABM	-0.26	-4.30 to 4.01	0.906	0.013					
Follow-up	Control	-2.03	-9.16 to 3.94	0.591	0.008					
	ABM	-5.91	-13.85 to 1.70	0.097	0.490					
Group		-3.70	-7.87 to -0.92	0.118						
Group $ imes$ post		2.15	-4.87 to 9.94	0.488						
$\operatorname{Group} imes \operatorname{follow-up}$		-3.88	-14.97 to 7.44	0.453						
DASS-21 depression										
Intercept	Control	11.67	10.88 to 12.43	0.001†		19.73	14.66-25.56	0.001†		
intoroopt	ABM	12.19	11.43 to 12.67	0.001†		10.10	17.00 20.00	0.001		
Post	Control	-0.13	-1.23 to 0.97	0.824	0.028					
1 001	ABM	-0.13 -0.39	-1.62 to 0.87	0.624	0.065					
Follow-up	Control	-0.39 -5.79	-7.17 to -4.45	0.001†	1.113					
i uluw-up	ABM									
	ADIVI	-5.77 0.52	-7.63 to -3.74	0.001†	1.799					
Croup		0.02	-0.46 to 1.28	0.355						
Group		0.00	1 00 10 1 15	0 7 4 0						
Group Group × post Group × follow-up		-0.26 0.02	-1.98 to 1.45 -2.45 to 2.61	0.743 0.983						

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Table 3 (continued)										
	Group	Fixed effe	cts		Cohen's d	Random effe	ects			
		b	95% CI	Р		Variance	95% CI	Р		
DASS-21 anxiety										
Intercept	Control	12.98	12.21 to 13.72	0.001†		23.00	17.19-30.77	0.001†		
	ABM	12.75	12.06 to 13.13	0.001†						
Post	Control	-0.48	-1.63 to 0.66	0.422	0.092					
	ABM	-0.65	-1.71 to 0.50	0.277	0.109					
Follow-up	Control	-6.66	-8.04 to -5.15	0.001†	1.318					
	ABM	-6.60	-8.58 to -4.37	0.001†	1.837					
Group		-0.24	-1.25 to 0.54	0.679						
Group imes post		-0.16	-1.61 to 1.45	0.848						
$\operatorname{Group} imes \operatorname{follow-up}$		0.06	-2.59 to 2.72	0.968						
DASS-21 stress										
Intercept	Control	13.37	12.50 to 14.30	0.001†		25.92	19.44-34.56	0.001†		
	ABM	13.08	12.46 to 13.36	0.001†						
Post	Control	1.11	-0.02 to 2.21	0.079	0.202					
	ABM	0.37	-0.72 to 1.58	0.533	0.058					
Follow-up	Control	-4.99	-6.29 to -3.80	0.001†	0.835					
1	ABM	-4.92	-7.06 to -2.72	0.001†	1.501					
Group		-0.29	-1.21 to 0.22	0.619						
Group imes post		-0.74	-2.24 to 1.03	0.389						
Group $ imes$ follow-up		0.08	-2.52 to 2.98	0.951						
RFIQ										
Intercept	Control	51.15	47.90 to 54.74	0.001†						
	ABM	48.53	43.89 to 53.18	0.001†						
Post	Control	-8.01	-14.15 to -2.90	0.017*	0.407					
	ABM	-3.78	-8.39 to 0.83	0.107	0.215					
Follow-up	Control	-1.43	-7.61 to 4.46	0.737	0.065					
	ABM	1.57	-4.93 to 8.07	0.634	0.065					
Group		-2.62	-6.62 to 0.93	0.201						
$\dot{Group} \times post$		4.23	-3.55 to 11.98	0.301						
Group $ imes$ follow-up		3.00	-7.01 to 15.05	0.551						

Random effects were estimated using a variance components covariance matrix.

* *P*≤ 0.05.

 $+ P \leq 0.01.$

ABM, attention bias modification group; ASI-3, Anxiety Sensitivity Index Third Version; DASS-21, Depression Anxiety Stress Scales 21-item; ISI-R, Illness-Injury Sensitivity Index Revised; PASS-20, Pain Anxiety Symptoms Scale 20-item; RFIQ, the Revised Fibromyalgia Questionnaire; SF-MPQ, the McGill Pain Questionnaire—Short Form; SF-MPQ VAS, the McGill Pain Questionnaire; SF-MPQ, the McGill Pain Questionnaire.

small, but statistically significant, decreases in the experience of their pain from pretreatment to posttreatment; but, the reductions were no longer statistically significant at follow-up. The control group also reported small, but statistically significant, decreases in the experience of their pain from pretreatment to posttreatment, which were no longer statistically significant at follow-up.

The current results suggest the initial statistically significant reductions pain intensity were time-limited, dose-dependent, or possibly the result of expectancy effects.⁶¹ The reductions were seen specifically in the control group, but not in the ABM group. Assuming that some of the experiences of participants with fibromyalgia result from components of the contemporary chronic musculoskeletal pain models that emphasize the central role of attentional processes, 11,26,27,66 having participants in the control group direct their attention at a comparable rate to threat and neutral stimuli may have served as an implicit form of exposure therapy⁶⁸ or may have increased general attentional control.¹³ Alternatively, the control condition may have been increasing cognitive flexibility akin to some cognitive behavioral therapies for chronic pain.¹¹ In either case, the suppositions are consistent with previous theoretically driven behavioral research,68 as well as some,21,36 but not all,20 previous ABM results from patients with social anxiety disorder.

In assessing the self-reported pain-related constructs, both the ABM and control groups produced results that were inconsistent with our hypotheses; specifically, there were no significant changes for either group from pretreatment to posttreatment, or from

pretreatment to follow-up, on measures of anxiety sensitivity, illness/injury sensitivity, pain-related fear, or pain-related anxiety. There were also no significant changes in either group from pretreatment to posttreatment on general symptom measures assessing depression, anxiety, and stress; however, there were significant changes for both the ABM and control groups from pretreatment to follow-up on general symptom measures assessing depression, anxiety, and stress. The pattern of differences suggests potential expectancy effects, ^{61,72} or a regression towards the mean. In any case, the unexpected results suggest against a specific and direct effect of the ABM group relative to the control group.

Participants in the ABM group, but not in the control group, were expected to demonstrate reductions in pain-specific attentional biases; however, the current results evidenced no attentional biases at baseline. The absence of an attentional bias at baseline may seem contrary to the ABM model, 13,38 but is consistent with research⁵⁸; in addition, researchers have argued that benefits from ABM may result from improved general attentional control rather than corrections of a valence-specific bias.¹³ In the current study, participants in the ABM group, but not in the control group, evidenced the increasingly well-established reduction in reaction times from pretreatment to posttreatment^{20,28,46}; nevertheless, there were no significant relationships between mean reaction times and any variables of interest for either group. The absence of a significant relationship suggests against an influence of either group on attentional biases, which has potential implications for the nonsignificant and the significant

Multilevel Models for Reaction Time from Pretest to Follow-up.

	Fixed effects			Random effects			
	b	95% CI	Р	Variance	95% CI	Р	
Neutral							
Intercept	659.14	628.69 to 694.64	0.001†	9750.91	6219.21-15,288.16	0.019*	
Post	-75.84	-107.20 to -47.57	0.001†				
Follow-up	8.54	-39.97 to 54.37	0.818				
Control*ABM	-7.32	-37.69 to 22.43	0.572				
Threat congruent							
Intercept	660.34	630.61 to 702.32	0.001†	7547.27	4281.80-13,303.11	0.172	
Post	-71.38	-104.64 to -43.31	0.003†				
Follow-up	15.29	-38.29 to 58.42	0.743				
Control*ABM	-12.04	-48.44 to 17.03	0.381				
Threat incongruent							
Intercept	647.58	584.02 to 699.62	0.001†	6773.29	1461.28-31,396.29	0.844	
Post	-72.19	-119.22 to -33.93	0.054				
Follow-up	86.46	-29.40 to 213.19	0.491				
Control*ABM	14.39	-41.26 to 76.41	0.649				

* $P \le 0.05$.

 $\pm P \le 0.01$.

ABM, attention bias modification group.

symptom changes observed in the current study. If attentional biases and associated changes are causally related to pain experiences, the absence of changes to the biases may explain the nonsignificant results; however, that same rationale would then mean that the significant results were due to expectancy effects, chance, or the aforementioned exposure effect. The results suggest that decreases in symptoms for ABM group did not differ significantly from the control group from pretreatment to posttreatment, or from pretreatment to follow-up. In any case, the results suggest there is no specific and direct effect of ABM relative to the control condition, which is consistent with the extant literature.^{20,21,28,34–36,46,69}

The current study had several limitations that provide directions for future research. First, all measures were self-reported and future research should include behavioral assessments. Second, the sample size for the study, although comparable with some previous studies, 3,38,47,55 and larger than the previous study focused on fibromyalgia, 19 could be larger and therein produce different results; however, the current effect sizes suggest that a very large sample would be necessary to produce different conclusions.^{29,62} Third, only 30% of participants who consented completed the pretreatment attention task and the intervention. The attrition may indicate challenges with the acceptability, tolerability, or effectiveness of the intervention for persons with fibromyalgia. Future research should assess for possible treatment barriers associated with ABM that may or may not be specific to chronic pain populations (eg, remaining seated at a computer). Fourth, no manipulation check was performed to assess whether participants believed they were in the active or control group. Future research should include such a check to account for the relatively innocuous nature of the active group. Fifth, the current investigation did not assess the reliability of the dot-probe protocol, which recent research has called into question.⁷¹ A lack of reliability of the dot-probe protocol may also help to explain the lack of difference between the 2 groups. Sixth, participants' environmental conditions were not held constant, potentially influencing the current results. Indeed, there are several outstanding questions regarding protocols and tools for measuring attentional biases, including concerns about conducting such measurements through the Internet⁴⁵; as such, the current protocol may have masked biases and future research should assess for, or control for, such possibilities. Seventh, using words throughout, rather than images, may have masked previously identified attentional biases.^{5,55} Future research should directly compare different types of stimuli. Eighth, although the plan and hypotheses were followed as outlined in the grant application, the trial was not preregistered on a clinical trials registry. Preregistration of clinical trials is well justified and increasingly expected³¹; as such, future research should ensure preregistration of clinical trials.

In summary, the findings from the current study represent an important next step in assessing the potential impact of ABM for persons with fibromyalgia and, arguably, for persons with any chronic musculoskeletal pain. The current randomized controlled trial design included recommended advances based on previous research, ¹⁹ such as a larger sample; use of idiosyncratic selection of stimuli; inclusion of a fibromyalgia-specific measure of function, overall impact, and symptoms; and, a 1-month follow-up assessment. The current results, overall, suggest no significant, substantial, or robust differences between the ABM group and the control group. The only significant changes in self-reported symptoms over time occurred for participants in the control condition; nevertheless, there were reductions in fibromyalgiaspecific measure of function, overall impact, and symptoms that may have resulted from a variation of an implicit graded exposure effect. There were no significant relationships between attentional biases and any self-report measures of interest; accordingly, in line with growing recommendations, research emphasis should shift to understanding the mechanisms responsible for the disparate results across attention modification studies. Improved understanding of the mechanisms and differences may provide critical information regarding ABM as an intervention.

Conflict of interest statement

The authors have no conflicts of interest to declare.

Acknowledgements

The authors thank Dr Christopher Oriet for his assistance with the reaction time data analyses. The authors also thank Dr Ardyth Milne for her feedback on the initial study proposal and her assistance with recruitment.

R.N. Carleton's research is supported in part by the Canadian Institutes of Health Research (CIHR) through a New Investigator Award (FRN: 285489). J.W. Vlaeyen's research is supported by the "Asthenes" long-term structural funding-Methusalem grant by the Flemish Government, Belgium (METH/15/011). Authors contributions: All authors made substantial contributions consistent with the International Committee of Medical Journal Editors. The details describing the contributions are presented below alphabetically by last name. Initial design for the current article was a collaborative effort based on the following contributors, each of whom was responsible for overseeing their areaspecific domains for assessment, all of whom reviewed, revised as necessary, and approved the final design in its entirety: G.J.G. Asmundson, R.N. Carleton, J.D. Katz, G. Crombez, and J. W.S. Vlaeven, Implementation was a collaborative effort primarily driven by R.N. Carleton, K. Hozempa, and S.L. Korol. Analysis for the current article was a collaborate effort primarily driven by each of the following: R.N. Carleton, S.L. Korol, and D.M. LeBouthillier; however, area-specific analytic information was provided by different authors as required. Write up for the current article was a collaborate effort primarily driven by R.N. Carleton and S.L. Korol; however, all authors reviewed the document and provided detailed feedback that was ultimately integrated into the submitted manuscript. All authors also approved the submitted version of the manuscript.

Ethics approval and consent to participate: The study was approved by the University of Regina Institutional Research Ethics Board (File # 37R1314). We complied with Canadian Psychological Association ethical standards in the treatment of our sample. All interested persons were directed to a website with study details and were required to explicitly indicate consent before proceeding.

Article history:

Received 10 July 2019 Received in revised form 16 October 2019 Accepted 30 October 2019 Available online 4 November 2019

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