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- Psicoterapeuta.
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- Master en Pedagog3a Sist3mica. Universidad M3xico CUDEC
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Art3culos publicados

-A Mindfulness-Based Programme Plus Amygdala and Insula Retraining (MAIR) for the Treatment of Fibromyalgia: A Pilot Randomized Controlled Trial. Clinical Journal 2020. Juan P. Sanabria-Mazo ^{1,2,3,4,#}, Jes3s Montero-Mar3n ^{5,#}, Albert Feliu-Soler ^{1,2,3,*}, Virginia Gasi3n ⁶, Mayte Navarro-Gil ^{6,7}, H3ctor Morillo-Sarto ⁸, Mattie Tops ⁹, Juan V. Luciano ^{1,2,*,*†} and Javier Garc3a-Campayo ^{6,7,†}

-Attachment-Based Compassion Therapy for Ameliorating Fibromyalgia: Mediating Role of Mindfulness and Self-Compassion. Mindfulness. Springer. Jesus Montero-Mar3n, William Van Gordon, Edo Shonin, Mayte NavarroGil, Virginia Gasi3n, Yolanda L3pez-delHoyo, Juan V. Luciano, et al. <https://link.springer.com/article/10.1007/s12671-019-01302-8>

-Feasibility and Effectiveness of a Workplace- Adapted Mindfulness- Based Programme to Reduce Stress in Workers at a Private Sector Logistics Company: An Exploratory Mixed Methods Study Jesus Montero- Marin 1, Willem Kuyken 1, Virginia Gasi3n 2,* , Alberto Barcel3- Soler 2,3,* , Lynda Rojas 4, Ana Manrique 5, Rosa Esteban 5 and Javier Garc3a Campayo 2,3,6 <https://www.mdpi.com/1660-4601/17/5/1643>

Actualidad

Desde 2013, formo parte del equipo de investigaci3n de Mindfulness y Compasi3n de la Universidad de Zaragoza, participando en investigaciones relacionadas con mindfulness, estr3s, empresa, compasi3n entre otros.

Docente en el 3rea de empresas del Master de Mindfulness de la Universidad de Zaragoza.

Desarrollo procesos de implantaci3n de intervenciones de psicolog3a positiva y mindfulness en empresas, emprendedores, equipos de alto rendimiento etc.

Codirectora de Congreso de Mindfulness y Organizaciones celebrados en 2017.

Acompañamiento en procesos psicoterapéuticos.

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Colaboro con la ONG La Akademia.

Integrante del Equipo de la Asociación de Fibrimialgia y Fatiga Crónica de ASAFIMA Vitoria, trabajando en terapia de grupal de Reentrenamiento Amigdalal, Mindfulness y Compasión.

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He completado mi formación estudiando y practicando diferentes caminos de meditación con el Zen y el budismo tibetano.



1 *Communication*

2 **A Mindfulness-Based Programme Plus Amygdala and Insula Retraining (MAIR)**
3 **for the Treatment of Fibromyalgia: A Pilot Randomized Controlled Trial**

4
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33 **Abstract:**

34 The lack of highly effective treatments for fibromyalgia (FM) represents a great challenge for public
35 health. The objective of this parallel, pilot randomized controlled trial (RCT) was two-fold: (1) to
36 analyse the efficacy of mindfulness plus amygdala and insula retraining (MAIR) compared to a
37 relaxation therapy (RT) in the treatment of FM; and (2) to evaluate its impact on brain-derived
38 neurotrophic factor (BDNF) and inflammatory markers in serum. A total of 41 FM patients were
39 randomized into two study arms: MAIR (intervention group) and RT (active control group); both as
40 add-on of treatment as usual (TAU). The primary outcome was functional impairment (FIQ), and the
41 secondary outcomes were clinical severity (CGI-S), pain catastrophizing (PCS), anxiety (HADS-A),
42 depression (HADS-D), perceived health (EQ-5D), acceptance (AAQ-II), mindfulness (FFMQ), and

43 self-compassion (SCS). MAIR demonstrated significantly greater reductions in functional
44 impairment, clinical severity, anxiety, and depression, as well as higher improvements in health-
45 related quality of life, mindfulness, and self-compassion at post-treatment and follow-up, with
46 moderate-to-large effect sizes. A significant decrease in pain catastrophizing was found at follow-up,
47 but not at post-treatment, with large effects sizes. The number needed to treat (NNT) was 3 based on
48 criteria of $\geq 50\%$ FIQ reduction post-treatment. Compared to RT, MAIR showed significant decreases
49 in BDNF. No effect of MAIR was observed in inflammatory biomarkers (i.e., TNF- α , IL-6, IL-10, and
50 hs-CRP). In conclusion, these results suggest that MAIR as coadjuvant of TAU appears to be effective
51 for the management of FM symptoms and for reducing BDNF levels in serum.

52 **Keywords:** fibromyalgia; mindfulness; amygdala and insula retraining; mind–body techniques;
53 multicomponent intervention; randomized controlled trial; pilot study.

55 1. Introduction

56 Fibromyalgia (FM) is a disabling syndrome of unknown etiology mainly characterized by
57 widespread musculoskeletal pain and symptoms such as fatigue, stiffness, sleep problems, perceived
58 cognitive dysfunction, and distress [1]. FM affects about 2% of the general population worldwide,
59 generating a great economic burden for public health [2]. The lack of curative treatments for FM
60 represents a challenge for clinicians and researchers [3]. The complexity of managing the multiple
61 factors involved in FM and the lack of highly effective treatments have motivated the testing of
62 innovative non-pharmacological therapies in recent years [4]. The scientific evidence compiled to
63 date suggests that multi-component treatments are the most effective for the management of chronic
64 pain and FM [5,6].

65 In this scenario, non-pharmacological treatments based on psychoeducation, physical exercise,
66 mindfulness, and cognitive-behavior therapy (CBT) have proven their effectiveness for improving
67 mental health, increasing physical function, decreasing symptoms, and strengthening the acceptance
68 of FM, obtaining small to medium effect sizes [5-15]. Furthermore, multicomponent treatments
69 integrating some of these practices have been considered the gold-standard for managing FM [6, 12].
70 Meta-analyses have provided evidence that mindfulness-based interventions (MBIs) are especially
71 effective for improving quality of life and pain compared to usual care and even some active control
72 treatments [11,12]. In addition, MBIs have been shown to be effective modifying FM-related
73 inflammatory markers [e.g., 13]. Specifically, amygdala retraining (AR), a mind-body approach, has
74 preliminarily demonstrated improvements in physical health, energy, pain, distress, and fatigue in
75 patients with FM and chronic fatigue syndrome (CSF) [16]. AR was originally designed for patients
76 with CFS [17] as a method of reducing chronic over sensitization of the amygdala and heightened
77 fear conditioning which may underlie some of the symptoms related to both CSF and FM [17, 18].

78 Taking this state of the question as its foundation, the objective of this 8-weeks, parallel pilot
79 RCT was two-fold: (1) to analyse the efficacy of mindfulness plus amygdala and insula retraining
80 (MAIR) compared to a relaxation therapy (RT) in the treatment of FM; and (2) to evaluate its impact
81 on brain-derived neurotrophic factor (BDNF) and inflammatory markers in serum.

82

83

84 2. Materials and Methods

85 2.1. Research Design

86 An 8-weeks parallel pilot RCT with two arms (MAIR vs. RT). The assessment periods were pre-
87 treatment, post-treatment, and 3-month follow-up. The present work reports secondary data
88 embedded in a larger RCT examining the efficacy of MAIR and Attachment-Based Compassion
89 Therapy (ABCT) in the treatment of FM patients (TrialTrials.gov Registration: NCT02454244). Effects
90 of ABCT arm on clinical outcomes and inflammatory biomarkers were reported elsewhere [19,20].
91 The RCT was conducted following the “Initiative on Methods, Measurement and Pain Assessment in
92 Clinical Trials” (IMMPACT) recommendations [21] and the “Consolidated Standards of Reporting
93 Trials” (CONSORT) guidelines [22].

94 2.2. Study Sample

95 Potential participants were recruited from eight primary health-care centers in Zaragoza, Spain.
96 The inclusion criteria were: (1) male or female aged between 18 and 65 years; (2) able to read and
97 understand Spanish; and (3) diagnosed with FM criteria (American College of Rheumatology [ACR],
98 1990) by a rheumatologist working for the Spanish National Health Service (SNHS). The exclusion
99 criteria were: (1) presence of a severe Axis I psychiatric/somatic disorder, autoimmune disease, or
100 use of corticosteroid medication; and (2) current participation in another RCT. Medication use was
101 permitted as part of usual care as long as the patient agreed not to change the dosage during the
102 study period. Of the 83 patients who were invited to the study, 41 were randomly allocated either to
103 MAIR ($n = 22$) or RT ($n = 19$). Sample size estimation for the RCT primary outcome of FM functional
104 status (Fibromyalgia Impact Questionnaire [FIQ]) was based on a clinically relevant expected
105 difference of at least 20%. A previous study with similar features found a FIQ mean and SD of 70.8
106 and 15.2, respectively [23]. Therefore, a difference of 14.6 points between groups was our target
107 (equivalent to 0.95 SDs). To detect this difference with a 5% significance level and 80% statistical
108 power in a two-tailed test, we needed 18 patients per group. We expected a dropout rate of
109 approximately 20%, so we increased the numbers to reach an initial total sample size of 41 subjects.

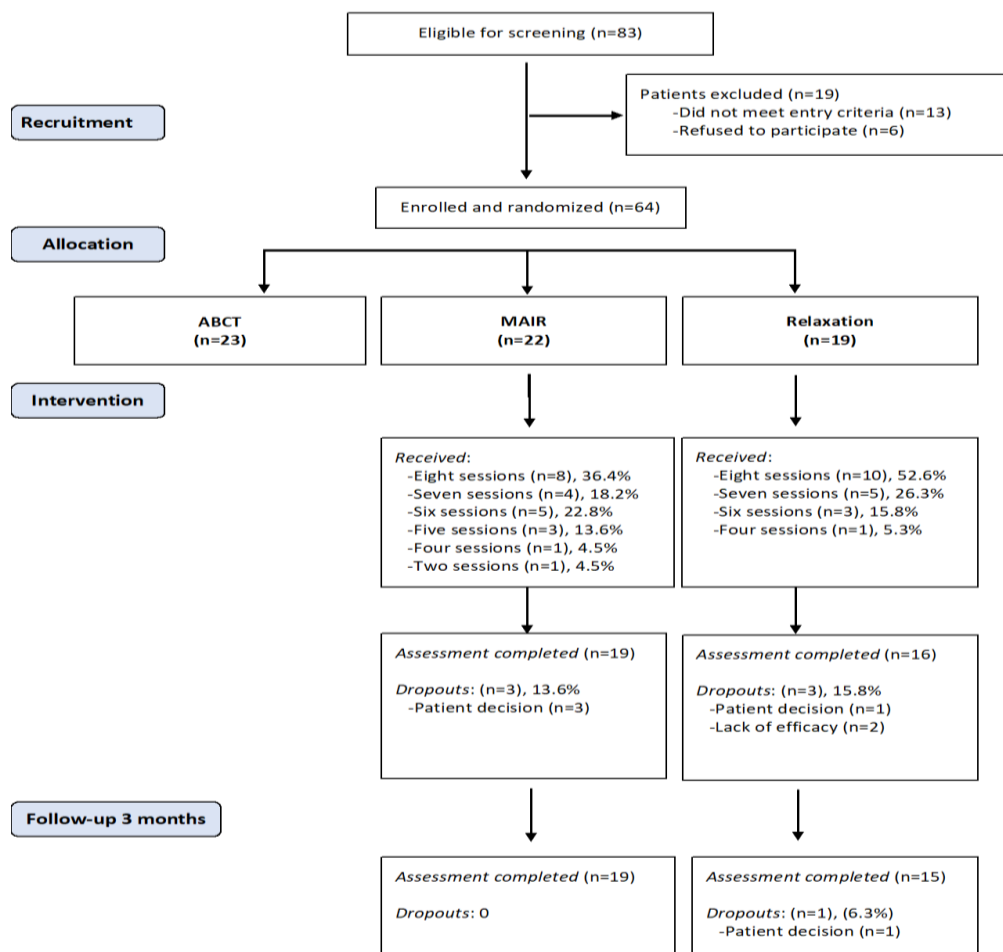
110 2.3. Procedure

111 General practitioners (GPs) identified potential patients who were then face-to-face interviewed
112 at the same clinic by an independent researcher until the required sample size was achieved. Those
113 patients who met the eligibility criteria and gave their written informed consent before the baseline
114 assessment were included in the study and randomized. A researcher who had no involvement in
115 the study generated a simple random allocation sequence by using computer software to determine
116 group assignment. Randomization was implemented via telephone, and the allocation details were
117 concealed from the other researchers involved until all patients had been assigned. Patients were not
118 informed of group allocation until after completion of baseline assessments, and they were not
119 informed which allocation condition was the target intervention. The outcome assessor remained
120 blind to patient allocation (Figure 1).

121 Patients were scheduled for blood extraction prior to treatment (as part of the baseline
122 evaluation) and within 5 days following treatment (post-treatment assessment). To minimize
123 circadian variability in immunological markers, all blood samples were collected between 8:00 and
124 8:30 a.m., after night fasting. Upon completion of the extraction, blood was centrifuged and serum
125 was frozen to $-80\text{ }^{\circ}\text{C}$ until the biochemical analyses at LABCO laboratories. The parallel design of the
126 study ensured that the groups would display equivalent seasonal variability. A battery of measures
127 was administered to patients in both study arms at pre-treatment, post-treatment, and 3-months
128 follow-up. Biomarkers were measured in both groups at pre-treatment and post-treatment.

129 The study protocol was approved by the ethical review board of the regional health authority of
 130 Aragon (CEICA), Spain (PI15/0049; 01/04/2015). A more detailed explanation of the procedure is
 131 published elsewhere [19].

132 **Figure 1:** Flowchart of participants in the pilot RCT



133

134 2.4. Treatments

135 2.4.1. Relaxation therapy (RT)

136 The active control group completed a relaxation program consisting of 8 weekly 2-hour sessions
 137 followed by 3 monthly sessions. RT was based on the four techniques described by Montero-Marín
 138 et al. [18]: (1) *visualisations* (e.g., guided relaxation exercises through imagery; deepening guided
 139 relaxation through landscape visualisations; and working with emotions through imagination); (2)
 140 *autogenic relaxation* (e.g., imagining a ball of light and heat to aid sensations of relaxation; and working
 141 on body sweeping heaviness sensations); (3) *progressive relaxation* (e.g., tensing and relaxing the
 142 muscles to focus awareness of different bodily sensations and foster relaxation); and (4) *breathing*
 143 (e.g., using deep inhalation and exhalation to calm anxiety; and learning different breathing
 144 techniques based on pulmonary ventilation and cellular respiration) (Table 1). The therapist was a
 145 clinical psychologist with accredited expertise in relaxation techniques. This treatment was added to
 146 TAU.

147 2.4.2. Mindfulness + Amygdala and Insula Retraining (MAIR)

148 Patients completed some practices included in the mindfulness-based stress reduction (MBSR)
 149 programme that were added to the amygdala and insula retraining techniques (AIR) developed by

150 Gupta [17]. This psychotherapeutic approach focuses on coping with stressful situations and
 151 retraining the amygdala. It also allows the body to recover from a disease state, and is composed of
 152 psychological techniques such as breathing, meditation, and neuro-linguistic programming (NLP)
 153 (Table 1). MAIR consists of 8 weekly 2-hour sessions followed by 3 monthly sessions. The programme
 154 includes daily homework assignments that take approximately 15 to 20 minutes to complete. The
 155 therapist was a psychologist with accredited training in MBSR and AIR. This treatment was added
 156 to TAU.

157 **Table 1:** Session outlines of RT and MAIR

Session	RT	MAIR
1	<i>Visualizations I.</i> Introduction to the different relaxation techniques and learning the distinct types and their usefulness.	<i>General overview.</i> Theoretical aspects of the brain, the limbic system, fear, conditioning and reconditioning. Visualization of 100% recovery.
2	<i>Visualizations II.</i> Imagination training. Deepening in guided relaxation through visualizations. Knowing the effects in the body and mind and learning when to use it.	<i>Developing FM.</i> How stress triggers the nervous system. Mindfulness and self-awareness. Anchoring presence in the body and breathing.
3	<i>Visualizations III.</i> Working with emotions through imagination. Emotional burdens are symbolically released and thrown down, helping the mind to be free of emotions that cause discomfort.	<i>Amygdala technique.</i> Re-conditioning. Breaking negative thoughts, meanings, and emotions, and somatic answers in the body. Breathing and meditation.
4	<i>Autogenic relaxation I.</i> Autogenic relaxation initiation. Knowing its effects. Imagining a ball of light and heat to aid sensations of relaxation.	<i>Regulation of negative emotions and symptoms.</i> The “soften and flow” self-regulation through mindfulness practice. Body scan meditation.
5	<i>Autogenic relaxation II.</i> Deepening in autogenic relaxation. Learning in which situations it could be useful and how to use it. Working on heaviness sensations.	<i>The accelerator of MAIR.</i> Internal dialogue, patterns and behaviours related to illness in FM. Importance of mindfulness as a daily practice. Walking meditation.
6	<i>Progressive relaxation.</i> Initiation to the progressive relaxation. Explanation of this technique and its benefits. Tensing and relaxing the muscles to become aware of the different sensations.	<i>Dealing with stress.</i> Awareness of negative thoughts related to external stimuli. Over-reactions of the nervous system. Mindfulness in daily activities.
7	<i>Breathing I.</i> Learning to use breathing exercises. Knowing its benefits. Deep inspiration and exhalation. Using breathing to calm anxiety.	<i>Awareness of limiting beliefs.</i> How to identify and change them through re-conditioning. Motivation and sense of life. Meditation on values.
8	<i>Breathing II.</i> Deepening in breathing exercises and their benefits. Learning different techniques and exercises based on deep breathing.	<i>Recovery, cycles, and stages and returning to regular life.</i> Fear of failure in terms of recovery. Positive visualizations of the future. Review and summary of the protocol.

158 RT = Relaxation Therapy; MAIR: Mindfulness + Amygdala and Insula Retraining.

159 2.5. Measures

160 2.5.1. Socio-Demographic Characteristics

161 Patients completed a socio-demographic survey at baseline that included: age, sex, marital status
162 (in a stable relationship vs. not in a stable relationship), dwelling (homeowner vs. renter), place of
163 residence (urban vs. non-urban), education (Primary, High school, University), and employment
164 status (looking after the family/home, employed, sick leave/disabled, unemployed).

165 2.5.2. Primary Outcome

166 The Fibromyalgia Impact Questionnaire (FIQ) is the gold-standard self-report measure for
167 assessing functional impact of FM, and it is based on 20 items capturing a broad spectrum of
168 symptoms and difficulties related to FM (e.g., ability to perform physical activities, subjective
169 feelings, work ability, pain, fatigue, morning tiredness, stiffness, anxiety, and depression). Scores
170 range from 0 to 100, with greater scores indicating higher functional impact of FM. The current study
171 used the Spanish version of the FIQ, which has shown good psychometric properties [24].

172 2.5.2. Secondary Outcomes

173 The Clinical Global Impression-Severity Scale (CGI-S) is a 7-point scale asking for clinician's
174 perception of severity regarding a patient's specific disease. Severity of the patient can be stated in
175 terms of normal, not at all ill (1); borderline ill (2); mildly ill (3); moderately ill (4); markedly ill (5);
176 severely ill (6); or extremely ill (7). Scores range from 1 to 7, with greater scores indicating higher
177 clinical severity. CGI-S is one of the most used brief assessment tools, and it has been administered
178 to FM patients in previous studies [e.g., 25]).

179 The Pain Catastrophizing Scale (PCS) is a 13-items self-report measure that measures pain
180 catastrophizing, and comprises three dimensions: rumination (focusing excessively on pain
181 sensations), magnification (magnifying the threat value of pain sensations), and helplessness
182 (perceiving oneself as unable to control the intensity of pain). Items are rated in relation to their
183 frequency of occurrence on a 5-point scale, from never (0) to almost always (4). A total score is
184 computed by summing up item ratings, and ranges from 0 to 52, with greater scores indicating higher
185 pain catastrophizing. The Spanish version of the PCS has shown good psychometric properties in
186 patients with FM [26].

187 The Hospital Anxiety and Depression Scale (HADS) is a 14-item self-report questionnaire that
188 assesses the severity of anxiety and depressive symptoms in community and hospital settings. Items
189 are rated on a 4-point Likert-type scale with two subscales: anxiety (HADS-A) and depression
190 (HADS-D), each score ranging from 0 to 21, with greater scores indicating higher severity of
191 symptoms (anxiety and depression). The Spanish adaption of the HADS demonstrates adequate
192 psychometric properties in patients with FM [27].

193 The Visual Analogue Scale (VAS) from the EuroQol instrument (EQ-VAS) asks the patient to
194 rate their perceived current health status in a line from the best and worst possible health states (from
195 100 or 0 points, respectively). It is a standardized, non-disease-specific instrument for describing and
196 valuing health-related status in terms of health-related quality of life. The Spanish version of the EQ-
197 5D is a reliable and valid outcome measure [28].

198 The Acceptance and Action Questionnaire (AAQ-II) is a 7-item instrument assessing
199 psychological inflexibility as the (a) unwillingness to experience unwanted emotions and thoughts
200 and (b) and the inability to be in the present moment and behave towards values-directed actions

201 when experiencing distressing psychological events. Items are in a 7-point Likert scale (from 1 = never
202 to 7 = always) with scores ranging from 7 to 49 (higher scores are indicative of more psychological
203 inflexibility). The Spanish version of the AAQ-II has good psychometric properties [29].

204 The Five Facet Mindfulness Questionnaire (FFMQ) evaluates mindfulness and consists of 39
205 items rated on a 5-point Likert scale (from 1 = never or very rarely true to 5 = very often or always
206 true). The mindfulness facets assessed are: (1) observing (i.e., noticing internal and external
207 experiences), (2) describing (i.e. labelling internal experiences with words), (3) acting with awareness
208 (i.e., focusing on one's activities in the here and now), (4) non-judging of inner experiences (i.e., taking
209 a non-evaluative stance toward thoughts and feelings), and (5) non-reacting (i.e., allowing thoughts
210 and feelings to come and go, without getting caught up in or carried away by them). A total FFMQ
211 score can be calculated by summing item scores [30].

212 The Self-Compassion Scale (SCS) is a 26-item measure designed to evaluate overall self-
213 compassion considering the facets of common humanity, mindfulness, and self-kindness assessed in
214 six subscales. Items are on a 5-point Likert scale (from 1 = almost never to 5 = almost always) and a
215 total score can be calculated by summing up the subscales means (scores can range from 6 to 30). The
216 Spanish version of the SCS showed adequate psychometric properties [31].

217 Treatment credibility (on a scale from 0 to 10) and the patient's preferred choice of intervention
218 (i.e., MAIR, RT, other, indifferent) were assessed before group assignment. All sessions were audio
219 recorded, and two of the researchers (J.G.-C. and H.M.-S.), randomly assessed two sessions of each
220 study arm to confirm that the psychological treatments followed the corresponding protocol with a
221 high level of fidelity.

222 2.5.3. Biomarkers Outcomes

223 BDNF was analysed with ELISA (R&D systems©), Interleukin (IL)-6, TNF- α , and IL-10 with
224 Immulite© 1000 (Siemens), and high sensitivity C-Reactive Protein (hs-CRP) with
225 immunoturbidimetry (CRP Beckman Coulter©). The kits were used, and the levels of biomarkers
226 calculated according to the manufacturer instructions. All biomarkers were obtained from serum.

227 2.6. Data Analyses

228 All statistical analyses were computed using SPSS v.25. Baseline between-group differences in
229 sociodemographic, clinical variables, and biomarkers were evaluated, applying the Student t-test, for
230 continuous variables, and the χ^2 -test, for categorical data (Fisher's test was used when adequate). All
231 outcome measures were evaluated for normality with the Kolmogorov-Smirnov test. Concentrations
232 of cytokines and hs-CRP measures were subjected to a natural logarithmic transformation to
233 normalize the significantly skewed data distributions (all clinical variables and BDNF showed a
234 normal distribution, so they were always analysed without transformation).

235 Treatment effects analyses were performed on an intention-to-treat (ITT) basis and linear
236 mixed-effects models for each outcome variable (FIQ, secondary clinical variables, and biomarkers)
237 were performed. Statistical analyses for clinical outcomes included pre, post and follow-up data, data
238 on biomarkers were only available for pre and post-intervention assessments. Restricted maximum
239 likelihood regression (REML) was used to account for the correlation between repeated measures for
240 each individual. REML produces less biased estimates of variance parameters when using small
241 sample sizes or unbalanced data [32]. Regression coefficients (B) and 95% confidence intervals (95%
242 CI) were calculated for the Group \times Time interaction between groups at posttest and 3-month follow-
243 up. Separate models for each outcome variable were calculated. We reported Cohen's *d* (*d*) for each

244 pairwise comparison, using the pooled pretest SD to weight the differences in the pre-post means,
 245 and to correct for the population estimate [33]. The rule of thumb is usually that a d of 0.20 is small,
 246 0.50 is medium, and 0.80 is large. For parsimony reasons, only the total score of each measure was
 247 analysed.

248 We differentiated patients into two categories (responders/non-responders to treatment) using
 249 two different cut-off criteria: (a) $\geq 20\%$ reduction in the pre-post FIQ total score and (b) $\geq 50\%$
 250 reduction in the pre-post FIQ total score [34]. These two classifications were used to calculate the
 251 number needed to treat (NNT) in the MAIR group compared to the RT. NNT refers to the estimated
 252 number of patients who need to be treated with the new proposed treatment (i.e., rather than the
 253 control comparison treatment) for one additional patient to benefit. A confidence interval (95% CI)
 254 for each NNT was calculated. This index allows findings from RCTs to be more meaningful to
 255 clinicians.

256

257 3. Results

258 3.1. Patients flow and compliance

259 Of the 83 potential patients who were eligible, 13 were excluded for not meeting screening
 260 criteria and 6 were excluded because they refused to participate. The 64 patients enrolled were
 261 randomized into 3 study arms, with 23 patients for ABCT, 22 for MAIR, and 19 for RT (Fig. 1). As
 262 indicated above, in this study we specifically explored the results of the 41 patients in MAIR and RT
 263 groups. The measurement completion rate was high, with 34 (82.93%) complying all of the biomarker
 264 outcomes. The median number of sessions attended in the MAIR was 7 (Q1 = 6, Q3 = 8), while in the
 265 RT was 8 (Q1 = 7, Q3 = 8), which was not a statistically significant difference ($p > .05$). The retention
 266 rate for MAIR was 86.36% and 86.36% at post-treatment and follow-up, respectively; and for RT was
 267 84.21% and 78.94%, respectively. The ratio of dropouts was very similar in the 2 arms, both post-
 268 treatment ($p > .05$) and at follow-up ($p > .05$).

269 3.2. Baseline socio-demographic and clinical characteristics of patients

270 The distributions of socio-demographic and clinical characteristics of patients at baseline for
 271 each group are shown in Table 2. Patients were all female, in their early fifties, mostly with a partner,
 272 and dwelling in their own home in an urban residence. In clinical terms, patients presented moderate
 273 severity [34] regarding their functional status [FIQ: M = 67.00 (SD = 17.98)]. There were no significant
 274 differences between groups in any of the referenced variables.

275 **Table 2.** Baseline socio-demographic and clinical features of patients^a

Characteristics at baseline	RT (n = 19)	MAIR (n = 22)	(p)
Sex, female	19 (100)	22 (100)	-
Age	52.21 (5.95)	52.77 (13.45)	0.86
Marital status, stable relationship	13 (68.4)	12 (54.5)	0.39
Residence, urban	19 (100)	22 (100)	0.27
Dwelling, own home	17 (89.5)	18 (81.8)	0.76
Education			0.66
Primary	4 (21.1)	7 (31.8)	
Secondary	8 (42.1)	8 (36.4)	
University	7 (36.8)	7 (31.8)	

<i>Employment</i>			0.43
Employed	5 (26.2)	3 (13.6)	
Sick leave/inability	8 (42.2)	8 (36.4)	
Unemployed	6 (31.6)	11 (50.0)	
<i>Fibromyalgia impact</i>			
FIQ (0-100)	62.83 (18.41)	70.61 (17.21)	0.17
<i>Clinical severity</i>			
CGI-S (1-7) [†]	4.32 (1.16)	4.59 (1.14)	0.45
<i>Pain catastrophizing</i>			
PCS (0-52)	25.00 (10.92)	29.50 (9.73)	0.17
<i>Anxiety and depression</i>			
HADS-A (0-21)	11.37 (5.40)	12.32 (3.48)	0.52
HADS-D (0-21)	8.05 (6.03)	9.73 (5.19)	0.35
<i>Perceived health</i>			
EQ-VAS (0-100)	54.00 (20.19)	48.18 (17.01)	0.32
<i>Psychological inflexibility</i>			
AAQ-II (10-70)	37.32 (13.34)	41.00 (10.45)	0.33
<i>Mindfulness facets</i>			
FFMQ (39-195)	118.74 (14.96)	116.32 (18.48)	0.65
<i>Self-compassion</i>			
SCS (6-30)	16.81 (4.13)	16.63 (3.81)	0.89

276 RT: Relaxation Therapy; MAIR: Mindfulness, Amygdala and Insula Retraining; FIQ:
 277 Fibromyalgia Impact Questionnaire; CGI-S: Clinical Global Impression Severity; PCS: Pain
 278 Catastrophizing Scale; HADS-A: Hospital Anxiety and Depression Scale-Anxiety; HADS-D:
 279 Hospital Anxiety and Depression Scale-Depression; EQ-VAS: Visual Analogue Scale from
 280 EuroQol; AAQ-II: Acceptance and Action Questionnaire; FFMQ: Five Facets of Mindfulness
 281 Questionnaire; SCS: Self-compassion scale. ^aData is presented as the mean (SD) or frequency (%).

282 3.3. Effects on primary and secondary outcomes

283 Table 3 shows descriptive statistics and between-group analyses for the primary and secondary
 284 outcomes. For the primary outcome, MAIR was significantly superior to RT for reductions in
 285 functional impact (FIQ) at post-treatment ($B = -25.94$, 95% CI -40.63 to -11.25, $d = -1.34$) and follow-up
 286 ($B = -25.15$, 95% CI -40.02 to -10.27, $d = -1.25$), both with large effect sizes.

287 Regarding the secondary outcomes, significantly moderate effects sizes of MAIR in comparison
 288 to RT were observed. We found decreases in clinical severity (CGI-S) at post-treatment ($B = -1.09$, 95%
 289 CI -1.84 to -0.34, $d = -0.62$) and follow-up ($B = -1.03$, 95% CI -1.80 to -0.27, $d = -0.79$), as well as large
 290 effects in pain catastrophizing (PCS) at follow-up ($B = -10.02$, 95% CI -16.42 to -3.63, $d = -1.20$), but no
 291 difference was found at post-treatment. Compared to RT, MAIR showed a significant improvement
 292 in anxiety (HADS-A) at post-treatment ($B = -4.76$, 95% CI -7.29 to -2.23, $d = -0.68$) and follow-up ($B = -$
 293 4.09 , 95% CI -6.68 to -1.51, $d = -0.78$); and depression (HADS-D) at post-treatment ($B = -5.24$, 95% CI -
 294 7.69 to -2.79 , $d = -0.59$) and follow-up ($B = -3.85$, 95% CI -6.35 to -1.35, $d = 0.56$), all with moderate effect
 295 sizes. However, significantly large effects sizes of MAIR were obtained for reduction in psychological

296 flexibility (AAQ-II) at follow-up ($B = -14.76$, 95% CI -22.50 to -7.01 , $d = -1.08$), but no difference was
 297 found at post-treatment.

298 MAIR achieved significant moderate effects sizes compared with RT for increasing perceived
 299 health (EQ-VAS) at post-treatment ($B = 16.81$, 95% CI 5.20 to 28.43 , $d = 0.69$) and follow-up ($B = 15.48$,
 300 95% CI 3.63 to 27.33 , $d = 0.75$); and large effects sizes in self-compassion (SCS) at post-treatment ($B =$
 301 3.85 , 95% CI 1.10 to 6.51 , $d = 0.99$) and follow-up ($B = 6.83$, 95% CI 4.13 to 9.52 , $d = 1.73$). Likewise,
 302 significantly moderate effects sizes of MAIR were obtained for improvement in mindfulness scores
 303 (FFMQ) at post-treatment ($B = 13.30$, 95% CI 1.54 to 25.06 , $d = 0.71$) and follow-up ($B = 13.06$, 95% CI
 304 1.14 to 24.98 , $d = 0.70$).

305 **Table 3.** Descriptive and analysis of primary and secondary clinical variables

	RT ($n = 15$)	MAIR ($n = 19$)	d	B (95% CI)	z (p)
	M (SD)	M (SD)			
<i>FIQ (0-100)</i>					
Baseline	61.12 (20.21)	68.03 (17.02)			
Post-Treatment	61.22 (25.90)	42.84 (20.57)	-1.34	-25.94 (-40.63 – -11.25)	-3.46 (0.001)
Follow-up	67.82 (17.77)	51.05 (16.30)	-1.25	-25.15 (-40.02 – -10.27)	-3.31 (0.001)
<i>CGI-S (1-7)[†]</i>					
Baseline	4.27 (1.28)	4.47 (1.12)			
Post-Treatment	4.33 (0.82)	3.79 (0.86)	-0.62	-1.09 (-1.84 – -0.34)	-2.84 (0.005)
Follow-up	4.07 (0.80)	3.32 (1.00)	-0.79	-1.03 (-1.80 – -0.27)	-2.64 (0.008)
<i>PCS (0-52)</i>					
Baseline	25.93 (10.14)	30.13 (8.40)			
Post-Treatment	23.47 (14.49)	22.67 (13.14)	-0.52	-3.45 (-10.03 – 3.13)	-1.03 (0.305)
Follow-up	23.53 (13.58)	16.20 (9.83)	-1.20	-10.02 (-16.42 – -3.63)	-3.07 (0.002)
<i>HADS-A (0-21)</i>					
Baseline	11.53 (6.06)	12.42 (3.73)			
Post-Treatment	10.53 (5.24)	8.05 (3.60)	-0.68	-4.76 (-7.29 – -2.23)	-3.68 (0.001)
Follow-up	9.80 (4.84)	6.84 (1.54)	-0.78	-4.09 (-6.68 – -1.51)	-3.11 (0.002)
<i>HADS-D (0-21)</i>					
Baseline	8.33 (6.67)	9.32 (5.11)			
Post-Treatment	7.53 (4.81)	5.05 (3.70)	-0.59	-5.24 (-7.69 – -2.79)	-4.20 (0.001)
Follow-up	7.80 (5.99)	5.47 (3.57)	-0.56	-3.85 (-6.35 – -1.35)	-3.02 (0.003)
<i>EQ-VAS (0-100)</i>					
Baseline	53.07 (21.71)	47.89 (16.10)			
Post-Treatment	56.87 (18.95)	64.74 (16.87)	0.69	16.81 (5.20 – 28.43)	2.84 (0.005)
Follow-up	61.67 (15.66)	70.63 (14.29)	0.75	15.48 (3.63 – 27.33)	2.56 (0.010)
<i>AAQ-II (10-70)</i>					
Baseline	38.00 (14.23)	40.95 (11.20)			
Post-Treatment	39.07 (13.90)	34.79 (11.65)	-0.57	-7.51 (-15.16 – 0.14)	-1.93 (0.054)
Follow-up	37.00 (12.78)	26.21 (4.74)	-1.08	-14.76 (-22.50 – -7.01)	-3.73 (0.001)

<i>FFMQ (39-195)</i>					
Baseline	120.07 (16.36)	117.16 (18.41)			
Post-Treatment	121.87 (23.71)	131.79 (17.95)	0.71	13.30 (1.54 – 25.06)	2.22 (0.027)
Follow-up	122.67 (19.88)	132.32 (13.06)	0.70	13.06 (1.14 – 24.98)	2.15 (0.032)
<i>SCS (6-30)</i>					
Baseline	17.23 (4.40)	16.31 (3.64)			
Post-Treatment	17.19 (4.57)	20.31 (4.25)	0.99	3.85 (1.10 – 6.51)	2.84 (0.005)
Follow-up	17.14 (4.53)	23.28 (3.35)	1.73	6.83 (4.13 – 9.52)	4.96 (0.001)

306 RT: Relaxation Therapy; MAIR: Mindfulness + Amygdala and Insula Retraining; M: mean; SD: standard
 307 deviation; d: Cohen’s d effect size corrected for repeated measures; B: unstandardized regression coefficient;
 308 95% CI: 95% confidence interval; FIQ: Fibromyalgia Impact Questionnaire; CGI-S: Clinical Global Impression
 309 Severity; PCS: Pain Catastrophizing Scale; HADS-A: Hospital Anxiety and Depression Scale-Anxiety; HADS-
 310 D: Hospital Anxiety and Depression Scale-Depression; EQ-5D-VAS: Visual Analogue Scale from EuroQol;
 311 AAQ-II: Acceptance and Action Questionnaire. FFMQ: Five Facets of Mindfulness Questionnaire; SCS: Self-
 312 compassion scale.

313 *3.4. Effects on biomarkers*

314 As seen in Table 4, significant moderate effects sizes of MAIR in comparison to RT were observed
 315 in BDNF levels at post-treatment ($Z = -5.94$ 95% CI -9.65 to -2.22, $d = -0.58$). There were no significant
 316 differences between groups in hs-CRP, TNF- α , IL-6, and IL-10 at post-treatment.

317 **Table 4.** Analyses of biomarkers

	RT (n = 16)	MAIR (n = 19)	d	B (95% CI)	z (p)
	M (SD)	M (SD)			
BDNF					
Pre-	19.34 (6.62)	22.72 (8.24)			
Post-	21.54 (7.08)	20.47 (6.13)	-0.58	-5.94 (-9.65 – -2.22)	-3.13 (0.002)
CRP					
Pre-	3.54 (4.36)	4.68 (6.42)			
Post-	4.00 (4.12)	3.85 (5.50)	-0.23	-0.54 (-1.19 – 0.11)	-1.64 (0.101)
TNF					
Pre-	5.99 (2.74)	5.92 (1.65)			
Post-	5.93 (4.13)	5.60 (2.30)	-0.12	-0.06 (-0.25 – 0.12)	-0.68 (0.497)
IL6					
Pre-	3.04 (1.18)	3.35 (2.63)			
Post-	3.14 (1.87)	3.44 (1.12)	-0.01	0.12 (-0.25 – 0.49)	0.65 (0.518)
IL10					
Pre-	5.13 (0.43)	5.59 (1.44)			
Post-	5.02 (1.41)	5.31 (0.53)	-0.15	-0.07 (-0.16 – 0.02)	-1.50 (0.134)

318 M: mean. SD: standard deviation. d: Cohen’s d. B: regression coefficient. 95% CI: 95% confidence interval.

319 *3.5. Absolute risk reduction and number needed to treat (NNT)*

320 First, 84.2% and 18.8% of the patients in the MAIR and RT (16 of 19, and 3 of 16, who completed
321 pre- and post-treatment), respectively, reached the criterion of $\geq 20\%$ FIQ reduction after treatment.
322 Therefore, the probability of success in MAIR compared to RT increased by 65.5% (95% CI = 40.3% to
323 90.7%), with an NNT = 2 (95% CI = 1.1% to 2.5%). Second, 36.8% and 0% of the patients in the MAIR
324 and RT (7 of 19, and 0 of 16, who completed pre- and post-treatment), respectively, reached the
325 criterion of $\geq 50\%$ FIQ reduction after treatment. Thus, the absolute risk reduction MAIR compared
326 to RT increased by 36.8% (95% CI = 15.2% to 58.5%), with a NNT = 3 (95% CI = 1.7% to 6.6%).

327 3.6. Patient preferences and credibility of therapies

328 The preferred intervention of each patient was evaluated before allocating to interventions,
329 and a similar distribution was observed between the arms. Specifically, 8 (42.1%) patients in the RT
330 and 10 (45.5%) in the MAIR had no specific preference. Each patient rated the credibility of his or her
331 assigned intervention after receiving it (scores ranging from 0 -minimum credibility- to 10 -maximum
332 credibility-), and similar values were found between groups in this regard [MAIR, *Median* = 8, (Q_1 =
333 8, Q_3 = 9); RT, *Median* = 8, (Q_1 = 7, Q_3 = 9)].

334 4. Discussion

335 In line with previous literature testing MBIs for FM (e.g. [14]) and AR [16,17], this pilot study showed
336 that MAIR, as an add-on to TAU, is an efficacious intervention -with moderate-to-large effect sizes-
337 for improving a wide range of outcomes: functional impairment, clinical severity, quality of life along
338 with cognitive processes associated to psychopathology, such as mindfulness, and self-compassion.
339 The beneficial effects of MAIR remained significant in the 3-month follow-up assessment and even
340 improved in terms of pain catastrophizing and psychological flexibility. Additionally, a significant
341 reduction in BDNF levels was observed in MAIR group at post-intervention evaluation. However,
342 no significant effect of MAIR on cytokine and hs-CRP levels was detected.

343 We observed an overall significant pre-post decrease in FIQ scores (i.e., 37% of reduction) in the
344 MAIR group, with a large effect size. Compared to the results obtained by Toussaint et al. [16] in
345 patients with FM allocated to a “pure” amygdala retraining group where a more modest overall
346 improvement (24% reduction in FIQ scores) was observed, our results suggest a potential superior
347 effect of the synergistic combination of mindfulness and amygdala retraining. However, a
348 comparison between both studies is only tentative since MAIR was a 2-month on-site therapy and
349 amygdala retraining in Toussaint et al.’s study [16] had only 2.5h of on-site teaching plus one-month
350 of video-based home course and a very small sample ($n = 7$). Coherently with the idea of a synergic
351 effect between mindfulness and AR, effect sizes of pre-post changes in the MAIR group were even
352 greater than those observed after MBIs of equivalent duration (e.g., [14]). The positive effects of MAIR
353 were also observed in a wide range of clinical measures and salutary cognitive variables such as
354 mindfulness, psychological flexibility and self-compassion. Remarkably, these benefits were
355 maintained or even improved at 3-month follow-up, specially in the case of pain catastrophizing and
356 psychological inflexibility that are known to be crucial cognitive elements in explaining the impact
357 of the syndrome [36].

358 Although some studies have reported significant changes in inflammatory biomarkers after non-
359 pharmacological interventions in FM [37], including mindfulness training [13], MAIR did not impact
360 on pro- or anti-inflammatory cytokines neither hs-CRP levels. In this regard, our results resemble
361 those in which proinflammatory markers (i.e., IL-6, TNF) remained stable in the mindfulness group
362 in comparison with the active control group. However, Andrés-Rodríguez et al. [13] observed a

363 positive effect of mindfulness intervention on the levels of the anti-inflammatory cytokine IL-10 and
364 we did not. A recent systematic review and meta-analysis [13] has brought into question the
365 hypothesis on a disbalance between pro- and anti-inflammatory cytokines in FM [37] so a lack of
366 effects of MAIR on inflammatory biomarkers may simply rely on a bottom/ceiling-effect.

367 Nevertheless, decreases in BDNF levels (moderate effect size) were found in the MAIR group.
368 BDNF is known to play a crucial role in a variety of neuroplasticity processes, including pain
369 modulation, pain transduction, nociception, and hyperalgesia [38], all of which are altered in FM.
370 Notwithstanding, some studies have also suggested that FM and other central sensitivity syndromes
371 may particularly present abnormalities in biomarkers related to neuronal plasticity, such as BDNF
372 [39]. In this regard, increased plasma levels of BDNF have been reported in patients with FM [41].
373 However, divergent results have been obtained regarding the role of BDNF in FM, with studies
374 finding a lack of association between BDNF and patients' clinical complaints [41,42] or finding
375 comparable levels between FM and healthy subjects [43]. Significant pre-post decreases in BDNF
376 observed in MAIR group are in agreement with those observed in other effective cognitive-behavioral
377 third-wave intervention such as Attachment-Based Compassion Therapy [20] and after a 2-week
378 thermal therapy programme [44]. Interestingly, the BDNF levels of the MAIR group at post-test
379 approached those of pain-free controls in the referenced study [39].

380 There are some potential limitations in this pilot study that should be acknowledged when
381 interpreting the effects of treatment. First, while the final sample size used was within the limits of
382 the power calculation, it was small to generate strong conclusions. Second, the possible influences of
383 therapist variables were not controlled, making it impossible to recognize their effect on treatment.
384 Third, the intervention was not compared with other psychological treatments that have
385 demonstrated effectiveness for FM (e.g., CBT or Acceptance and Commitment Therapy [ACT]) or
386 with an inactive control group alone. Fourth, the two treatment components (mindfulness and
387 amygdala and insula retraining) were not evaluated independently, and therefore their specific
388 effects with respect to the combination could not be compared. Finally, it was not possible to follow-
389 up the levels of the biomarkers.

390 To sum up, the lack of curative treatments for FM represents a great challenge for public health.
391 MAIR (compared to an active control group) demonstrated to be an innovative and effective
392 treatment for improving several outcomes in patients with FM, as well as for increasing mindfulness
393 and self-compassion. Furthermore, improvements in all evaluated variables were also observed at 3-
394 months follow-up, with even larger effect sizes compared to post-intervention assessment. Although
395 no effect of MAIR was observed for inflammatory biomarkers (i.e., TNF- α , IL-6, IL-10, and hs-CRP),
396 reductions in serum BDNF levels were observed being suggestive of a normalizing effect of the
397 intervention on the levels of this neuroprotective agent.

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541



Article

Feasibility and Effectiveness of a Workplace-Adapted Mindfulness-Based Programme to Reduce Stress in Workers at a Private Sector Logistics Company: An Exploratory Mixed Methods Study

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Abstract: There is a high prevalence of stress in the logistics sector owing to very demanding, fast-paced and unpredictable tasks. Mindfulness-based programmes may reduce stress but require considerable practice. Our aim was to evaluate the feasibility and effectiveness of a shortened, workplace-adapted mindfulness-based programme for the logistics sector (WA-MBP-LS) for the purpose of reducing stress. A nonblinded, nonrandomised, two-arm controlled trial was conducted. The WA-MBP-LS ($n = 32$) consisted of six weekly 90-min mindfulness sessions. The control group ($n = 36$) attended a psycho-educational seminar. The Perceived Stress Scale (PSS) and Five Facets of Mindfulness Questionnaire (FFMQ) were measured at pretest, posttest and 6-month follow-up. Differences between groups were evaluated using mixed-effects models. Qualitative methods were used to analyse implementation issues. A 64.2% reduction was observed between initial volunteers and actual participants. Attrition at six-month follow-up was 45.6%. Participants attended a median of five sessions. Decreases in PSS favoured the WA-MBP-LS group at posttest and follow-up. FFMQ played a mediating role in PSS reductions. Barriers were disinterest, lack of programming, work overload and absences from work. Facilitators were curiosity, timing, company facilities and audio recordings. The WA-MBP-LS was feasible and effective in reducing stress, but more efforts to improve the practicalities of implementation are desirable.

Keywords: mindfulness; WA-MBP-LS; feasibility; stress; logistics sector; workplace

1. Introduction

The intensification of the conditions imposed in the context of globalization by the dominant economic paradigm, including processes such as the rationalization and control of production and distribution of goods and services by the implementation of technological and bureaucratic systems, has resulted in important transformations in the structure of modern workplaces [1]. The logistics sector has acquired a prominent role in the context of the current economic paradigm. Whatever their nature, companies in this sector pursue two essential objectives: optimization of the constant flow of

materials through agent networks, and the coordination of the necessary resources to achieve the effective delivery of products to customers.

The employees of logistics sector companies suffer from highly competitive, demanding, fast-paced, unpredictable and high-turnover job positions [2–4]. These employees are also under tight deadlines and pressure to prevent the late delivery of goods, and they are dependent on different factors, some of which are beyond their control, e.g., the weather, which can result in direct negative consequences such as the loss of earnings, sales and customer loyalty [5,6]. All of these conditions, in addition to the increasingly prevalent imposition of new forms of employment contracts, job insecurity, work intensification and poor work-life balance, require workers to make great psychological efforts in order to adapt to the changing demands of their jobs [7], and entail an enormous challenge for this type of worker and their ability to overcome such circumstances, which contributes to enhancing workers' vulnerability to stress [8]. Work-related stress is the response people may have when presented with work demands and pressures that are not matched to their knowledge and skills, and which threaten their ability to cope [9]. It involves a psychosocial risk of major challenges to occupational health and safety [7]. However, research into the stress experienced by employees of private sector logistics companies is rather scarce at present [10].

Stress constitutes a considerable personal and economic burden for individuals, organizations and society at large. For individuals, stress increases the risk of suffering from mental health problems [11,12], health-impairing behaviours such as smoking or alcohol consumption [13,14], obesity [15], sleep disturbances [16], fatigue [17], musculoskeletal pain [18] and cardiovascular disease [19]. In organizational terms, stress has been related to reduced performance and productivity [20], poor safety outcomes [21], staff turnover [22], long-term sickness absences [23] and early retirement [24]. The cost of work-related stress to society is considerable [25], estimated at approximately €9.2 billion in the EU [26].

Mindfulness-based programmes (MBPs), which constitute a new approach within psychological medicine and are integrated into third-wave psychotherapies [27], have been expanded in recent years and have proven effective for a variety of health-related outcomes and populations [28–30]. The first MBP, mindfulness-based stress reduction (MBSR), was originally developed to reduce stress in clinical settings [31], although a number of reviews and meta-analyses on the salutary effects of MBPs have also demonstrated positive outcomes in nonclinical fields, including the workplace [32–39]. In fact, it has been recently concluded that stress reduction is a promising target area of MBPs for promoting workplace wellness [40], and some studies have also shown improvements in other outcomes such as emotion regulation, job satisfaction, sleep quality, heart rate variability, mental well-being and performance [41–44]. Nevertheless, the majority of studies in this field have been conducted using samples of public sector employees, principally health care professions and teaching staff, while very few have been conducted in the private sector, where there may be greater difficulties associated with the implementation of these types of programmes owing to particular practice requirements [38].

MBPs are a type of mind-body intervention that aim to train the mind to adopt nonjudgemental, present-focused awareness [45]. This type of training for the self-regulation of attention might decrease stress and facilitate well-being by helping the practitioner to learn to stay in the present moment with curiosity and acceptance [31,46]. By training the mind to realise how intention and behaviour are formed in the stream of sensory-perceptual events, negative thoughts, sensations, emotions and behaviours begin to be seen as something changeable, allowing practitioners to experience the world in a less threatening way [44,46]. Two different mechanisms through which mindfulness could promote and facilitate psychological adjustment have been proposed [47]: mindfulness might directly facilitate clarity to current experience, promoting an accurate point of view of reality without the discriminatory and prejudiced thought filter [48]; and it might indirectly enhance self-regulated functioning from attentional sensitivity to somatic, psychological and environmental cues [49].

MBPs require participants to be quite disciplined in the practice of meditation exercises and to invest a substantial amount of time [50]. This characteristic of MBPs might represent a barrier in terms of suitability if we are to implement this type of intervention in the workplace, particularly in the

context of the private sector, and even more so in the logistics sector, where work obligations can make participation and practice very difficult [37]. For this reason, original standard programmes, such as MBSR, which usually comprise 8 weekly 150-min sessions plus a one-day retreat, as well as 20–45 min of individual practice per day [51], need to be reduced when applied in the workplace, giving rise to shortened versions of MBP [41–43,52]. It has been observed that a reduced MBP consisting of only half of the standard version could obtain similar effect sizes to those of the standard MBP in terms of trait mindfulness, affectivity, anxiety and depressive symptomatology, compared to waiting list controls when applied to nonclinical populations such as undergraduate students [53]. In view of this, further research studies are warranted to address specific application contexts (e.g., workplace occupational domains such as those of for-profit logistics companies in the private sector), in which brief adaptations of standard MBPs have not previously been tested, in order to make them more accessible to larger numbers of participants without losing their effectiveness [36].

Against this background, the main objective of this study was twofold: to evaluate (a) the feasibility and (b) potential effectiveness of a workplace-adapted MBP for reducing stress in workers of a private sector logistics company. The workplace-adapted MBP for the logistics sector (WA-MBP-LS) was developed by the authors to be a brief, suitable, cost-effective, evidence-based and replicable MBP curriculum to enhance mindfulness and reduce stress among employees of for-profit, privately-owned logistics operators. The WA-MBP-LS was inspired by the theory and practice of contemplative traditions and psychological science; it seeks to address and relieve human distress and promote well-being by training individuals to engage in a new way of relating to experiences based on a present moment orientation, proposes to develop greater attentional self-regulation and values such as compassion, and engages participants in mindfulness meditation practice. Therefore, the WA-MBP-LS is an MBP curriculum that meets the most recently proposed definition for an MBP [54]. It was skilfully adapted to the workplace so that it can be delivered onsite at logistics platforms among company employees. Exploring the possibilities of applying an MBP to reduce stress in new populations and specific workplace contexts such as those of private sector logistics companies, is relevant for advancing our understanding of the scope and possible limitations of these types of mind-body programmes in settings that are in need of intervention; however, difficulties might also be encountered in terms of the implementation process, owing to job-related idiosyncratic aspects, e.g., time pressure constraints [55].

Specifically, with regard to the employees of a for-profit, privately-owned logistics company, we aimed to explore: (1) the feasibility of the recruitment procedure and retention of the initial group of volunteers until completion of the WA-MBP-LS programme; (2) the acceptability of the WA-MBP-LS by means of the rates of adherence to the practice; (3) the data collection procedure in terms of the response rate to surveys; (4) the potential effectiveness of the WA-MBP-LS at reducing perceived stress, as well as improving mental well-being, job satisfaction and trait mindfulness; (5) the extent to which participation in the WA-MBP-LS intervention influences gains in trait mindfulness, and whether these gains in the condition of mindfulness are associated with improvements in perceived stress, mental well-being and job satisfaction; and (6) the barriers and facilitators that might determine the successful implementation of the WA-MBP-LS intervention in the logistics sector, using qualitative methods.

2. Materials and Methods

2.1. Design

As a mixed-methods, naturalistic feasibility trial with a nonblinded, nonrandomised, controlled, two-arm and parallel-group design, the WA-MBP-LS was offered to a group whose levels of perceived stress, well-being, job satisfaction and trait mindfulness were measured at baseline, postintervention and six-month follow-up, and compared to control participants who only attended a psycho-educational seminar. Both groups were interviewed about aspects of the programme implementation process. The study was revised and approved by the corresponding company's human resources section (01/06/2018). This study was conducted in accordance with the Declaration

of Helsinki of 1975, revised in 2013. The data (totally anonymised) used to produce the study results and descriptions of the project are available in full on the following open access repository (more information for replication studies are available upon request): <https://www.openicpsr.org/openicpsr/project/108743/version/V8/view>.

2.2. Study Sample and Procedure

The study was incorporated into a voluntary training course to reduce perceived stress that was offered by the human resources department of a privately-owned Spanish logistics company to the 300 people working at their head office in February 2018. The course was free of charge for employees and consisted of six weekly 90-min mindfulness-based sessions integrated into their work schedule, with the possibility of 15 min of daily practice also taking place within working hours. Participants received no reimbursement for their participation in the study. The concept of mindfulness, as well as its possible applications to an occupational context in the logistics sector was explained in two 30-min, face-to-face recruitment group sessions held in two shifts at the company's facilities and facilitated by the company's human resources manager and a psychologist representing the research group. Attendees at these informative sessions were able to ask questions to clarify any doubts after having been given the opportunity to review information sheets detailing the possible benefits of the programme, the confidentiality with which the data would be processed and the ethical implications of participation, and which contained a link to the online survey. A total of 190 employees agreed to participate in the study on the condition they would be able to choose the specific group in which they would participate. Randomization was therefore not viable. The experimental group consisted of the WA-MBP-LS (its contents are explained in detail below), and the control condition was based only on a psycho-educational seminar with a duration of 2 h on the transactional model of stress and the salutary effects of MBPs regarding coping with stressful situations in the workplace.

Since this was an exploratory pilot study, a strict sample size calculation was not performed. However, we aimed for approximately 50 participants (25 in each group) because this would be a large enough sample to inform us about the practical aspects under study and to reach statistical significance for perceived stress using a 95% confidence interval and a statistical power of 80% in a two-tailed contrast with a large effect size ($d = 0.80$), as had previously been obtained using mind-body stress reduction programmes in the workplace [44]. The inclusion criteria were as follows: a) ability to understand spoken/written Spanish; b) online submission of a signed written informed consent form; and c) completion of the online baseline evaluation before beginning the intervention. Of all the volunteers who initially agreed to participate, a total of 122 workers did not complete the baseline assessment and were therefore excluded from the study. The participants were allowed to choose the group in which they wished to participate, with 32 of them included in the WA-MBP-LS condition and 36 in the control group, for a total of 68 participants at baseline.

Workplace-Adapted Mindfulness-Based Programme for the Logistics Sector (WA-MBP-LS)

The WA-MBP-LS is a stress management intervention based upon the principles and practices of mindfulness for organizations [56], but specifically customised to 'just-in-time' contexts of application in which seconds count and where stock breaks in assembly lines represent economic penalties and losses in terms of the reputation of the company. These organizational contexts are dynamic environments that require individuals to make a series of interdependent decisions in real time, to show flexibility in the face of changes, creativity in the resolution of contingencies, and a resilient attitude in order to maintain efficiency by providing immediate solutions despite difficulties. This is a type of setting in which developing nonjudgemental observation might have a practical bearing because high levels of attention are needed to solve the challenges that continuously arise. The practice of mindfulness gradually allows individuals to realise that events can be more fluid. In other words, even stressful situations at work that generate apparently negative behaviours, thoughts and sensations come to be seen as more flexible and changeable, allowing them to shift their experience by learning to pay attention to the present moment, with a curious and accepting attitude, and higher concentration over long periods of time [46,57]. While these processes are not necessarily

conscious ones, their results could allow individuals to experience the workplace in a less stressful way.

The WA-MBP-LS condition was divided into two subgroups, each with 16 participants, and sessions were held in the workplace in March–April and May–June 2018 by a trained mindfulness teacher, certified in MBSR and with 5 years' experience. The teacher in charge of delivering the intervention also contributed to the development of the specific adaptations to the WA-MBP-LS, and was also the person who presented the psycho-educational seminar attended by the control group. The entire programme was delivered at the employee workplaces. The WA-MBP-LS is an adaptation of the MBSR programme [31]. The original standard programme was reduced to six weekly 90-min sessions. No full-day retreat was offered, but it included the possibility of 15-min, audio-recorded daily practices. This reduction in terms of the length of sessions and daily practices, as well as the absence of a day of silence retreat (full day), meant a shortening by approximately half of the amount of practice of the original programme. This level of intensity is within the range of practice that has shown effective results on well-being outcomes among nonclinical samples in previous research [53], and it was considered an acceptable level of practice that might be included in the schedule of privately-owned companies in the logistics sector, characterised by important time pressure constraints.

The WA-MBP-LS sessions were eminently practical and interactive, combining explanations about the transactional stress model, as well as processes of the mind and the body, with attention practices, conscious movements and meditation exercises. The exercises were relatively brief (5–15 min) and were specifically designed to be used in workplace settings. The dynamic of the practices included alternation between moments of silence and periods of collective exploration that involved inquiring strategies for facing stress and difficult situations, and discussion on how to practically apply these strategies in the professional sphere related to the logistics sector. At the same time, daily practices were also held in the workplace. For these daily practice sessions, the company allotted two 15-min timeframes in the morning, from 8:00 to 8:15 a.m. and from 8:15 to 8:30 a.m. The daily practice sessions were conducted using audio-recorded exercises that had been previously explained and put into practice under supervision during the training sessions. Once the programme was concluded, the participants were encouraged to continue with the practice at home on an individual basis, but no more interventions involving the MBP teacher or any electronic device or Internet platform were made available after that time in order to evaluate the impact of the WA-MBP-LS as an exploratory, low-intensity starting point for implementation. Some details of the WA-MBP-LS sessions, contents and daily practice exercises can be found in Table 1.

Table 1. Workplace-adapted mindfulness-based programme for the logistics sector (WA-MBP-LS).

Sessions	Contents	Daily Practices
1. Mindfulness vs automatic pilot	<ul style="list-style-type: none"> • Presentation of teachers/participants • Group norms, expectations • What is mindfulness? • Raisin exercise • Body scan exercise • Three-minute practice • Work-related stress in the logistics sector 	<ul style="list-style-type: none"> • Body scan • Three-minute practice
2. Living in the present and not in the mind	<ul style="list-style-type: none"> • Body scan exercise • Review of current practice and practices at home • Analysis of difficulties • What to do with the body and the mind • Meditation in breathing: (a) three anchor points; (b) nuclear practice; (c) breath counting • Formal practice at work in the logistics sector 	<ul style="list-style-type: none"> • Body scan • Mindful breathing
3. Increasing our attention	<ul style="list-style-type: none"> • Informal practices • Review of current practices and of the week • Seeing what is seen and hearing what is heard • Deal with thoughts 	<ul style="list-style-type: none"> • Mindful breathing • Mindfulness of a daily activity

	<ul style="list-style-type: none"> • Exercise: 'hello', 'thank you' and 'goodbye' • Informal practice at work in the logistics sector 	
4. Understanding how mindfulness works	<ul style="list-style-type: none"> • Seated meditation (breathing, body, sounds, thoughts and consciousness without choice) • Review of current and home practice • How does mindfulness work? • Mindfulness in movement and walking meditation • Three-minute period with thoughts • Mindful attitudes at work in the logistics sector 	<ul style="list-style-type: none"> • Seated meditation • Three-minute period • Mindful walking and mindfulness in movement
5. Values approach	<ul style="list-style-type: none"> • Breathing exercise • Review of current practice and of the week • How do you feel before the end of the course? 3 stages: challenge, disappointment and acceptance. How does it work? (in pairs) • Concept of values in life and work-life • Resilience and energy balance at work in the logistics sector 	<ul style="list-style-type: none"> • Mindful breathing or body scan • Regular three-minute periods in adverse situations • Walking meditation
6. Compassion: caring for me and others	<ul style="list-style-type: none"> • Breathing exercise • Review of current practice and of the week • What is compassion? • Self-support patterns in difficult situations • Compassionate gestures, phrases and confrontations • Self-care at work in the logistics sector • Revision of the course. How to keep up practice 	<ul style="list-style-type: none"> • Mindful breathing or body scan • Compassionate coping • Three-minute practice

2.3. Measures

2.3.1. Socio-Demographic and Occupational Characteristics

An online data collection procedure was used. The survey included socio-demographic variables at baseline, such as age, sex, relationship (yes, no), number of children, residence (urban, rural), level of education (primary, secondary, university), weekly working hours, years of service in the company, sick leave in the last year (yes, no), type of contract (temporary, permanent), income satisfaction (not satisfied, slightly satisfied, moderately satisfied, very satisfied), minutes of vigorous weekly physical activity, and mindfulness practice during the previous six months (yes, no).

2.3.2. Attrition and Acceptability

Recruitment of and attrition from the total group of workers through the initial group of interested volunteers until the final completion group were assessed by recording the flow of participants throughout the study. Acceptability was measured by recording the number of programme sessions attended and attendance at daily practices. Data collection was evaluated by means of the number of online records completed at pretest, posttest and six-month follow-up.

2.3.3. Perceived Stress

Stress levels were measured at pretest, posttest and six-month follow-up by the 'Perceived Stress Scale' (PSS) [58]. The PSS is a self-report instrument that evaluates the level of perceived stress during the previous month. This scale consists of 10 items asking about the frequency of thoughts and feelings experienced using a Likert-type scale with 5 response options, between 0 ('never') and 4 ('very often'). The total scale is obtained as the sum of all the items and ranges between 0 and 40; higher scores correspond to higher levels of perceived stress. The PSS Spanish version has demonstrated good psychometrics in previous research [59]. Cronbach's alpha in the present study was $\alpha = 0.90$.

2.3.4. Mental Well-Being

The short 'Warwick-Edinburgh Mental Wellbeing Scale' (SWEMWB) [60] was used to assess mental well-being at pretest, posttest and six-month follow-up. It is a self-report questionnaire consisting of 7 items that are ranked by a Likert-type scale from 1 ('never') to 5 ('always'). This scale considers mental health from a positive perspective, more in relation to functioning than to feelings; as such, it covers eudaimonic aspects of psychological functioning—i.e., well-being as something related to the development of a person's abilities, challenges, purpose in life and growth—but it also includes some hedonic aspects, i.e., related to the presence of positive affectivity and satisfaction with life. The total scale is the sum of all the items and presents a range from 7 to 35, where higher scores correspond to higher levels of well-being. This scale has demonstrated appropriate psychometrics in its Spanish version [61]. Cronbach's alpha in the present study was $\alpha = 0.80$.

2.3.5. Job Satisfaction

Job satisfaction was evaluated using the 'Job Satisfaction Scale' (JSS) at pretest, posttest and six-month follow-up. The JSS is a self-report questionnaire that was designed for exploring general occupational aspects of job satisfaction in the present study. It asks questions on five topics: relationship with superiors, relationships with other workers, level of assigned responsibility, acknowledgement obtained for work well done, and attention paid by the company to worker suggestions. The degree of satisfaction for each of these items is assessed using a Likert-type scale with 7 response options, from 1 ('very unsatisfied') to 7 ('very satisfied'). A total job satisfaction score is calculated as the sum of all the items, ranging between 5 and 35 points; higher scores correspond to higher levels of job satisfaction. The factorial validity of the JSS in the present study presented very good fit to the data (CFI = 0.998; TLI = 0.999; RMSEA = 0.064; SRMR = 0.015), also with an adequate internal consistency of $\alpha = 0.88$.

2.3.6. Mindfulness

Mindfulness as a trait was assessed by the 'Five Facet Mindfulness Questionnaire' (FFMQ) [62] at pretest, posttest and six-month follow-up. The FFMQ is a 39-item, self-report measure of trait mindfulness that is based on the following five skills: observing, describing, acting with awareness, and nonjudging of and nonreactivity to inner experience. Observing refers to the ability to realise external and internal experiences (e.g., sensations, thoughts and emotions); describing is the ability to label internal experiences with words; acting with awareness includes focusing intently on the activities of the present moment; nonjudging refers to the adoption of a nonevaluative posture towards the feelings and thoughts that are experienced; and nonreactivity involves relating to internal experiences by allowing feelings and thoughts to reach and leave the focus of consciousness without being trapped by them. Respondents indicate on a 5-point Likert-type scale the degree to which each item is true for them, from 1 ('never true') to 5 ('always true'). Higher scores indicate higher levels of trait mindfulness. A total FFMQ score is obtained as a result of the sum of all the items, ranging between 39 and 195. The FFMQ Spanish version has shown appropriate psychometric properties [63]; in the present study, Cronbach's alpha internal consistence value for the total scale was $\alpha = 0.92$.

2.4. Statistical Analysis

First, socio-demographic data were described at baseline by frequencies (%), medians (interquartile range, IQR) or means (standard deviation, SD), and the study groups were compared by means of a chi-square test (or Fisher's test when necessary), Mann-Whitney test or *t*-test, respectively, depending on the level of measurement and distribution of each socio-demographic variable.

Recruitment and attrition were described using frequencies (%). The number of WA-MBP-LS sessions and daily practice sessions attended were reflected using frequencies (%), medians (IQR) and means (SD). As a guideline, we expected a rate of attrition of approximately 50% between the initial group of volunteers to the final group of participants at baseline, and of approximately 30% from the final group of participants at baseline to the final group at the six-month follow-up [64]. In terms of acceptability, a mean value of half of the sessions attended (≈ 3.0) was considered appropriate

but in need of improvement, and a mean value of 2/3 of the sessions attended (≈ 4.0) was considered feasible [65]. Given the high time pressure suffered by workers in the logistics sector, a mean value of 1 daily practice session at workplace facilities per week during programme implementation was defined as appropriate but in need of improvement, and a mean value of ≥ 2 daily practices per week during this period was defined as feasible. Values lower than those specified were considered nonfeasible results.

The effectiveness of the WA-MBP-LS in reducing perceived stress (PSS) and improving well-being (SWEMWBS), job satisfaction (JSS) and trait mindfulness (FFMQ) compared to that for the control group was analysed using the variables in a continuous manner. We developed a repeated measures design with an intention to treat approach using mixed-effects regression models, including time as an independent variable and subjects as a random effect. The restricted maximum likelihood method was used, which produces unbiased estimates of parameters when using small sample sizes or unbalanced data [66]. Nonstandardised slopes, i.e., 95% confidence intervals (95% CIs), were calculated by adjusting the baseline scores and those socio-demographic variables with significant differences at pretest. The 'group \times time' interaction was considered to determine whether possible differences between groups remained consistent over time. Within-group tests were performed for each group separately in order to evaluate their specific changes over time. Effect sizes (ESs) were assessed using Cohen's d statistic, calculated by the combined SD weighing the mean difference [67]. Cohen [68] defined ESs as small when $d \leq 0.2$, as medium when $d = 0.5$, and as large when $d \geq 0.8$. Sensitivity analyses were conducted to assess the effects of missing data and to evaluate how robust our effectiveness analyses were at follow-up. Missing values were replaced using multiple imputations based on chained equations after ensuring that the data were missing at random. We developed an exploratory comparison of pre–post improvements between subgroups of participants in the WA-MBP-LS condition in terms of sex and level of education following the same analytical procedure, and also explored whether age and weekly working hours were related to pre–post change scores using Pearson's r coefficients.

We evaluated the clinical relevance of improvements in PSS by differentiating participants into 'responders' vs 'nonresponders' to the intervention. To do so, we used the baseline 25th percentile from our total sample as a cut-off criterion to classify participants [58,59], determining that they had reached low perceived stress (i.e., responders) if they scored under the specified cut-off at posttest and six-month follow-up. This classification was used to calculate the absolute risk reduction and the number needed to treat (NNT) in the WA-MBP-LS condition compared to the control group. NNT refers to the number of participants who need to be treated with the intervention (i.e., rather than the control condition) for one additional participant to benefit; a 95% CI was calculated for each NNT.

We evaluated the extent to which the level of participation in the programme, i.e., the total hours of participation in WA-MBP-LS sessions and daily practice sessions from pretest to posttest treatment, was related to pre–post and pre–follow-up gains in trait mindfulness (FFMQ), perceived stress (PSS), mental well-being (SWEMWBS) and job satisfaction (JSS) using Pearson's r coefficients. In addition, we also used Pearson's r correlations to evaluate to what extent pre–post gains in FFMQ were associated with pre–follow-up improvements in PSS, SWEMWBS and JSS.

The sample size of the present study was not primarily estimated to assess mediating effects. Thus, the potential mediating role of FFMQ on PSS, SWEMWBS and JSS was evaluated by merging subjects inside a within-participant path-analytical framework in order to gain statistical power [69,70]. For this purpose, we explored the relationships between the repeated-measures factor (independent variable), the FFMQ pre–post differential scores (mediating variable), and the PSS, SWEMWBS and JSS pre–follow-up differential scores (dependent variables) using ordinary least squares (OLS) analysis with unstandardised path estimates from linear regression coefficients. It was estimated that about 68 participants would allow us to identify significant indirect effects (IEs) as the product of paths 'a' and 'b'—which has been shown to approximate the power of bootstrap estimates [71]—with a statistical power of 0.80, assuming the existence of intermediate effects with a standardised value of about 0.35 in both 'a' and 'b' paths of the mediating model, and of 0.45 in the 'c' path (direct effects controlling for the IEs), and therefore considering a partial mediation scenario with room for other possible mediators. The unstandardised regression coefficients and their

corresponding standard error for IEs were calculated, as were their 95% bias corrected CIs based on 10,000 bootstrap samples. This test is applied to overcome possible problems of asymmetry in the distribution of the IEs [72]. IEs are considered significant when their 95% CI does not include zero. Multiple determination coefficients (R^2) were used to estimate the ES of the mediating models, with values of 0.00 = null effect, 0.14 = small effect, 0.39 = medium effect, and 0.59 = large effect [73].

No interim analyses were performed prior to finishing the complete study trial. An alpha level of 0.05 was set using a two-tailed test. Analyses were carried out using the STATA v12.0 and the IBM SPSS v19.0 statistical software packages.

2.5. Qualitative Analysis

To understand the challenges associated with implementing the WA-MBP-LS intervention in a private sector logistics company, a psychologist trained in qualitative methods held in-depth interviews with participants after follow-up in order to assess: (a) why people chose to participate in the experimental group vs the control group; (b) why they continued attending or stopped attending sessions; and (c) why their attendance was regular or sporadic. Interviews were conducted until data saturation and were recorded and transcribed verbatim. The textual corpus was extracted for analysis using qualitative methods. A content analysis was performed iteratively by two independent researchers to identify the emerging categories from which all the transcripts could be coded [74]. As a first step, a general thematic framework analysis identified the main topics. Secondly, we determined which aspects of the general framework might act as barriers to and facilitators for implementation of the WA-MBP-LS intervention in the logistics context. Finally, we described each of the emerging categories by using empirical segments of the verbatim recordings and transcriptions, establishing possible relationships between them to discover the underlying core and secondary dimensions, which were subsequently defined. The necessary ability of the category system to adequately capture all of textual materials, as well as whether each category was comprehensive and exclusive of the others [75], was subject to debate and solved by consensus (in case of discrepancies, a third researcher was consulted). The data analysis was performed with the Maxqda 2018 software package.

3. Results

3.1. Participant Flow and Compliance

The CONSORT recommendations for reporting pilot and feasibility trials were followed [76]. Figure 1 reflects the flow of participants through the study. Out of a total of 300 employees of the logistics company, 110 declined to participate. Of the 190 remaining subjects who were potential volunteers, 122 were excluded because they did not complete the baseline evaluation. Thus, 68 subjects were finally included in the study (35.8% of the initial volunteers), 32 of whom went on to the WA-MBP-LS arm and 36 of whom formed the control group attending a psycho-educational seminar. The 32 subjects participating in the WA-MBP-LS arm attended a mean of 4.34 (SD = 1.86) training sessions (median = 5; Q_1 – Q_3 = 3–6). A total of 13 participants (40.6%) attended all the training sessions, while 9 (28.2%) attended 4 or 5 sessions, and 10 participants (31.3%) attended < 4 sessions (1 participant did not attend any training sessions). The total daily practices held presented a mean of 8.44 (SD = 7.78) practice sessions (median = 6; Q_1 – Q_3 = 2–15). A total of 12 participants (37.5%) attended ≥ 10 daily practice sessions, while 7 participants (21.9%) attended ≥ 4 but < 10 sessions, and 13 participants (40.6%) attended < 4 sessions (4 participants did not attend any daily practice sessions). The mean of total hours participating in both training sessions and daily practice sessions from pretreatment to posttreatment in the WA-MBP-LS group was 8.63 h (SD = 4.12), with a minimum of 0.50 h and a maximum of 15.25 h. All the control subjects attended the two-hour psycho-educational seminar.

The PSS questionnaire was completed by 31 subjects in the WA-MBP-LS group and by 34 subjects in the control group at postintervention, and it was completed by 16 subjects in the WA-MBP-LS group and 19 subjects in the control group at six-month follow-up, representing 95.6% and

51.5% of the participants who entered the study, respectively (see Figure 1 for the other outcomes). At the six-month follow-up, 6 (31.6%) participants in the control group and 11 participants (64.7%) in the WA-MBP-LS condition had been practising mindfulness after posttreatment ($\chi^2 = 4.46$; $p = 0.035$). No baseline-level differences in the socio-demographic data or in the psychological outcomes were observed either at pretest or posttest between those who completed the survey at the six-month follow-up and those who did not. Thus, dropouts were considered to be random [77].

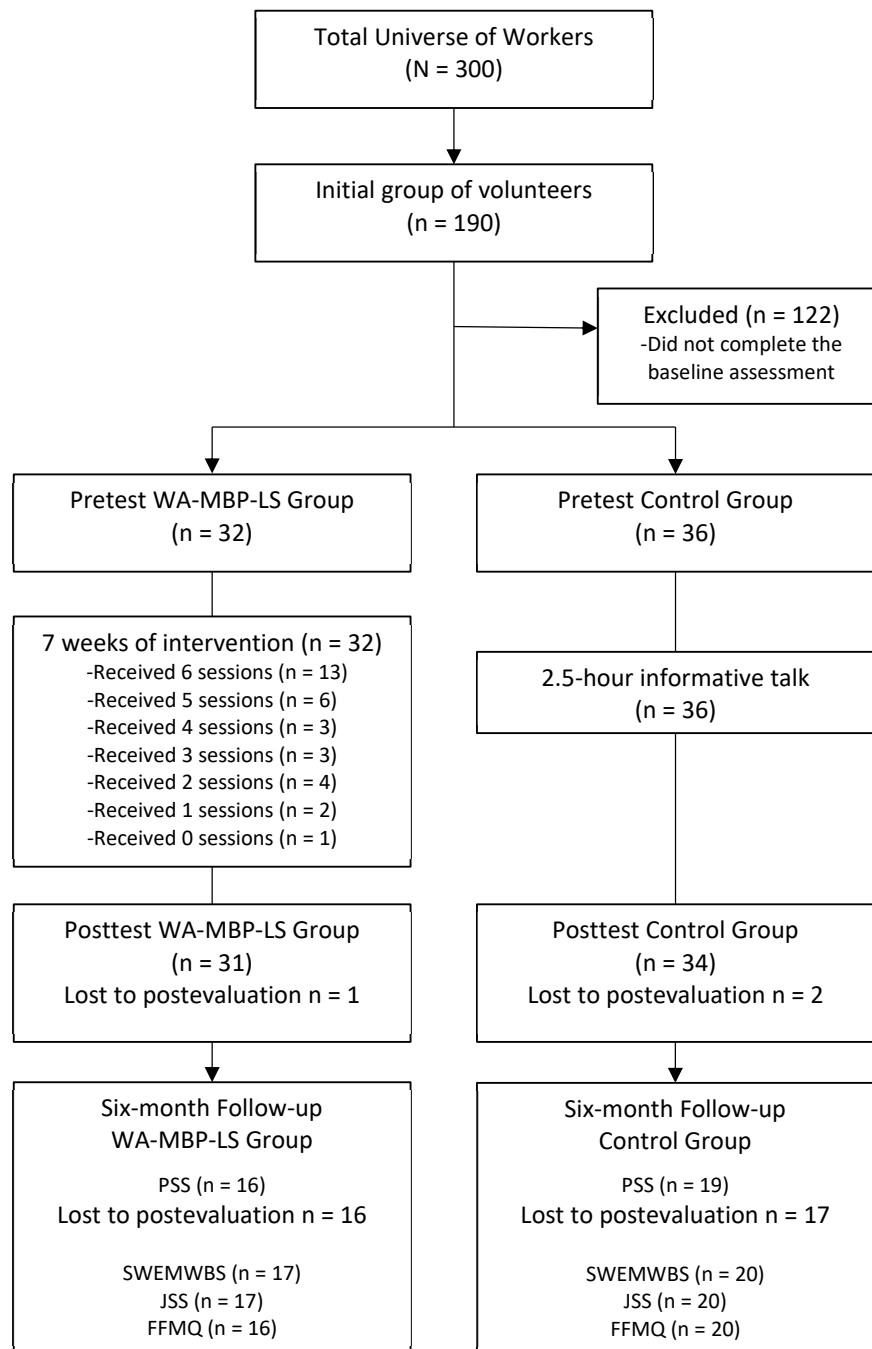


Figure 1. Flow of study participants.

3.2. Group Baseline Characteristics

Slightly more than half of the participants were women in their late thirties, with partners, no children, and a university education, living in an urban setting (Table 2). The mean working week was roughly 40 h. The participants had accumulated approximately 6 years of service in the company, and the majority had not been on sick leave in the previous year. The majority of the participants' contracts were permanent, and more than half of the participants were moderately satisfied with their income. The mean weekly time spent on vigorous physical activity was less than an hour, and only a minority had practised meditation during the previous six months. There were significant between-group differences at baseline in terms of age ($p = 0.025$) and meditation practice during the previous six months ($p = 0.026$); thus, both of these variables were controlled in the effectiveness analyses.

The mean PSS score for the total group at baseline was 18.28 (SD = 7.00), ranging between 1 and 31 (median = 19; IQR = 14–23). Therefore, we considered a score of ≤ 13 as the cut-off point to classify participants as 'responders' vs 'nonresponders' to the intervention in terms of perceived stress. This same cut-off point had already been used in previous studies to differentiate participants with low levels of perceived stress using the PSS questionnaire [78–80]. There were no significant differences between the WA-MBP-LS and control groups in the number of subjects below this classification criterion at baseline [WA-MBP-LS: 5 (15.6%); controls: 11 (30.6%); $\chi^2 = 2.10$; $p = 0.147$].

Table 2. Socio-demographic and labour data of participants at baseline.

Variables	Total (n = 68)	Control (n = 36)	WA-MBP-LS (n = 32)	p
Age, (range: 25–60 years), Mean (SD)	38.56 (7.64)	36.61 (7.76)	40.75 (6.99)	0.025
Sex, women, n (%)	44 (64.7)	25 (69.4)	19 (59.4)	0.386
Relationship, yes, n (%)	44 (64.7)	24 (66.7)	20 (62.5)	0.720
Children, median (Q1–Q3)	0 (0–2)	0 (0–2)	1 (0–2)	0.421
Residence, urban, n (%)	62 (91.2)	33 (91.7)	29 (90.6)	0.999
Education level, n (%)				
Primary	4 (5.9)	3 (8.3)	1 (3.1)	0.462
Secondary	18 (26.5)	11 (30.6)	7 (21.9)	
University	46 (67.6)	22 (61.1)	24 (75.0)	
Weekly working hours, mean (SD)	42.13 (4.24)	41.64 (4.04)	42.69 (4.46)	0.313
Years of service, mean (SD)	6.51 (5.11)	5.66 (5.21)	7.33 (4.97)	0.212
Sick leave last year, yes, n (%)	11 (16.2)	6 (16.7)	5 (15.6)	0.907
Contract type, temporary, n (%)	8 (11.8)	6 (16.7)	2 (6.3)	0.266
Income satisfaction, n (%)				
Not satisfied	1 (1.5)	0 (0.0)	1 (3.1)	0.108
Slightly satisfied	22 (32.4)	9 (25.0)	13 (40.6)	
Moderately satisfied	42 (61.8)	24 (66.7)	18 (56.3)	
Very satisfied	3 (4.4)	3 (8.3)	0 (0.0)	
Minutes of weekly vigorous physical activity, mean (SD)	49.33 (70.88)	52.00 (78.39)	46.41 (62.76)	0.750
Meditation practice last 6 months, yes, n (%)	6 (8.8)	6 (16.7)	0 (0)	0.026

Note: WA-MBP-LS: Workplace-adapted mindfulness-based programme for the logistics sector. Data are presented as the means (SD), medians (Q1–Q3) or frequencies (%), according to each variable. p: value of the statistical significance associated with the contrast between groups, using a *t*-test, Mann-Whitney test, or χ^2 (or Fisher) test.

3.3. Effectiveness of the WA-MBP-LS Intervention

Table 3 shows the descriptive and between-group analyses for PSS, SWEMWBS, JSS and FFMQ (Figure 2 presents a graphical representation of outcomes over time). As can be seen, there were significant between-group differences in PSS, with the WA-MBP-LS participants performing better than controls at posttest and six-month follow-up, with moderate and high ESs, respectively. Within-group tests showed that participants in the WA-MBP-LS group significantly improved on PSS at posttest ($B = -5.39$, 95% CI = -7.04 – -3.74 , $d = -0.80$; $z = -6.39$, $p < 0.001$), and follow-up ($B = -5.82$, 95% CI = -7.82 – -3.82 , $d = -1.02$; $z = -5.69$, $p < 0.001$). On the contrary, participants in the control group did

not show significant within-group improvements at posttest, although there was a trend ($B = -1.74$, 95% CI = -3.50 – -0.03 , $d = -0.60$; $z = -1.93$, $p = 0.054$) and follow-up ($B = 0.31$, 95% CI = -1.78 – 2.40 , $d = -0.12$; $z = 0.29$, $p = 0.770$).

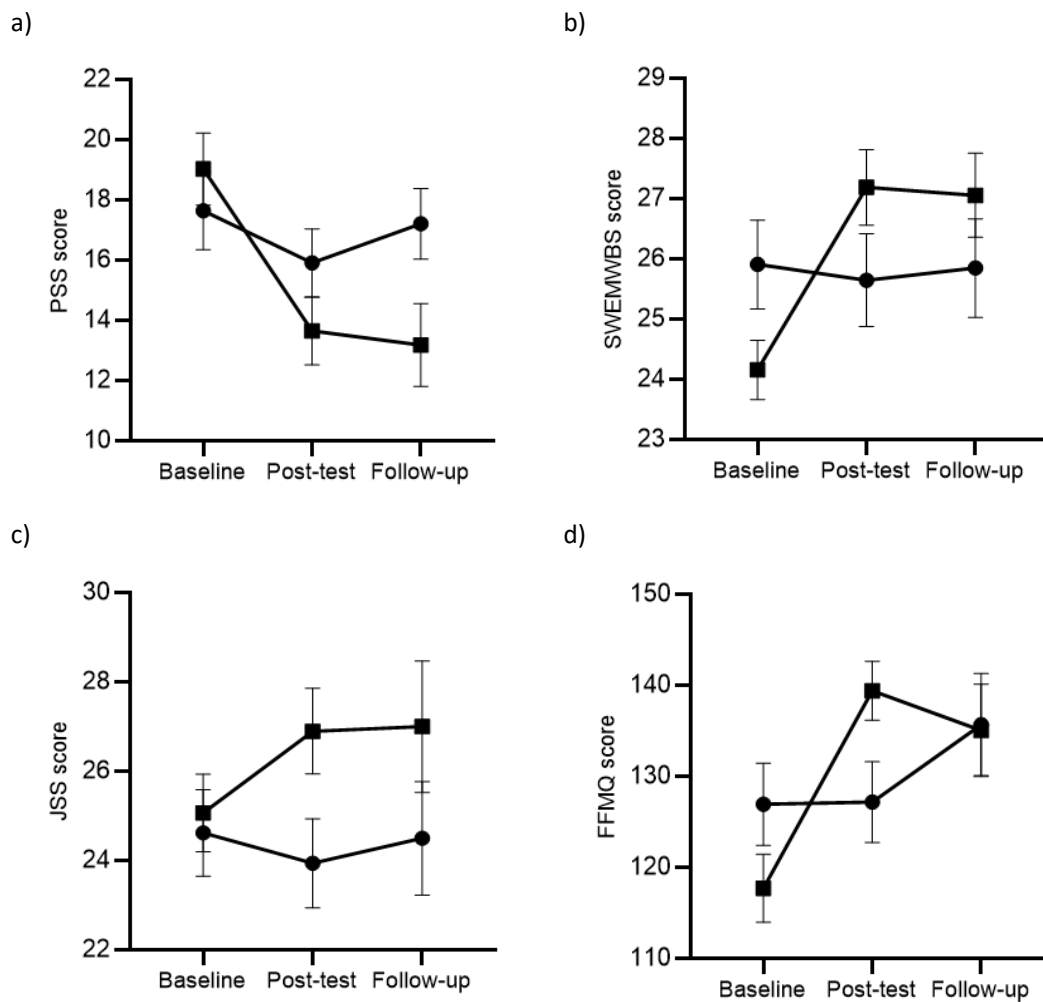


Figure 2. Graphical representation of WA-MBP-LS and control groups on outcomes over time. *Note:* WA-MBP-LS: Workplace-adapted mindfulness-based programme for the logistics sector. (a) PSS: Perceived Stress Scale. (b) SWEMWBS: Warwick-Edinburgh Mental Wellbeing Scale. (c) JSS: Job Satisfaction Scale. (d) FFMQ: Five Facet Mindfulness Questionnaire. ■ WA-MBP-LS group. ● Control group.

There were also significant between-group differences in the SWEMWBS, with the WA-MBP-LS participants performing better than controls at posttest and at six-month follow-up, with high ESs (Table 3). Within-group tests showed that participants in the WA-MBP-LS group significantly improved on SWEMWBS at posttest ($B = 3.03$, 95% CI = 2.07 – 4.00 , $d = 1.10$, $z = 6.16$, $p < 0.001$) and follow-up ($B = 2.51$, 95% CI = 1.35 – 3.68 , $d = 1.30$, $z = 4.24$, $p < 0.001$). Participants in the control group did not show significant within-group improvements at posttest ($B = -0.27$, 95% CI = -1.49 – 0.96 , $d = -0.07$, $z = -0.42$, $p = 0.671$) and follow-up ($B = -0.14$, 95% CI = -1.56 – 1.29 , $d = -0.02$, $z = -0.19$, $p = 0.852$).

We observed a trend with a moderate ES at posttest on the JSS, favouring the WA-MBP-LS participants, and differences were significant at six-month follow-up (Table 3). Within-group tests showed that participants in the WA-MBP-LS group significantly improved on JSS at posttest ($B = 1.84$, 95% CI = 0.19 – 3.49 , $d = 0.42$, $z = 2.19$, $p = 0.029$), and they showed a trend very close to significance and of similar ES at follow-up ($B = 1.94$, 95% CI = -0.03 – 3.90 , $d = 0.48$, $z = 1.94$, $p = 0.053$). Participants

in the control group did not show significant changes at posttest ($B = -0.68$, 95% CI = -2.59 – 1.23 , $d = -0.11$, $z = -0.69$, $p = 0.487$) and follow-up ($B = -0.97$, 95% CI = -3.20 – 1.26 , $d = -0.03$, $z = -0.85$, $p = 0.393$).

Finally, we found significant differences in the FFMQ total score, favouring the WA-MBP-LS participants at posttest and at six-month follow-up, with high and moderately low ESs, respectively (Table 3). Within-group tests showed that participants in the WA-MBP-LS group significantly improved on FFMQ at posttest ($B = 21.71$, 95% CI = 15.34 – 28.08 , $d = 1.07$, $z = 6.68$, $p < 0.001$) and follow-up ($B = 18.02$, 95% CI = 10.10 – 25.93 , $d = 0.89$, $z = 4.46$, $p < 0.001$). Participants in the control arm did not show significant improvements at posttest ($B = 0.24$, 95% CI = -4.33 – 4.80 , $d = 0.02$, $z = 0.10$, $p = 0.920$), but they did at follow-up ($B = 6.88$, 95% CI = 1.57 – 12.19 , $d = 0.58$, $z = 2.54$, $p = 0.011$).

Models with imputed missing values at the six-month follow-up showed similar results for the regression coefficients, reinforcing the significant differences observed in PSS, SWEMWBS and JSS scores, but not in the FFMQ total scores, which presented a considerable reduction in the regression coefficient and showed a nonsignificant difference between groups (Table 3).

Considering only the WA-MBP-LS group, we observed that men, compared to women, obtained greater pre–post reductions of moderate ES in PSS, and although they were not significant, they did show a trend ($B = -2.73$, 95% CI = -5.51 – 0.05 , $d = -0.42$; $z = -1.92$, $p = 0.054$). No other noticeable differences in outcomes were observed according to sex or level of education in the WA-MBP-LS group. On the other hand, we found that older participants showed greater pre–post reductions in PSS, with no significant but moderate effects that showed a trend ($r = 0.34$; $p = 0.063$). Finally, we observed that longer working hours per week were significantly related to less pre–post SWEMWBS improvement, with moderate effects ($r = -0.36$; $p = 0.045$). No other noticeable relationships were observed regarding the other outcomes.

Table 3. Between-group analyses of perceived stress, mental well-being, job satisfaction and mindfulness.

	WA-MBP-LS		Control		Between-Group Analyses		
	n	Mn (SD)	n	Mn (SD)	<i>d</i>	<i>Z</i> (<i>p</i>)	<i>B</i> (95% CI)
PSS							
Pre-test	31	19.03 (6.63)	34	17.65 (7.58)			
Post-test	31	13.65 (6.28)	34	15.91 (6.62)	-0.52	-2.93 (0.003)	-3.65 (-6.10–1.21)
Follow-up	16	13.19 (5.65)	19	17.21 (5.25)	-0.75	-4.15 (<0.001)	-6.20 (-9.13–3.28)
						-5.08 (<0.001)	-4.03 (-5.58–2.47)
SWEMWBS							
Pre-test	31	24.16 (2.73)	34	25.91 (4.31)			
Post-test	31	27.19 (3.48)	34	25.65 (4.49)	0.91	4.05 (<0.001)	3.30 (1.70–4.89)
Follow-up	17	27.06 (2.88)	20	25.85 (3.65)	0.82	2.79 (0.005)	2.67 (0.80–4.55)
						7.79 (<0.001)	2.92 (2.19–3.66)
JSS							
Pre-test	31	25.07 (4.81)	34	24.62 (5.66)			
Post-test	31	26.90 (5.31)	34	23.94 (5.80)	0.48	1.92 (0.052)	2.52 (-0.05–5.08)
Follow-up	17	27.00 (6.07)	20	24.50 (5.68)	0.40	2.00 (0.045)	3.07 (0.05–6.09)
						3.81 (<0.001)	2.40 (1.16–3.63)
FFMQ							
Pre-test	31	117.71 (20.80)	31	126.94 (26.33)			
Post-test	31	139.42 (18.05)	31	127.18 (25.84)	0.90	5.44 (<0.001)	21.47 (13.74–29.21)
Follow-up	16	135.06 (21.00)	20	135.70 (25.19)	0.36	2.33 (0.020)	11.12 (1.76–20.47)
						-0.17 (0.864)	-0.33 (-4.12–3.45)

Note: Models developed by repeated measures (RM) linear mixed-effects regression analysis controlling for the baseline, age and meditation practice in the previous six months. SWEMWBS: Short Warwick-Edinburgh Mental Wellbeing Scale. PSS: Perceived Stress Scale. JSS: Job Satisfaction Scale. FFMQ: Five Facet Mindfulness Scale. *Italic*: sensitivity analyses by imputing missing values at six-month follow-up using chained equations. WA-MBP-LS: Workplace-adapted mindfulness-based programme for the logistics sector group. Control: Control group.

3.4. Absolute Risk Reduction and Number Needed to Treat

We calculated the absolute risk reduction and NNT to determine the clinical significance of improvements in perceived stress (PSS) of the WA-MBP-LS group compared to controls. A total of 54.8% of the WA-MBP-LS participants and 38.2% of the controls [17 of 31 (WA-MBP-LS) and 13 of 34 (controls)] reached the criterion of ≤ 13 on the PSS after treatment. Therefore, the absolute risk reduction in the WA-MBP-LS condition increased by 16.6% (95% CI includes zero) compared to that in the control group, with an NNT = 7 (95% CI includes zero). On the other hand, 68.8% of the WA-MBP-LS participants and 26.3% of the controls [11 of 16 (WA-MBP-LS) and 5 of 19 (controls)] who completed the follow-up assessment reached the criterion of ≤ 13 on the PSS at follow-up. Therefore, the absolute risk reduction in the WA-MBP-LS increased by 42.4% (95% CI = 13.3–72.6) compared to that in the control group, with an NNT = 3 (95% CI = 1.4–8.1).

3.5. Level of Practice and Gains in Mindfulness, Stress, Well-Being and Job Satisfaction

The total time (training sessions and daily practice sessions) invested in participating in the programme was significantly related to pre–post gains in FFMQ ($r = 0.59, p < 0.001$), PSS ($r = -0.27, p = 0.031$) and SWEMWBS ($r = 0.41, p = 0.001$), but it was not significantly related to JSS ($r = 0.13, p = 0.320$). On the other hand, the time invested in participating in the programme was also significantly related to pre–follow-up gains in FFMQ ($r = 0.49, p = 0.002$), PSS ($r = -0.45, p = 0.007$) and SWEMWBS ($r = 0.41, p = 0.012$), but it was not significantly related to JSS, although there was a trend ($r = 0.30, p = 0.075$).

3.6. Mediating Role of Mindfulness on Perceived Stress, Well-Being and Job Satisfaction

Pre–post change scores in FFMQ were significantly related to pre–follow-up change scores in PSS ($r = 0.37, p = 0.029$) and SWEMWBS ($r = 0.33, p = 0.048$), but they were not significantly related to change scores on the JSS ($r = 0.26, p = 0.116$). As can be seen in Table 4, pre–post increases in FFMQ ($a = 11.91, p = 0.003$) played a mediating role for pre–follow-up improvements in PSS ($b = -0.10, p = 0.031$; $IE = -1.20, 95\% \text{ CI} = -2.57, -0.20$) and SWEMWBS ($b = 0.04, p = 0.048$; $IE = 0.50, 95\% \text{ CI} = 0.05, 1.13$) with small to medium effects. The percentage of the effect of the study condition mediated through the FFMQ was 49.4% on PSS, and of 47.6% on SWEMWBS. Pre–post increases in FFMQ did not significantly mediate pre–follow-up improvements on the JSS ($b = 0.06, p = 0.122$; $IE = 0.64, 95\% \text{ CI} = -0.14, 1.48$).

Table 4. Mediation analyses of mindfulness on perceived stress, mental wellbeing and job satisfaction.

Outcome	R ²	Path	Direct Effects					Indirect Effects			
			B	SE	t	p	95% CI	Path	Boot.	SE	95% CI
PSS (n = 35)	0.17	a	11.91	3.67	3.25	0.003	4.46, 19.37				
		b	-0.10	0.04	-2.26	0.031	-0.19, -0.01	ab	-1.20	0.61	-2.57, -0.20
		c'	-1.23	1.09	-1.14	0.265	-3.45, 0.98				
SWEMWBS (n = 37)	0.18	a	11.46	3.48	3.29	0.002	4.40, 18.52				
		b	0.04	0.02	2.05	0.048	0.01, 0.09	ab	0.50	0.28	0.05, 1.13
		c'	0.55	0.51	1.08	0.290	-0.49, 1.59				
JSS (n = 37)	0.07	a	11.46	3.48	3.29	0.002	4.40, 18.52				
		b	0.06	0.04	1.58	0.122	-0.02, 0.13	ab	0.64	0.41	-0.14, 1.48
		c'	-0.37	0.83	-0.44	0.664	-2.06, 1.33				

Note: PSS: Perceived Stress Scale. SWEMWBS: Warwick-Edinburgh Mental Wellbeing Scale. JSS: Job Satisfaction Scale.

3.7. Barriers and Facilitators to Implementation of the WA-MBP-LS Programme

A total of 12 workers were interviewed in depth until data saturation ($n = 6$ WA-MBP-LS participants and $n = 6$ controls), with a total mean age of 39.58 years ($SD = 9.02$), 50% of whom were women, with a mean for years of service with the company of 7.17 ($SD = 5.80$). Figure 3 provides a graphic representation of the structure of relationships found between the core and secondary

emergent dimensions, as well as its constituent categories and properties determining the implementation of WA-MBP-LS according to employees’ perspectives, while Table 5 contains transcribed quotes regarding the results of all the properties found.

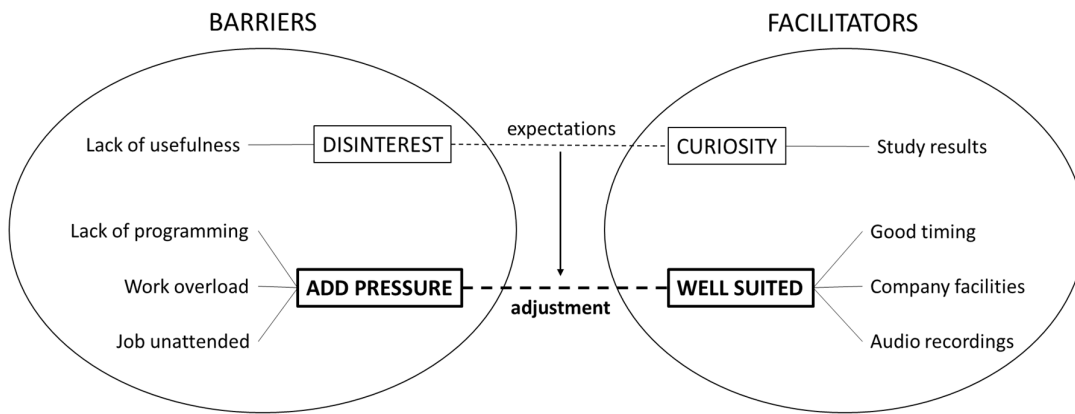


Figure 3. Dimensions, categories and properties determining the implementation of the WA-MBP-LS.
 Note: WA-MBP-LS: Workplace-adapted mindfulness-based programme for the logistics sector.

Table 5. Quotes regarding the WA-MBP-LS implementation from participants point of view.

Dimensions (Centrality)	Categories (Role)	Properties	Quotes
Adjustment (core)	Add pressure (barrier)	Lack of programming	Q3: ‘In my department, the hours of the day where you have dead times are not exactly first thing in the morning’ (Control, 50 years old, man, 15 years of service with the company).
		Work overload	Q2: ‘I have had a lot of work, and that’s why I wasn’t able to reconcile the two things, I was in a moment of a lot of work and that’s why I decided not to do the course’ (Control, 28 years old, woman, 4 years of service with the company).
		Job unattended	Q3: ‘At that time there was no one to replace me, I could have taken part but I felt bad leaving work’ (Control, 43 years old, woman, 4 years of service with the company).
	Well suited (facilitator)	Good timing	Q4: ‘I decided to participate in the intervention because the schedule suited me very well’ (WA-MBP-LS group, 36 years old, man, 6 years of service with the company).
		Company facilities	Q5: ‘The fact that it was held at the company’s facilities and during working hours was very valuable’ (WA-MBP-LS group, 38 years old, woman, 3 years of service with the company).
		Audio recordings	Q6: ‘The audio recordings made it easy for me to practise, sometimes I even did exercises at night’ (WA-MBP-LS group, 36 years old, man, 7 years of service with the company).
Expectations (secondary)	Disinterest (barrier)	Lack of usefulness	Q7: ‘I don’t believe in these things, and that’s why I didn’t take part. I don’t think it offers any benefits’ (Control, 42 years old, man, 13 years of service with the company).
		Curiosity (facilitator)	Study results

company' (WA-MBP-LS group, 48 years old, woman, 7 years of service with the company).

Note: WA-MBP-LS: Workplace-adapted mindfulness-based programme for the logistics sector.

The qualitative analysis of the verbatim recording and transcription showed that 'lack of programming' when adjusting the course schedule, peaks of 'work overload' and the need to leave the 'job unattended' with no replacement personnel were responsible for 'adding pressure' to the workers, and thus, functioned as important barriers. Controls specifically said that the first hour of the morning, i.e., the time in which sessions were held, was a critical moment in terms of time pressure and workload, and that they did not want to leave the job at that time. On the other hand, 'good timing' within working hours, as well as using 'company facilities' and the 'availability of audio recordings' to practise individually at peak work times and at home were seen as a well-suited configuration that facilitated the implementation of the programme. The two poles of 'add pressure' and 'well suited' were the two extremes of the underlying 'adjustment' dimension, which was the core category from which the whole speech was structured, pointing to the importance of considering specific job-related aspects, such as the moment of delivery, possible workload peaks, the need for staff reinforcement, being able to choose between different practice times (e.g., morning, afternoon), using company facilities inside and outside of working hours, and the availability of audio materials to allow for more flexible individual practice.

Parallel to this, there was another dimension that crossed between the barrier and facilitator zones. This dimension reflected individual 'expectations' at the time of choosing participation, and they could be negative, e.g., 'disinterest', with ideas of 'lack of usefulness' of mindfulness interventions, probably due to ignorance of the field. However, they also could be positive, e.g., 'curiosity', with interest in knowing what mindfulness is and to what extent it could be of help for them according to 'study results'. WA-MBP-LS participants decided to choose to be active participants as a result of a certain attitude of curiosity that was aroused in them. Interestingly for this group, being overloaded was precisely the incentive to try to overcome a stressful job, but one important difference with the other group was that they were able to manage in order to allow the programme to suit their job positions well. Thus, expectations reflect a secondary dimension of adjustment that should be considered in the first phases of implementation (e.g., informative talks), with a possible influence on the adjustment of the WA-MBP-LS programme, which, in turn, is a core dimension that requires specific work from the human resources department. Table 6 shows the theoretical definitions for these two dimensions of the qualitative model.

Table 6. Theoretical definitions for the dimensions of the qualitative model.

Dimensions	Importance	Definitions
Adjustment	Core	Specific job-related aspects of the WA-MBP-LS implementation, such as the moment of delivery, possible workload peaks, the need for reinforcement staff, being able to choose between different practice shifts, using company facilities inside and outside of working hours, and the availability of audio materials to allow a flexible and adaptable individual practice.
Expectations	Secondary	Sub-dimension of adjustment that reflects individual preferences regarding the WA-MBP-LS programme, from general disinterest to curiosity regarding mindfulness practices and study results.

Note: WA-MBP-LS: Workplace-adapted mindfulness-based programme for the logistics sector.

4. Discussion

The purpose of this study was to evaluate the feasibility of delivering the WA-MBP-LS and its potential effectiveness in reducing perceived stress in employees of a for-profit, privately-owned logistics company, i.e., a context in which high levels of stress are generally experienced with high impacts on health [8,10]. Most of the experimental evidence on mindfulness programmes has been

generated within the context of basic research with nonworkplace samples or with public sector employees, such as healthcare providers and teachers, raising generalizability questions and doubts that need to be addressed [36–38]. To overcome this, we adapted a mindfulness-based programme to the specified target population and context of application, i.e., for employees of a private sector logistics company, with the intention of evaluating the practicalities that can facilitate the refinement of various aspects of MBP implementation, and also to assess the preliminary effectiveness of such a reduced MBP through direct experience, before moving to a more comprehensive, fully powered investigation.

We first observed that within the imposed study conditions, the employee volunteers were not willing to be randomised between groups; they preferred to choose to join a group instead of being randomly assigned to the intervention or the control groups, and thus, their expectations may have determined the study findings in part. This aspect does not emerge explicitly in noncontrolled trials, but it needs to be considered in terms of whether more robust studies should be conducted [81,82]. In fact, the results of our qualitative analyses suggested negative expectations in the form of disinterest and, more particularly, through ideas of lack of usefulness of mindfulness programmes, which may have been an important barrier that negatively influenced the implementation processes. Other important reasons for participants' unwillingness to be randomised were because of added pressure to the worker on the job, for instance by the lack of a possibility to temporarily choose or change the time of the course in relation to peaks of greater workload, and also of having to leave the job uncovered by another person. In short, the possibility of adequately managing one's workload during the particular intervention programme was an aspect that could cause differences in the willingness to participate actively, i.e., precisely those workers who were most in need of the intervention could have more difficulties in accessing the programme; this should be given special consideration [83]. Interestingly, the control group was composed of employee volunteers who were significantly younger, and therefore, holding a less secure position in the structure of the company, and had previously had more practical mindfulness experience, and thus, perhaps had 'nothing new to learn' from the programme.

Initial interest in participation suggested that it might be very feasible to deliver the WA-MBP-LS to employee volunteers in the workplace context under study. However, only about 36% of potential volunteers completed the baseline assessment, which signifies a limited reach. Reasons for not completing the baseline assessment and not being involved with the programme could be related to the aforementioned barriers of a perceived lack of usefulness and added pressure. Although the response rate to questionnaires was very high at posttreatment, it was approximately 55% at the six-month follow-up, which was less than expected for MBPs in other settings [30,64], suggesting possible extra difficulties in this specific context of application. One possible strategy to increase interest and compliance, thereby reducing attrition, might be to offer an individualised personal feedback report to participants after completing the study, in addition to the anonymised group report that is usually presented to employers [81]. Moreover, the use of face-to-face measurements by employing an independent assessor to collect self-report data instead of the online procedure may also be more productive in this regard. These procedures might increase the importance and centrality of the research for participants, thereby facilitating recruitment and retention. Furthermore, the use of stepped-wedge designs, in which clusters of subjects are randomly selected to receive the intervention after a period in which no subjects are exposed to the programme, could be especially adaptable to the needs of the workplace of a for-profit, privately-owned company in the logistics sector, facilitating recruitment and the collection of more complete and richer data, and more particularly, reconciling the need to attend mindfulness sessions and evaluations with idiosyncratic workplace constraints [84–87].

We observed that the mean number of training sessions and daily practice sessions attended were 4.3 and 8.4, respectively, which could be considered appropriate acceptability values, although there might be some room for improvement [64]. Improvements in acceptability could be achieved, for instance, by implementing a virtual community of support through a WhatsApp group administered by the WA-MBP-LS teacher, who could be entrusted with the task of offering daily reminders to complete the practice along with motivating messages [88]. In general, MBPs suffer from

high rates of attrition [30,64], and failure to consolidate practice may undermine the benefits related to the intervention [89,90]. It has been observed that an individual's exposure to the programme might facilitate acceptability [91]. This suggests that introducing a small practice session during the presentation of the programme might improve expectations, facilitating curiosity and also initial interest, and in turn, recruitment. This could also be important in order to improve follow-up rates, which might be possible by increasing acceptability through adherence to practice. According to our results, a well-suited programme might be achieved by facilitators such as good timing of the programme, the use of company facilities both inside and outside of working hours, even with different shifts, and the promotion of a variety of materials, e.g., audio recordings for individual use.

We found that employee volunteers who participated in the WA-MBP-LS experienced moderate reductions in perceived stress after receiving the intervention, compared to controls who attended a brief psycho-educational seminar, with six-month sustainability and large effects at follow-up. We also observed that the WA-MBP-LS might have a potential clinical relevance to reduce perceived stress at the six-month follow-up in the WA-MBP-LS intervention group when compared to controls. These preliminary findings are in line with previous research on the general impact of MBPs among treated participants in comparison with waiting list controls [30], and they are also similar to other workplace MBPs regarding reductions obtained in perceived stress [38]. In addition, we also observed that the WA-MBP-LS might contribute to improving other outcomes, such as general mental well-being, with large ESs, and job satisfaction, with moderate ESs. Considering the level of practice reached by participants, this supports the idea of a 'parsimonious intervention', in the sense that it may be beneficial at a minimum dose for different psychological outcomes, improving distinct aspects of the general psychological functioning of workers [36]. In addition, the level of participation in the programme was significantly and linearly related to gains in mindfulness, perceived stress and overall mental well-being. Gains in mindfulness seemed to be a mechanism of change for improvements in perceived stress and overall mental well-being. This reinforces the theoretical assumptions that explain the efficacy of this type of training to enhance psychological adjustment by means of self-regulation of attention and acceptance processes [31,44,46]. Nevertheless, the influence of the level of participation and the possible mediating role of mindfulness on job satisfaction issues was not entirely clear, and further research is needed using more powerful designs to detect possible lower effects.

MBPs are increasingly being implemented in work settings [40]. However, they are usually truncated versions of standardised programmes that are adapted to the specific features of each context of application, which is why research on optimal designs are important in the search for maximum efficacy and sustainability [41–43]. In terms of mindfulness as a trait, we observed large improvements in the WA-MBP-LS participants compared to controls at posttest but moderately low effects at the six-month follow-up. The latter result was due to unexpected improvements in trait mindfulness in the control group at follow-up, and we believe these improvements might be a consequence of the informative talk they received in the seminar and of the external practice of mindfulness exercises by some of these control subjects outside of the workplace programme between posttest and follow-up. It seems some interest in mindfulness practices could be activated as a consequence of the talk the control group received, and possibly by sharing experiences with the WA-MBP-LS participants. Here, again, the use of stepped-wedge designs, in which all the subjects are eventually treated, could help to understand this result and manage this situation, alleviating possible ethical concerns derived from not being completely treated, and further favouring greater sustainability of the programme [84–86]. In general, we observed that the minimum dose of treatment required to obtain positive changes in mindfulness as a trait seemed to be achieved during the intervention. Nevertheless, we also observed possible moderating effects of sex, age and weekly working hours. Although underpowered to analyse this, our results suggest that women and younger participants could be benefiting less from the WA-MBP-LS in terms of stress reduction. The possible causes of this, e.g., structural issues, require further research. We have also observed that those participants with longer working hours could be improving well-being to a lesser extent than those with shorter hours. This might indicate that positive outcomes are harder to improve on under this condition, but it needs to be confirmed and explained with more detail in future research. Only

very recently have studies examined the implementation of MBIs in health [92] and education [93]. These studies have used an established theoretical framework to map the key contextual and facilitating factors that support implementation, with some overlap (e.g., the importance of “champions”) and some differences (e.g., importance of clinical guidelines in health and “perceptions of mindfulness” in education). Future research could use our results and that explanatory framework to better understand how to effectively implement an MBP in workplace contexts.

Limitations and Strengths

As we have stated previously, further research is needed involving more powerful and higher-quality designs in order to provide a more precise idea of the possibilities of the WA-MBP-LS and its potential role in extending the observed improvements to other organizational and work life areas. Firstly, participants who did not complete the baseline assessment might differ from those who did, and this could involve generalizability issues. Moreover, even considering the impossibility of enrolling participants based on randomization principles, this remains as a limitation of the present study. Other limitations of this study include the use of a small set of self-report questionnaires, with special emphasis on overall measures of perceived stress and mental well-being, and not accounting for other additional and more specific work-related variables such as job performance, organizational climate and culture, burnout, absenteeism and presenteeism. This limitation must be given specific consideration in future research to offer a deeper understanding of the possible impact of the WA-MBP-LS on workers in for-profit privately owned companies in the logistics sector [81]. In general, addressing more complex designs, ensuring intervention integrity [90], and promoting a more flexible training through other modes of delivery, including mobile applications or online platforms that could reinforce individual levels of practice, would be desirable [88,94]. Finally, a cost-effectiveness analysis of the WA-MBP-LS would provide an additional economic perspective on feasibility. The main strengths of the study were the collection of long-term follow-up data, which is important in order to evaluate the sustainability of effects and possible mechanisms of change, as well as the integration of the programme within working hours, facilitating participation. Another strength was the use of qualitative methods to understand the implementation processes from the perspectives of the actual participants.

5. Conclusions

In general, our results suggest that the WA-MBP-LS could be feasible when applied to for-profit, private sector logistics companies, but that it should be amended to optimise the procedure in order to achieve greater rates of recruitment and retention. The WA-MBP-LS seemed to be acceptable in this professional context, although there may be room for improving compliance. The application of WA-MBP-LS was related to reductions in perceived stress and improvements in mental well-being and job satisfaction, but it is not yet clear to what extent this programme could improve other work-specific outcomes, and further studies using randomised controlled trials are needed to investigate whether changes found can be directly attributed to the WA-MBP-LS. All in all, our data reflect the procedure of only one pilot study, but the findings may serve as a template for more complex and powerful future designs to test other intervention formats, intensities, outcomes, etc., considering the necessary adaptations to suit different professions in order to gain flexibility when applying the programme.

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Attachment-Based Compassion Therapy for Ameliorating Fibromyalgia: Mediating Role of Mindfulness and Self-Compassion

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Abstract

Objectives The aim of this study was to evaluate the efficacy of Attachment-Based Compassion Therapy (ABCT)—a standardised programme that includes practices to improve compassionate awareness with the aim of addressing maladaptive attachment—for improving mindfulness and self-compassion in fibromyalgia (FM) patients, and to determine whether gains in mindfulness and self-compassion mediate improvements in FM functional status together with comorbid anxiety and depression.

Methods The study comprised a randomised controlled trial of individuals undergoing ABCT, with a Relaxation condition as an active control group. Baseline, post-test, and 3-month follow-up assessments were included. Participants ($n = 42$) were FM patients randomly assigned to ABCT or relaxation. Outcomes were functional status (FIQ), anxiety (HADS-A), depression (HADS-D), mindfulness (FFMQ), and self-compassion (SCS). Differences between groups were estimated using mixed-effects regression models, and mediation analyses were conducted using path analyses.

Results Compared with the Relaxation condition, the ABCT group was more effective for improving mindfulness and self-compassion, as it observed through changes in the FFMQ and SCS subscales. Effect sizes were in the moderately large to large range (Cohen's d between 0.60–2.20). Reductions in FM functional status were not mediated by either mindfulness or self-compassion. However, the self-compassion facet of common humanity was a mediator for reductions in both anxiety ($B = -2.04$; bootstrapped 95% CI = $-4.44, -0.04$) and depression ($B = -2.12$; bootstrapped 95% CI = $-4.40, -0.45$).

Conclusions The improvement of common humanity via ABCT might be an active component for the reduction of comorbid anxiety and depression in FM patients.

Trial registration NCT02454244

Keywords ABCT · Fibromyalgia · Anxiety · Depression · Mindfulness · Self-compassion

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Fibromyalgia (FM) syndrome is a chronic and debilitating rheumatic disease of unknown and complex aetiology. It is characterised by widespread pain and other physical and/or psychological symptoms such as fatigue, disturbed sleep, cognitive problems, and psychological distress. FM shows a high degree of comorbidity with psychiatric disorders such as anxiety and depression (Fietta et al. 2007; Vincent et al. 2015; Wolfe et al. 2010). In fact, the symptoms of FM are non-specific and overlap with many other disorders, causing challenges in terms of diagnosis and treatment (Kumbhare et al. 2018). Middle-aged women appear to be at highest risk for FM (Gran 2003), which has an estimated global prevalence of 2.7% (2.9% in European populations). FM is considered to be the most common cause of generalised musculoskeletal pain in women aged 20–55 years, with a female/male ratio of 3:1 (Branco et al. 2010; Cabo-Meseguer et al. 2017; Queiroz 2013). FM substantially impacts on

healthcare resources and work productivity owing to both direct (medical visits, prescription of medications, etc.) and indirect (absenteeism, work loss, etc.) burdening factors (Chandran et al. 2012; Schaefer et al. 2011). Furthermore, FM results in high rates of unemployment, sick leave, and disability, as well as a high volume of disability benefit claims (Leadley et al. 2012).

A number of studies have highlighted the role of the Central Nervous System in the pathogenesis of FM (Cagnie et al. 2014). Specifically, altered pain pathways, involving low-grade baseline chronic neuro-inflammation processes with stress peptides, are thought to trigger the release of neuro-sensitising mediators (Theoharides et al. 2015). In the absence of a single gold-standard treatment, some guidelines propose first-line pharmacological treatments for FM using antidepressants such as amitriptyline, duloxetine, or milnacipran (Häuser et al. 2008; Kia and Choy 2017; Macfarlane et al. 2017). However, the benefits of pharmacotherapy are of questionable clinical relevance as only a minority of patients report lasting benefits, and many of them discontinue pharmacotherapy due to intolerability (Häuser et al. 2014; Nüesch et al. 2013).

Consequently, multimodal approaches, including patient education, psychotherapy, physical exercise, and pain management, have been recommended (García-Campayo et al. 2008; Thieme et al. 2017). Cognitive behavioural therapy (CBT), which includes psycho-education as well as cognitive and behavioural components, has shown promising results in improving coping with pain, depressed symptoms, fear of activity, and healthcare-seeking behaviours (Hassett & Gevirtz, 2009; Nüesch et al. 2013). However, CBT has demonstrated limited benefits as a stand-alone modality, with neither clear nor maintainable effects on the core symptoms of FM (Bennett & Nelson, 2006; Bernardy et al. 2018; Hassett & Gevirtz, 2009). A “third wave” CBT approach known as acceptance and commitment therapy (ACT; Hayes et al. 2006) has shown some improvements in pain catastrophising, acceptance, anxiety, depression, well-being, and quality of life in FM patients (Luciano et al. 2014a). Furthermore, the ACT approach has demonstrated greater cost-effectiveness compared with pharmacological options (Luciano et al. 2017). However, ACT has not shown clear benefits when using strict criteria for FM treatment response (Luciano et al. 2014b). Other interventions, based on stress reduction exercises or complementary and alternative medicine—such as tai-chi, qigong, dance/movement therapy, balneotherapy, massage, dietary therapy or guided imagery—have been reported to improve symptoms, as they include components that might act as anti-inflammatory treatments (Sanada et al. 2015; Sosa-Reina et al. 2017). However, while even a low-intensity of such therapeutic approaches has been shown to improve FM symptoms (i.e. particularly those related to stretching and relaxing aerobic exercises), many of these studies have not sought to rule out potential confounding factors by comparing outcomes against a suitable active control condition (Meeus et al. 2015; Mist et al. 2013; Sanada et al. 2015; Sawynok and Lynch 2014).

Mindfulness-based programs (MBPs) have recently been proposed as a promising therapeutic approach for the treatment of FM patients, due to the demonstrable effect of certain MBPs on pain intensity, physical well-being, anxiety, depression, sleep quality, and quality of life (Amutio et al. 2018; Cash et al. 2015; Lauche et al. 2013; Van Gordon et al. 2017; Veehof et al. 2016). Nevertheless, despite the fact that some of the spiritual components of MBP training could facilitate reductions in FM core symptomatology (Van Gordon et al. 2016, 2017), there is insufficient evidence to support the use of MBPs to treat FM as a monotherapy (Langhorst et al. 2012). Indeed, recommendations on the use of MBPs for FM typically advocate their use with additional behavioural approaches (Veehof et al. 2016). It is in this context that a new protocol named “attachment-based compassion therapy” (ABCT)—based on mindfulness but also including compassion practices—has recently been developed (García-Campayo et al. 2016). ABCT comprises 8 sessions, each of a 2-h duration, and focuses on regulating attention processes in order to replace self-critical tendencies with self-compassionate attitudes via the development of a more secure attachment figure (Navarro-Gil et al. 2018). ABCT combined with treatment as usual (TAU) has demonstrated superior outcomes with clinical relevance in FM functional status and comorbid anxiety and depression, and it has also shown significant improvements in the clinical severity and quality of life of FM patients, compared with a suitable active control condition treated with relaxation therapy plus TAU (Montero-Marin et al. 2018). However, while ABCT may reflect a promising combination of both mindfulness- and self-compassion-based psychotherapeutic agents, it currently remains unclear which specific mindfulness and compassion components could be active ingredients of ABCT when treating FM patients.

The present study extends the recent findings of Montero-Marin et al. (2018) and seeks to investigate the possible mediating role of mindfulness and self-compassion components in the treatment of FM and its comorbid anxiety and depressive symptoms when using ABCT. In this context, the general exploratory hypotheses are that ABCT plus TAU will improve the levels of the mindfulness and self-compassion components to a greater extent than relaxation therapy plus TAU, and that the mindfulness and self-compassion components will play a mediating role on FM functional status and its comorbid anxiety and depression.

Method

Participants

A total of 42 participants were randomised to ABCT ($n = 23$) or Relaxation therapy ($n = 19$), and were assessed at baseline. In the ABCT group, 20 participants completed assessments at post-test and 20 participants completed assessments at follow-

up, and thus, 3 participants had missing data in the ABCT group. In the Relaxation group, 16 participants completed assessments at post-test and 15 participants completed assessments at follow-up, and thus, 4 participants had missing data in the Relaxation group. Finally, 35 patients (ABCT: $n = 20$; Relaxation: $n = 15$), who completed all of the assessment surveys (i.e. participants with no missing data), were included in the present study. The socio-demographic characteristics of participants are shown in Table 1. All participants were female, in their early fifties ($Mean = 51.68$; $SD = 7.47$), mostly married or in a stable relationship (80.0%), and a homeowner (94.2%) residing in an urban area (88.5%). There was a roughly equal distribution of participants who had completed primary (31.4%), secondary (42.9%) and university (25.7%) education, and they were mostly on sick leave or qualified as permanently disabled (45.7%). No significant differences between groups were found in relation to socio-demographic data, visits to mental health services during the previous year ($median = 2$, $Q_1-Q_3 = 0-10$), or in taking medication to treat FM symptomatology during the previous year (88.6%). No significant differences were also found between groups in

the specific categories of medication consumed to treat FM symptomatology during the previous year (Table 1).

Procedure

The primary data referred to in this paper was collected as part of a pilot randomised controlled trial published elsewhere (Montero-Marin et al. 2018) examining the efficacy of ABCT in the treatment of FM (Trial Registration: NCT02454244). Through two arms (ABCT vs Relaxation) and pre-, post-, and 3-month follow-up assessments, this study explores the possible influence of the ABCT programme on the improvement and possible mediating role of different mindfulness and self-compassion components in the treatment of FM-related symptoms. Findings from a third treatment arm outlined in the protocol NCT02454244, that received mindfulness plus amygdala retraining, are to be reported elsewhere.

FM patients were recruited from primary healthcare centres in January–March 2015. General practitioners were entrusted with the task of identifying potential participants, who were interviewed at their corresponding centre by an independent

Table 1 Socio-demographic characteristics of participants at baseline

Socio-demographic	Total ($n = 35$)	ABCT ($n = 20$)	Relaxation ($n = 15$)	test	p
Age, Mean (SD)	51.68 (7.47)	51.80 (8.42)	53.60 (5.08)	$t(32) = 0.78^*$.439
Sex female, n (%)	35 (100)	20 (100)	15 (100)	(a)	1.00
Married/stable relationship, n (%)	28 (80.0)	17 (85.0)	11 (73.3)	(a)	.672
Dwelling, homeowner, n (%)	33 (94.2)	19 (95.0)	14 (93.3)	(a)	1.00
Urban residence, n (%)	31 (88.5)	16 (80.0)	15 (100)	(a)	.119
Education, n (%)					
Primary	11 (31.4)	9 (45.0)	2 (13.3)	(a)	.128
Secondary	15 (42.9)	7 (35.0)	8 (53.3)		
University	9 (25.7)	4 (20.0)	5 (33.3)		
Employed, n (%)					
Looking after family/home	10 (28.6)	7 (35.0)	3 (20.0)	(a)	.298
Employed	5 (14.3)	1 (5.0)	4 (26.6)		
Sick leave/disabled	16 (45.7)	9 (45.0)	7 (46.7)		
Unemployed	4 (11.4)	3 (15.0)	1 (6.7)		
Visits to MHS (last year), Median (Q_1-Q_3)	2 (0–10)	2 (0–13)	1 (0–4)	$Z = -0.81$.438
On medication (last year), n (%)	31 (88.6)	19 (95.0)	12 (80.0)	(a)	.292
Type of medication (last year), n (%)					
Analgesics [‡]	10 (28.6)	6 (30.0)	4 (26.7)	(a)	.999
NSAIDs	11 (31.4)	8 (40.0)	3 (20.0)	(a)	.281
Anxiolytics	12 (34.3)	5 (25.0)	7 (46.7)	$Z = 0.95$.330
Opiates	12 (34.3)	9 (45.0)	3 (20.5)	(a)	.163
Antidepressants	19 (54.3)	11 (55.0)	8 (53.3)	$Z = 0.06$.807
Hypnotics	4 (11.4)	4 (20.0)	0 (0.0)	(a)	.119
Anticonvulsants	10 (28.6)	7 (35.0)	3 (20.0)	(a)	.458

*No equal variances were assumed. ^a Fisher probability test. Data are presented as means (SD), medians (Q_1-Q_3), or n (%). ABCT, attachment-based compassion therapy; Relaxation, relaxation group; MHS, mental health services. [‡] Painkillers in a broad sense, including triptans or anti-migraine drugs (e.g. Paracetamol, Metamizole, Sumatriptan, Rizatriptan)

researcher until the required sample size was achieved. Patients who met the inclusion/exclusion criteria (Montero-Marin et al. 2018) and gave their written informed consent before the baseline assessment were included in the study. Randomisation occurred in April 2015. The corresponding interventions were delivered from May to October 2015. The participant flowchart of the study can be seen in detail elsewhere (Montero-Marin et al. 2018).

Sample size estimation was based on an expected difference in FM functional status (Fibromyalgia Impact Questionnaire—FIQ) of at least 20%, representing a clinically relevant criterion (Bennett 2005; Dworkin et al. 2009) that could be translated to an FIQ mean difference between groups of 15 points in the population of reference (García-Campayo et al. 2010). Using a 5% significance level and a statistical power of 80% in a two-tailed test, it was established that 18 participants were required per group. Nevertheless, this study includes post hoc mediation analyses not pre-specified in the initial protocol. Thus, we carried out a post hoc power analyses based on mediation with the 35 patients finally included in the study. It was estimated as the product of the tests of paths “a” and “b”, which has been shown to closely approximate the power of bootstrap estimates in several simulations (Fritz and MacKinnon 2007; Hayes and Scharkow 2013). This number of participants allowed us to identify indirect effects (“ab”) with a statistical power of .80, supposing the existence of large effects in both paths “a” and “b” of the mediating models, with a standardised value of .45 each, and with intermediate effects in the path “c” (direct effects controlling for the indirect effects), with a value of .35, and thus considering a partial mediation scenario.

The study arms were combined with treatment as usual (TAU) offered by the Spanish National Health System (NHS) for FM patients. TAU is provided by the corresponding general practitioner, and consists of administering drugs for pain as well as antidepressants—this may also include pharmacological treatments for insomnia and fatigue, and even non-pharmacological rehabilitation techniques, although psychological treatments are not usually provided (Montero-Marin et al. 2018).

Attachment-Based Compassion Therapy

ABCT includes a manualised compassion training programme (García-Campayo and Demarzo 2015), based on the completion of 8 weekly 2-h sessions that were specially adapted for FM patients (Montero-Marin et al. 2018). The ABCT programme specifically focuses on improving participants’ ability to show kindness towards themselves and others when facing experiences of suffering. The eight weekly sessions are focussed on 1. *Foundations for compassion* (e.g. includes practices such as mindfulness breathing and compassionate body scan); 2. *Self-esteem and compassion* (e.g. trying to

connect affectionately and compassionately with other beings); 3. *Developing my compassionate world* (e.g. replacing the critical voice with a more compassionate and tolerant one); 4. *Relationships and compassion* (e.g. awareness of our capacity to receive affection from others); 5. *Working on ourselves* (e.g. becoming aware of our own ability to show affection to others and also to ourselves); 6. *Advanced compassion I* (e.g. the importance of forgiveness towards oneself and others); 7. *Advanced compassion II* (e.g. envy and the suffering of others when managing difficult relationships); 8. *Transmitting compassion to others* (e.g. practices to develop equanimity and gratitude). A group format was employed and the programme was facilitated by a psychologist who was specifically trained in ABCT.

Relaxation Therapy (Relaxation)

Relaxation therapy formed a low-intensity and non-specific control condition consisting of 8 weekly 2-h sessions including different relaxation techniques (Montero-Marin et al. 2018), such as 1. *Visualisations I* (e.g. guided relaxation exercises through imagery); 2. *Visualisations II* (e.g. deepening guided relaxation through landscape visualisations); 3. *Visualisations III* (e.g. working with emotions through imagination); 4. *Autogenic relaxation I* (e.g. imagining a ball of light and heat to aid sensations of relaxation); 5. *Autogenic relaxation II* (e.g. working on body sweeping heaviness sensations); 6. *Progressive relaxation* (e.g. tensing and relaxing the muscles to focus awareness of different bodily sensations and foster relaxation); 7. *Breathing I* (e.g. using deep inhalation and exhalation to calm anxiety); 8. *Breathing II* (e.g. learning different breathing techniques based on pulmonary ventilation and cellular respiration). The therapist was a clinical psychologist specifically trained in relaxation techniques, and the intervention was likewise delivered in group format. For ethical reasons, at the end of the study and after completion of the follow-up assessment, only participants assigned to the relaxation therapy condition were also offered and could choose to receive either ABCT or MBP plus amygdala retraining—which reflects a novel mind-body approach that has demonstrated improvements in physical health, energy, pain, distress, and fatigue in FM patients (Toussaint et al. 2012).

Measures

A battery of paper-and-pencil questionnaires were administered at baseline (pre-treatment), 8 weeks after the treatment commenced (post-treatment), and 3-months after post-treatment (follow-up). The socio-demographic data collected included age, sex, marital status (married or in a stable relationship vs not married or in a stable relationship), dwelling (homeowner vs renter), place of residence (urban vs non-urban), education (primary, secondary, university), employment (looking after the family/home, employed, sick leave/

disabled, unemployed), number of visits to mental health services during last year, using FM medication during the previous year (yes or no), and if so which ones (analgesics, NSAIDs, anxiolytics, opiates, antidepressants, hypnotics, and anticonvulsants).

The Spanish version of the Fibromyalgia Impact Questionnaire (FIQ), which has demonstrated good psychometric characteristics, was used as a measure of the functional status of participants (Rivera and González 2004). It is a self-report questionnaire developed to capture a broad spectrum of problems and difficulties associated with FM that is considered as a primary efficacy end-point measure of responses to therapy. It comprises ten items with a total score ranging from 0 to 100, with higher scores indicating worse functional status. The first item is focused on patients' capacity to perform physical activities. The second and third items ask for the number of days in the previous week that respondents felt good and how many work days they missed. The remainder of the items use a visual analogue scale (VAS) answer format and refer to pain, fatigue, morning tiredness, stiffness, anxiety, depression, and ability to work.

The Spanish version of the Hospital Anxiety and Depression Scale (HADS) was used to quantify the severity of anxiety and depressive symptoms. It is a self-report questionnaire that includes 14 items that are rated on a 4-point Likert-type scale, with two independent subscales, anxiety (HADS-A, e.g. "I feel tense or wound up") and depression (HADS-D, e.g. "I feel as if I am slowed down"). Each subscale ranges from 0 to 21, with higher scores indicating more severe symptoms. This questionnaire is one of the established scales for evaluating anxiety and depressive symptoms in patients with chronic pain disorders. The Spanish version of the HADS demonstrated appropriate psychometric properties when administered to Spanish FM patients (Luciano et al. 2014a; Vallejo et al. 2012).

The Spanish version of the Five Facets of Mindfulness Questionnaire (FFMQ) was used to measure trait mindfulness (Aguado et al. 2015; Cebolla et al. 2012). The FFMQ consists of 39 items rated on a Likert-type scale, ranging between 1 and 5 points (from "1 = never or very rarely true" to "5 = very often or always true"). Items measure personal disposition towards being mindful in daily life situations by using the five facets of "observing" (e.g. "When I'm walking, I deliberately notice the sensations of my body moving"), "describing" (e.g. "I'm good at finding words to describe my feelings"), acting with "awareness" (e.g. "When I do things, my mind wanders off and I'm easily distracted"—item reversed), "non-judging" of inner experience (e.g. "I make judgments about whether my thoughts are good or bad"—item reversed), and "non-reactivity" to inner experience (e.g. "I perceive my feelings and emotions without having to react to them"). The Spanish version of the FFMQ has demonstrated good psychometric properties in several studies (Aguado et al. 2015; Cebolla et al. 2012).

The Spanish version of the Self-Compassion Scale (SCS) (García-Campayo et al. 2014) was used to measure the self-compassion facets of "self-kindness" (e.g., "I try to be loving towards myself when I'm feeling emotional pain"), "common humanity" (e.g. "I try to see my failures as part of the human condition"), and "mindfulness" (e.g. "When I'm feeling down, I tend to obsess and fixate on everything that is going wrong"—item reversed). The SCS consists of 26 items that assess how respondents perceive their actions towards themselves at times of difficulty. Items are rated on a Likert-type scale, ranging between 1 and 5 (from "almost never" to "almost always"). The SCS has shown adequate psychometric properties in its Spanish version and cross-culturally (García-Campayo et al. 2014; Neff et al. 2018; Neff et al. 2008).

Data Analyses

Means (standard deviations, *SDs*), medians (interquartile range, IQR), and frequencies (percentages) were used to describe the socio-demographic characteristics in the total group and across arms at baseline according to the distribution of each variable. The corresponding *t* test for continuous variables, Mann-Whitney *U* for ordinal data, and χ^2 for categorical variables (or Fisher exact probability test, when necessary), were used for comparisons between conditions.

The effect of ABCT compared with the Relaxation condition on FM general functioning (FIQ total scores), anxiety (HADS-A), and depression (HADS-D) symptoms, as well as on mindfulness (FFMQ subscales) and self-compassion (SCS subscales) facets at post-test and follow-up was evaluated—results on FIQ and HADS have been presented in a previous publication (Montero-Marin et al. 2018) but are subjected to further analysis here in order to evaluate the mediating role of mindfulness and compassion. Between-group analyses using linear mixed-effects models and restricted maximum likelihood regression (REML) were used to account for the correlation between repeated measures. REML produces less biased estimates of variance parameters than classical methods when using small sample sizes and/or unbalanced data (Egbewale et al. 2014). Descriptive statistics (means and *SDs*) and *B* regression coefficients (and their 95% CI) were calculated, as well as the corresponding effect size (ES) for each pairwise comparison, which were calculated using the pooled *SD* for mean differences of different groups (Morris 2008). An ES of $d = 0.20$ is considered small; $d = 0.50$ is considered medium; and $d = 0.80$ is considered large.

An evaluation was undertaken of whether the effects of treatment condition (ABCT vs Relaxation) on reductions in symptoms at 3-month follow-up (FIQ, HADS-A, and HADS-D) were mediated through gains in the mindfulness (FFMQ) and self-compassion (SCS) facets at post-treatment. This was achieved by examining the direct and indirect relationships between group condition (independent variable) and pre–

follow-up FIQ, HADS-A, and HADS-D (dependent variables), through FFMQ and SCS pre–post change scores in each facet (process measures). Possible relationships between pre–post change scores in the FFMQ and SCS facets with pre–follow-up change scores in FIQ, HADS-A, and HADS-D were evaluated using Pearson's r correlations. To test the indirect effect (*IE*) path between treatment condition and FIQ, HADS-A, and HADS-D at follow-up through the FFMQ and SCS pre–post differential scores, simple mediation analyses using each facet as independent mediators were conducted using maximum likelihood-based path analysis for continuous dependent variables with unstandardised estimates from linear regression coefficients. Regression coefficients (B) of bootstrapped *IEs* and their 95% CI based on 10,000 bootstrap samples were calculated. This estimation produces a test that can be applied to small samples to overcome possible problems of asymmetry in *IE* distribution. *IEs* are considered statistically significant when the 95% CI of the B regression coefficient does not include zero (Lockhart et al. 2011).

The overall α level was set at .05 using two-sided tests. No corrections for multiple measurements were made because of the exploratory nature of the study (Feise 2002). Analyses were carried out using the STATA statistical software for Windows, Version 12.0. College Station, TX: StataCorp LLC and the IBM SPSS statistical software for Windows, Version 19.0. Armonk, NY: IBM Corp packages.

Results

There were significant differences in FIQ, HADS-A, and HADS-D at post-test and at follow-up, with ABCT performing better than Relaxation in all the cases—for more details, please refer to the aforementioned previous publication (Montero-Marin et al. 2018).

As shown in Table 2, significant improvements were observed in ABCT compared with the Relaxation condition for all the mindfulness (FFMQ) and self-compassion (SCS) components, and they appeared significant at all time points—except for describing at post-test, which showed a trend—with moderate to large ESs, and ranging between $d = 0.60$ in the case of the mindfulness facet of observing at follow-up, and $d = 2.20$ for the self-compassion facet of common humanity at follow-up.

There were significant correlations between pre–follow-up decreases in FM functional status (FIQ) and pre–post increases in non-judging ($r = -.37$; $p = .029$), non-reactivity ($r = -.38$; $p = .023$), self-kindness ($r = -.35$; $p = .037$), and common humanity ($r = -.50$; $p = .002$). However, although with considerable ESs in general, there were no significant effects in observing ($r = -.17$; $p = .332$), describing ($r = -.22$; $p = .214$), awareness ($r = -.28$; $p = .101$), and mindfulness ($r = -.28$; $p = .103$). On the other hand, there were

significant correlations between pre–follow-up decreases in anxiety (HADS-A) and pre–post increases in awareness ($r = -.47$; $p = .004$), non-judging ($r = -.44$; $p = .008$), self-kindness ($r = -.40$; $p = .016$), common humanity ($r = -.56$; $p < .001$) and mindfulness ($r = -.40$; $p = .016$). However, the correlations were not significant for observing ($r = -.01$; $p = .970$), describing ($r = -.15$; $p = .390$) and non-reactivity ($r = -.22$; $p = .210$). Finally, there were also significant correlations between pre to follow-up decreases in depressive symptoms (HADS-D) and pre–post increases in describing ($r = -.45$; $p = .007$), awareness ($r = -.46$; $p = .006$), non-judging ($r = -.58$; $p < .001$), self-kindness ($r = -.63$; $p < .001$), common humanity ($r = -.60$; $p < .001$), and mindfulness ($r = -.46$; $p = .006$). However, the correlations were not significant for observing ($r = -.32$; $p = .062$) and non-reactivity ($r = -.26$; $p = .125$).

As shown in Table 3, the treatment condition did not indirectly influence the FM functional status (FIQ) change at follow-up through its effects on pre–post differential scores of mindfulness (FFMQ) and self-compassion (SCS). However, participants in the ABCT group exhibited higher pre–post gains in the SCS facet of mindfulness vs those in the Relaxation condition ($a = 1.22$; $p = .023$). These gains were not related to significant reductions in HADS-A at follow-up ($b = -0.61$; $p = .148$), but it should be noted that the bias-corrected bootstrap CI for the *IE* ($ab = -0.75$) was below zero (95% CI = -1.93 – 0.10). However, it was observed that group location influenced the change in HADS-A regardless of its effect on the SCS facet of mindfulness ($c' = -3.87$; $p = .006$). On the other hand, the ABCT group also exhibited higher pre–post improvements in the SCS facet of common humanity vs those in the Relaxation condition ($a = 2.11$; $p < .001$), and these improvements showed a trend predicting reductions at follow-up in HADS-A ($b = -0.96$; $p = .058$). The bias-corrected bootstrap CI for the *IE* ($ab = -2.04$) was entirely below zero (95% CI = -4.48 – 0.16), and there was no evidence that group location influenced the change in HADS-A regardless of its effect on the SCS facet of common humanity ($c' = -2.58$; $p = .112$). The percentage of the effect of the study condition on HADS-A mediated through common humanity was 44.2%, and thus the non-significant direct path between the study condition and HADS-A accounted for the remaining 55.8% of the effect.

The ABCT group showed a trend in the pre–post improvements of the FFMQ facet of describing vs those in the Relaxation condition ($a = 3.78$; $p = .092$). These improvements were related to significant decreases in HADS-D at follow-up ($b = -0.20$; $p = .035$). The bias-corrected bootstrap CI for the *IE* ($ab = -0.76$) was below zero (95% CI = -2.49 – 0.01), but group location influenced the change in HADS-D regardless of its effect on the FFMQ facet of describing ($c' = -4.36$; $p = .001$). The ABCT group also exhibited higher pre–post improvements in the SCS facet of mindfulness vs the

Table 2 Mindfulness and self-compassion between group mixed-effects analyses

Outcomes/time points	ABCT ^a (n = 20)	Relaxation ^a (n = 15)	B (95% CI)	d	Z	p
Mindfulness (FFMQ)						
Observing						
Baseline	28.75 (4.56)	29.40 (5.34)	ref.			
Post-treatment	29.20 (5.34)	26.80 (4.54)	3.05 (0.45–5.65)	0.62	2.30	.022
Follow-up	29.80 (5.03)	27.33 (4.61)	3.12 (0.52–5.72)	0.60	2.35	.019
Describing						
Baseline	25.55 (4.53)	25.40 (2.72)	ref.			
Post-treatment	31.25 (6.73)	27.33 (5.80)	3.77 (–0.22–7.76)	0.97	1.85	.064
Follow-up	32.40 (4.96)	27.60 (5.72)	4.65 (0.66–8.64)	1.19	2.28	.022
Awareness						
Baseline	18.65 (5.84)	21.73 (6.11)	ref.			
Post-treatment	30.65 (6.02)	24.33 (6.91)	9.40 (4.61–14.19)	1.57	3.85	< .001
Follow-up	32.75 (4.95)	23.67 (5.92)	12.17 (7.38–16.96)	2.03	4.98	< .001
Non-judging						
Baseline	21.60 (7.91)	22.80 (6.88)	ref.			
Post-treatment	30.70 (5.61)	23.27 (9.28)	8.63 (4.45–12.82)	1.14	4.04	< .001
Follow-up	31.70 (3.91)	24.13 (8.27)	8.77 (4.58–12.95)	1.16	4.11	< .001
Non-reactivity						
Baseline	19.20 (5.49)	20.73 (3.24)	ref.			
Post-treatment	25.10 (3.71)	20.13 (3.18)	6.50 (3.37–9.64)	1.38	4.06	< .001
Follow-up	24.40 (2.58)	19.93 (2.79)	6.00 (2.87–9.14)	1.27	3.75	< .001
Self-compassion (SCS) ^b						
Self-kindness						
Baseline	5.01 (1.47)	5.60 (1.73)	ref.			
Post-treatment	7.20 (1.15)	5.57 (1.80)	2.22 (1.15–3.28)	1.39	4.09	< .001
Follow-up	8.13 (0.87)	5.68 (1.71)	3.04 (1.98–4.10)	1.90	5.61	< .001
Common humanity						
Baseline	5.19 (1.75)	6.12 (1.56)	ref.			
Post-treatment	7.45 (0.93)	6.27 (1.38)	2.11 (1.09–3.13)	1.25	4.07	< .001
Follow-up	8.69 (0.91)	5.91 (1.70)	3.71 (2.69–4.73)	2.20	7.14	< .001
Mindfulness						
Baseline	5.43 (1.85)	5.52 (1.47)	ref.			
Post-treatment	6.48 (1.15)	5.35 (1.87)	1.22 (0.09–2.35)	0.71	2.11	.035
Follow-up	8.26 (1.20)	5.55 (1.79)	2.80 (1.68–3.93)	1.63	4.87	< .001

FFMQ, five facets of mindfulness questionnaire; SCS, self-compassion scale. ^a Descriptive values are presented as means and standard deviations (SDs). ^b SCS facet scores were calculated by summing the corresponding scores of the positive and negative factors that compose them (e.g. self-kindness + self-judgement reversed; common humanity + isolation reversed; mindfulness + over-identification reversed) and dividing for the number of factors to reach the mean value of each facet of self-compassion. B, regression coefficient; 95% CI, 95% confidence interval; Z, z value related to the regression coefficient; p, p value for mixed linear regression models; d, Cohen's d effect size measure; ABCT, attachment-based compassion therapy; Relaxation, relaxation therapy

Relaxation condition ($a = 1.22$; $p = .023$). These improvements showed a trend predicting reductions in HADS-D at follow-up ($b = -0.74$; $p = .072$). The bias-corrected bootstrap CI for the IE ($ab = -0.90$) was below zero (95% CI = -2.70 – -0.10), but group location influenced the change in HADS-D regardless of its effect on the SCS facet of mindfulness ($c' = -4.21$; $p = .002$). In addition, the ABCT group showed higher gains in the FFMQ facet of non-judging vs the Relaxation

condition ($a = 8.63$; $p < .001$), and these gains predicted the change in HADS-D ($b = -0.20$; $p = .038$). A bias-corrected bootstrap CI for the IE ($ab = -1.75$) was below zero (95% CI = -3.50 – -0.51), but group location influenced the change in HADS-D regardless of its effect on the FFMQ facet of non-judging ($c' = -3.36$; $p = .023$). The ABCT group also showed higher pre–post improvements in the SCS facet of self-kindness vs the Relaxation condition ($a = 2.22$; $p < .001$),

Table 3 Indirect effects of self-compassion and mindfulness facets in response to treatment on FM functional status, as well as reductions in anxiety and depression symptoms ($n = 35$)

Symptoms/mediators	<i>B</i>	Boot <i>SE</i>	Boot <i>LLCI</i>	Boot <i>ULCI</i>
Functional Status (FIQ)				
Observing	0.01	3.27	-6.45	7.03
Describing	1.29	3.36	-2.55	11.26
Awareness	0.79	6.26	-13.13	11.51
Non-judging	4.24	5.76	-9.12	14.04
Non-reactivity	5.06	4.65	-3.96	14.69
Self-kindness	3.77	5.07	-4.71	15.68
Common humanity	11.22	6.23	-2.20	22.24
Mindfulness	2.29	3.41	-3.12	10.94
Anxiety (HADS-A)				
Observing	0.62	0.59	-0.27	2.19
Describing	0.02	0.45	-0.82	1.13
Awareness	-1.17	0.76	-3.04	0.06
Non-judging	-0.93	1.04	-3.28	0.90
Non-reactivity	0.38	0.78	-0.75	2.38
Self-kindness	-0.71	1.15	-3.36	1.28
Common humanity	-2.04	1.11	-4.44	-0.04
Mindfulness	-0.75	0.45	-1.93	-0.10
Depression (HADS-D)				
Observing	-0.39	0.55	-2.04	0.29
Describing	-0.76	0.60	-2.49	-0.01
Awareness	-0.91	0.80	-2.77	0.50
Non-judging	-1.75	0.75	-3.50	-0.51
Non-reactivity	0.24	0.86	-1.12	2.47
Self-kindness	-2.07	0.87	-4.16	-0.72
Common humanity	-2.12	0.99	-4.40	-0.45
Mindfulness	-0.90	0.62	-2.70	-0.10

Unstandardised maximum likelihood-based linear regression parameters. *B*, regression coefficient for the mediation indirect effect ("a × b"); *Boot SE*, bootstrapped standard error; *Boot LLCI*, bootstrapped lower-level for 95% confidence interval; *Boot ULCI*, bootstrapped upper level for 95% confidence interval (calculations based on 10,000 bootstrap samples)

and these improvements predicted the change in HADS-D ($b = -0.93$; $p = .007$). A bias-corrected bootstrap CI for the *IE* ($ab = -2.07$) was below zero (95% CI = -4.16 – 0.72), but group location influenced the change in HADS-D regardless of its effect on the SCS facet of self-kindness ($c' = -3.05$; $p = .027$). Finally, the ABCT group showed higher pre-post improvements in the SCS facet of common humanity vs the Relaxation condition ($a = 2.11$; $p < .001$), and this improvement predicted the change in HADS-D ($b = -1.01$; $p = .043$). The bias-corrected bootstrap CI for the *IE* ($ab = -2.12$) was entirely below zero (95% CI = -4.40 – 0.45), and although there was a trend, there was no evidence that group location influenced the change in HADS-D regardless of its effect on the SCS facet of common humanity ($c' = -2.99$; $p = .060$). The percentage of the effect of the study condition

on HADS-D mediated through the SCS facet of common humanity was 41.5%, and thus, the non-significant direct path between the study condition and HADS-A accounted for the remaining 58.5% of the effect.

Discussion

This study analysed the influence of ABCT on improvements in mindfulness and self-compassion, as well as the possible mediating role of the mindfulness and self-compassion components when using this programme to treat FM symptoms and comorbid anxiety and depression. ABCT is a novel standardised protocol that encourages an individual to re-contextualise their life by acceptance of their circumstances, and by improving positive and compassionate engagement with specific aspects of their life. This is achieved through awareness and clarification of personal values in family, social relationships, work, and personal development (García-Campayo et al. 2016). A previous study showed that clinically-significant improvements in FM symptoms were significantly more frequent in the ABCT group plus TAU, compared with the active control group based on relaxation practices plus TAU (Montero-Marin et al. 2018). This study also observed that ABCT was more effective than relaxation for reducing anxiety and depressive symptoms, which means that ABCT might constitute an effective coadjutant psychological intervention to reduce FM symptoms, as well as anxiety and depressive comorbidities. Furthermore, ABCT appears to have specific advantages over relaxation therapy, a low-intensity intervention that has been shown to improve FM, but with no clear specificity and evidence (Häuser and Bernardy 2015; Meeus et al. 2015).

As expected, ABCT plus TAU produced significantly greater increases in the mindfulness and self-compassion measures, compared with relaxation therapy plus TAU, with moderately high to large ESs. This is understandable given that ABCT, besides working on re-contextualisation of attachment style to improve self-image and interpersonal relationships, also aims to introduce the cultivation of lasting compassionate awareness (García-Campayo et al. 2016). However, as observed in the current study, none of the mindfulness and self-compassion components were mediators of the improvement in FM functional status. The aforementioned study by Montero-Marin et al. (2018) established that changes in psychological flexibility, as a result of the application of ABCT, might partially mediate FM global health status gains, possibly by guiding action through a values-based activation. However, the same study acknowledged that the role of other mechanistically-active factors could not be ruled out. Other works have observed that classical MBPs, which are mainly focused on cultivating awareness to the present moment, are not clearly superior to other active control conditions for the

treatment of FM (Carlson 2012). Therefore, among the conglomerate of components and synergies included in the ABCT programme, ascertaining the specific elements responsible for the change to a more secure attachment style—among which improvements in self-compassion might be included—and how the referred change to a more secure attachment style might contribute to FM clinical gains, would require further research (Navarro-Gil et al. 2018).

Nevertheless, it was observed in the current study that pre-post improvements in the self-compassion facet of common humanity constituted a significant mediator between the study condition and reductions in comorbid anxiety and depression at follow-up, suggesting that this might constitute the most important mechanism—in terms of mindfulness and self-compassion skills—by which the cultivation of compassionate awareness via ABCT helps to reduce psychological distress in FM patients. However, it should be noted that the present study findings do not indicate a full mediation effect in this regard, and other possible mechanisms (e.g. self-compassionate mindfulness and self-kindness, and mindful describing and non-judging) might also be acting in parallel (Kenny et al. 1998; Sun and Zhang 2008). Common humanity is a psychological condition that enables acknowledgement of one's difficult experiences as part of the larger human experience, rather than seeing them as isolating and exclusive of oneself (Neff et al. 2018). It is embedded in a compassionate response to suffering and constitutes an orientation of mind that recognises the universality of suffering in human experience as well as the inevitable adversity that all human beings will meet at some point in their lives (Feldman and Kuyken 2011). Thus, a sense of common humanity might contribute to relieve the habitual “second layers” of suffering constituted by patterns of avoidance and judgement which magnify the impact of pain, triggering further psychological distress.

It has been suggested that common humanity is a predictive trait of lack of depressive symptomatology (Hall et al. 2013), is correlated with salutary health-related behaviours (Gedik 2018), and constitutes the most important buffer between negative life events and suicidal behaviours (Chang et al. 2017). Furthermore, common humanity has reported to contribute to DNA telomere maintenance, slowing down cell ageing processes (Alda et al. 2016). In short, common humanity could be an emotion regulation strategy in which painful or distressing experiences are no longer avoided but held with a sense of shared humanity, protecting against the feeling of being disabled (Hoge et al. 2013). The general ability to be self-compassionate seems to be shaped by early attachment and interpersonal experiences (Mackintosh et al. 2018; Peter and Gazelle 2017). In this sense, ABCT attempts to release the insecure attachment style knot during the course of therapy by facilitating the disengagement of self-centred judgmental and critical attitudes, which seem to underlie transdiagnostic psychopathological processes (Cuppige et al. 2018; García-Campayo et al. 2016; Montero-

Marín et al. 2016; Montero-Marín et al. 2018). A critical and harsh attitude towards oneself is a predictor of psychological distress symptoms (López et al. 2016), and it has been observed that depression and negative mood impair recovery from chronic pain and FM (Davis et al. 2014). The finding in the present study relating to the self-compassion facet of common humanity being a mediator of improvements in anxiety and depressive symptoms has important implications because low mood is one of the key symptoms that can worsen the pathological course of FM (Vincent et al. 2013).

Limitations and Future Research

Notwithstanding the above findings, the present study should be interpreted with caution in light of its limitations. For instance, the sample size was rather small, which determined a relatively low statistical power so that possible between-group differences in medication consumption during the previous year were not observed, and also only simple mediation analyses could be conducted to evaluate large effects. Thus, more powered interventions to detect—and if necessary control for—possible between-group differences in medication consumption, and to search for possible multiple mediation paths, sequentialities, and interactions of at least a moderate size, are needed. In this sense, future studies should investigate the possible mediating role of changes in attachment style (which were not measured in the present study) as possible facilitators of therapeutic gains linked from improvements in self-compassion (Navarro-Gil et al. 2018). Ideally, this should be researched across different subgroups of FM patients (Ablin et al. 2016; Yim et al. 2016) to ascertain whether they are influenced by the same mediators, sequentialities, and interactions. In addition, this study includes post hoc mediation analyses not pre-specified in the initial protocol that were not corrected for multiple statistical testing. Although this practice is generally accepted in the framework of the present exploratory and hypothesis generating research (Feise 2002), it supposes a situation that needs to be adequately managed in order to reach a reasonable interpretation of results (Perneger 1998). The need to balance both type I and type II errors, due to the fact that one cannot be decreased without inflating the other (Rothman 1990), means that reducing the type I error for null associations increases the type II error for those associations that are not null, and thus increases the likelihood of missing possibly relevant findings. Considering all of this in the context of our results, it is necessary to bear in mind that the impact of common humanity as a mediator of changes was relatively weak, and taking into account the number of statistical tests that were conducted, with mediation tests for each subscale, it might not have survived a correction for multiple comparisons. Thus, this is not definitive evidence but only a preliminary result that common humanity is a possible mediator, which needs to be confirmed in a new study with the

intention to test this pathway set out prospectively in a new sample that is adequately powered with adjusting for multiple testing. Finally, it should be noted that the highly evaluative nature of self-report measures of mindfulness and self-compassion may suppose a possible measurement bias that should be overcome in future research by introducing ecological models of how mindfulness and self-compassion work in daily life (Kaplan et al. 2018).

Despite all of these limitations, an important strength of the present study was the use of a suitable active control condition that comprised the same “therapeutic intensity” level as the intervention group, thus eluding possible placebo effects. Furthermore, the similar distribution of socio-demographic characteristics between groups did not require the introduction of statistical controls, which would have undermined statistical power even more. In summary, the ABCT intervention added to TAU contributed to gain mindful and self-compassion skills, and proved to be more effective than relaxation therapy added to TAU in the treatment of FM functional status and comorbid anxiety and depressive symptomatology. Further, the self-compassion component of common humanity appeared to be a relevant mediating active ingredient of treatment to reduce comorbid anxiety and depressive symptoms, although it remains unclear whether other variables—such as attachment style—might also exert a mechanistic role.

Author Contributions JMM designed the study, developed the data analyses, and wrote and edited the manuscript. WVG collaborated in the writing and editing of the final manuscript. ES collaborated in the writing and editing of the final manuscript. MNG designed and executed the study. VG executed the study. YLH collaborated in editing of the final manuscript. JVL collaborated in the writing of the final manuscript. JGC designed and conducted the study and collaborated in the writing of the final version of the manuscript. All authors approved the final version of the manuscript for submission.

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Data Availability In accordance with the International Committee of Medical Journal Editors (ICMJE), all of the individual anonymised and completely de-identified participant data are available with no end date and for any analytical purpose that is related to achieve aims in the present study upon reasonable request to researchers (i) who provide a methodologically sound proposal and (ii) whose proposed use of the data has been approved by an independent ethical review committee. The database is encrypted and password protected and is available at the Open Science Framework (osf.io/mzrx5). Passwords will be provided by the corresponding author to interested researchers that meet the aforementioned criteria.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval The study protocol was approved by the ethical review board of the regional health authority of Aragon (CEICA), Spain (reference number: PI15/0049; 01/04/2015). All procedures performed in this study involving human participants were in accordance with the ethical standards of the regional health authority of Aragon (CEICA), with the 1964 Helsinki Declaration and its later amendments and modifications or comparable ethical standards, and the Declaration of Madrid of the World Psychiatric Association and Uniform Requirements for Manuscripts Submitted to Bio-Medical Journals.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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