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ORIGINAL ARTICLE

Pain catastrophizing mediates rapid benefits of accessing in-person chiropractic care during the COVID-19 lockdown

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Abstract

Background: In March 2020, the COVID-19 pandemic forced the Spanish government to declare a state of emergency. A stringent lockdown was enforced, restricting access to healthcare services, including chiropractic. Reduced access to care provision in combination with psychological stress, social isolation and physical inactivity during the lockdown were shown to negatively influence pain conditions. However, data on strategies to mitigate the impact of the pandemic on these conditions are lacking.

Methods: Upon easing of restrictions in May 2020, 51 chiropractic clinics throughout Spain pseudo-randomly invited patients, recruiting a total of 385 participants. During a 14-day period, participants were exposed to in-person chiropractic care in either one ($n = 177$) or multiple encounters ($n = 109$) or to no care ($n = 99$). The effects of access to chiropractic care on patients' pain-related and psychological outcomes were assessed online through validated self-reported questionnaires before and after the period of care. Coprimary outcomes included pain intensity, pain interference and pain cognitions.

Results: When comparing to participants without access to care, pain intensity and interference were significantly decreased at follow-up, irrespective of the number of encounters. Kinesiophobia was also significantly reduced at follow-up, though only after multiple encounters. The relationship between fear of movement, changes in pain intensity and interference was mediated by catastrophizing.

Conclusion: Access to in-person chiropractic care may provide pain relief, associated with reductions in interference and pain cognitions. Prioritizing in-person care for patients with maladaptive pain cognitions may help dampen the detrimental consequences of the pandemic on physical and psychological well-being.

1 | INTRODUCTION

Shortly after the Coronavirus disease 2019 (COVID-19) was declared a pandemic by the World Health Organization (Mahase, 2020), the Spanish government imposed a state of national emergency and the country went into full lockdown (Spain Government, 2020b). Citizens remained confined to their homes except for essential business. Non-essential services were interrupted, limiting access to healthcare (Henriquez et al., 2020; Tanne et al.,

2020), with adverse consequences for patient management (Clauw et al., 2020; Lugli et al., 2020). Home confinement led to substantial decreases in physical activity and increases in sitting time (Ammar et al., 2020; Tison et al., 2020). Depression, anxiety and stress increased in over 25% of the population (Garcia-Alvarez et al., 2020; Ozamiz-Etxebarria et al., 2020; Rodriguez-Rey et al., 2020). Considering previous evidence on quarantine and sedentarism, the pandemic and policy changes to mitigate their impact can both be presumed to result in deleterious effects on mental and physical well-being (Brooks et al., 2020; Hall et al., 2020).

Direct and indirect effects of the pandemic are expected to result in higher morbidity of pain conditions (Thacker & Mansfield, 2020), disproportionately affecting chronic pain (Clauw et al., 2020). Pandemic-induced psychological stress and restricted access to healthcare services during the lockdown were linked to increased pain severity and interference, partially mediated by pain catastrophizing (Fallon et al., 2020; Hruschak et al., 2021; Nieto et al., 2020; Page et al., 2021). Previous data showed that pain cognitions, particularly catastrophizing, strongly influenced pain intensity, pain interference and their relationship (Hirsh et al., 2011). Catastrophizing itself is not only dependent on previous painful experiences but can also be influenced by environmental factors (Petrini & Arendt-Nielsen, 2020). During COVID-19, psychological distress, catastrophizing, sedentarism and social isolation may all contribute to swell the burden of pain (Alzahrani et al., 2019; Hammig, 2019; Joseph et al., 2020; Zhaoyang et al., 2020).

Nearly 12 million people in Spain suffer from spine pain (Cruz-Sánchez et al., 2012), the most frequent reason to pursue chiropractic care (Beliveau et al., 2017). Access to chiropractic services has been linked to positive clinical outcomes for spine-related conditions (Blanchette et al., 2016; Garner et al., 2007; Goertz et al., 2018; Prater et al., 2020). During the state of emergency in Spain, chiropractic services were not deemed essential and clinics were to remain shut (Asociacion Espanola de Quiropractica, 2020). Whilst the pandemic may further increase the burden of pain on already overwhelmed healthcare systems, data on how to effectively tackle this crisis are missing (Carrillo-de-la-Pena et al., 2021).

We aimed to investigate the effects of accessing in-person chiropractic care on pain and psychological outcomes upon easing lockdown measures. Specifically, we were interested in measuring pain intensity, interference and cognitions in patients without access to care during the lockdown, and the effect of accessing in-person services on these variables and their interaction. We hypothesized that accessing care would reduce pain intensity and interference by influencing pain cognitions and

psychological factors. Furthermore, we intended to identify which patients would benefit most from accessing care in this context.

2 | METHODS

2.1 | Ethical approval

A pragmatic controlled clinical trial was performed in the settings of 51 private chiropractic clinics from 16 of the 17 autonomous regions of Spain. Ethical approval was obtained from the Madrid College of Chiropractic Research Ethics Committee (reference 300420). The study followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines (except for the allocation process as randomization was not possible) and was registered in ClinicalTrials.gov with the trial ID: NTC04573361.

2.2 | Study setting

On 3 May 2020, the Spanish government announced the end of the most stringent phase of lockdown (Spain Government, 2020a), which would go on to last until 21st June. Some services were allowed to reopen under strict hygiene and safety measures including chiropractic clinics. In particular, the Spanish Chiropractic Association published a set of guidelines for their members to reopen, enforcing social distance, universal mask-wearing, temperature control, ventilation and sanitization of surfaces, tables, instruments and practitioners' hands. The trial was conducted between 4 May and 26 May 2020, during the initial phase of lockdown *de-escalation*, as referred to by the Spanish healthcare authorities. Not all chiropractic clinics were open during this early phase, depending on practitioner preference and clinic capacity. Personal protective equipment was scarce and adapting the clinic to new sanitary regulations required time and monetary investments, making reopening difficult or infeasible in some cases. This set the stage for two possible scenarios: one in which patients had access to care and another in which they did not.

2.3 | Patient recruitment

All chiropractors registered in the Spanish Chiropractic Association were invited via e-mail to participate in the recruitment process, and 51 private chiropractic clinics throughout Spain accepted. Participants were chiropractic patients from these clinics over 16 years of age, presenting with pain at the time of recruitment. Only active

patients at the time of the closure of chiropractic clinics in March were to be included. By doing this, we intentionally excluded new patients or patients who had not been under care for long periods of time before the pandemic. One of the reasons was to minimize the number of patients who perceived no need to resume care. As lockdown measures were being eased, clinics contacted regular patients to provide information on the status of the clinic reopening, and when possible for both sides, to schedule an appointment. Participant clinics were requested to generate a contact list and to pseudo-randomly invite one of every three patients contacted to participate in the study, independently of whether they would be scheduling an appointment or not. This was done to reduce a recruitment bias on behalf of the person contacting potential participants. Contacts were made via phone calls, e-mails or text messages by the chiropractor or the administrative staff.

Patients accepting to participate were provided with a link to access the initial online questionnaire that was to be completed during the first 7 days of the trial (4 May–11 May), always before any treatment was initiated (see Figure 1). Access to the initial questionnaire was closed on 11 May. Participants in the study were instructed to fill out a follow-up questionnaire 14 days after the date of completion of their initial response. Access was secured until the end of the study (18 May–26 May) and a total of 500 responses were received. After removal of duplicates, non-paired and non-valid responses, participants receiving chiropractic teleconsultations or answering incorrectly all three screening questions, 385 patients were included (see Figure S1 for a patient inclusion and participation flowchart). A description of all demographic data is available in Table 1.

An a priori power analysis was conducted using G*Power for between–within interactions in ANOVA (Faul et al., 2007). The parameters for this analysis were an alpha of 0.05, a power of 0.95, a conservative estimate of the correlation amongst repeated measures of $r = 0$, for three groups, two measurements and an effect size of $f = 0.268$, based on pain intensity data reported in a pragmatic trial of chiropractic spinal manipulation for low back pain (Goertz et al., 2013). The analysis yielded a required sample of at least 111 participants, 37 participants in each group to reach statistical significance. Thus, our sample size of 385 largely exceeded this threshold.

2.4 | Study protocol

The present study is a pragmatic controlled clinical trial in which chiropractic patients were contacted by their clinic and were invited to participate in a pseudo-random order (one of every three patients contacted was invited, independently of future treatment). Therapists remained blinded to which patients eventually took part or did not, and investigators were blinded to participant recruitment and treatment received. During the 14 days following completion of the initial self-administered online questionnaire, patients participating in the study either resumed care with one (Group 1) or more than one visit (Group 2) to their chiropractor or else did not have access to care (Group 0). This assigned patients to one of three groups, depending on the opening times and availability of each clinic and the individual patient. The follow-up questionnaire was completed 14 days later, determining the end of the trial period (see Figure 1).
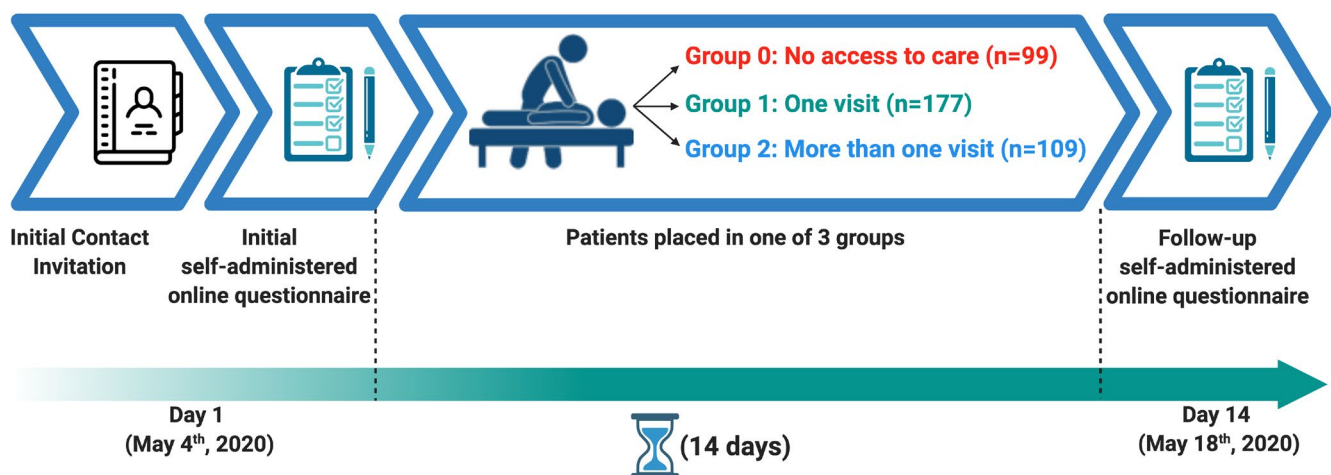

FIGURE 1 Trial protocol. Schema of the study protocol. Participants received the link to participate in the initial and follow-up questionnaires on their phone or via e-mail. Subsequently, according to the care received, they would be placed in one of the three groups. A flowchart based on the CONSORT recommendations is available in supplemental material

TABLE 1 Demographic characteristics of participants in the study

Characteristics	Whole sample (*n* = 385)	Experimental groups			*p* value
		Group 0 (*n* = 99)	Group 1 (*n* = 177)	Group 2 (*n* = 109)	
Demographics					
Mean (SD) age years	48.4 (12.4)	50.6 (13.8)	48.2 (11.8)	46.5 (11.8)	0.06[a]
Female gender (%)	272 (71)	70 (71)	114 (64)	88 (81)	*0.01*
Married (%)	210 (55)	55 (56)	99 (56)	56 (51)	0.73
Higher education (%)	231 (60)	59 (59)	112 (63)	60 (55)	0.38
Changes in employment status during the pandemic: *n* (%)					
Essential worker or volunteer	92 (25)	21 (21)	45 (25)	26 (24)	0.73
Working from home	107 (27)	24 (24)	53 (30)	30 (28)	0.60
Temporarily/permanently unemployed	79 (21)	14 (14)	35 (20)	30 (28)	0.06
No changes (retiree, student, sick-leave)	105 (26)	39 (39)	44 (25)	22 (20)	*0.005*
Impact of COVID-19 pandemic and restrictions: *n* (%)					
Diagnosed with COVID-19 (Yes)	12 (3)	4 (4)	3 (2)	3 (3)	0.50
Household diagnosed with COVID-19 (Yes)	20 (5)	5 (5)	13 (7)	5 (5)	0.57
Contact with COVID-19 diagnosis (Yes)	32 (8)	8 (8)	17 (10)	11 (10)	0.87
Consulted with a HCP during restrictions (Yes)	102 (26)	22 (22)	45 (25)	35 (32)	0.25
Would visit a chiropractor during restrictions if service available (Yes)	343 (89)	76 (77)	164 (93)	103 (95)	*<0.001*

Note: Data are absolute values and percentages, except for age, which shows the mean and standard deviation (SD).

p values are calculated using the Chi-square test except for the age[a], for which a one-way ANOVA was used. Numbers in italic represent significant *p* values.

Abbreviation: HCP, healthcare professional.

2.5 | Hands-on chiropractic care

Registered chiropractors, who were not aware of the study hypotheses and group allocation, provided routine care based on individual patient needs. Chiropractic is a type of conservative spine care, which consists mainly of the application of manual therapy (Nelson et al., 2005). Nearly four out of five chiropractic patients receive spinal manipulation, while soft tissue therapy, patient education and exercise therapy are less frequently part of care (Beliveau et al., 2017). The most common reasons for seeking chiropractic care are low back pain, neck pain and extremity complaints (Beliveau et al., 2017). In accordance with previous reports, clinics participating in the current trial provided in-person care primarily based on spinal manipulation (100% of patients), followed by patient education and exercise prescription. For details on the frequency of use of different interventions, see Table 2.

2.6 | Patient-reported outcome measures

Both the initial and follow-up questionnaires were designed and completed online using Google Forms (Google Inc.). The link to access the initial questionnaire was provided by the chiropractic clinics, whereas the link for

TABLE 2 Interventions used by chiropractors participating in the study

Type of intervention	% of patients receiving intervention
Chiropractic spinal manipulation	100%
Patient education, advice, reassurance	98.4 ± 3.7%
Prescription of therapeutic exercise	65.5 ± 31.6%
Myofascial techniques	44.8 ± 32.0%
Physical modalities (heat, ice...)	25.9 ± 34.5%
Nutritional advice	24.1 ± 30.1%

Note: Data are mean percentages and standard deviations (SD).

the follow-up questionnaires was provided either by the clinical staff or by one of two investigators not involved in data analysis (AOdM and FMC-B) for patients who had provided contact information. When planning the study, two representatives of the national chiropractic patient association (Asociación Española de Usuarios de Quiropráctica: http://www.aeuq.es/) provided feedback on the format and length of the questionnaires as well as on the adequacy of the outcome measures used. The questionnaires comprised three sections with the following data: demographics (first section), pain-related variables

(second section) and variables on the psychosocial impact of COVID-19 (third section). At the beginning of the initial questionnaire, participants provided informed consent to participate in the study and to use their responses. All questions and answers were provided in Spanish, using the validated versions in Spanish of structured questionnaires when available. Sections and individual items are detailed in Appendices I and II.

2.6.1 | Coprimary outcomes

Following the demographic questions, the second section of both the initial and follow-up questionnaires contained pain variables, including the coprimary outcomes: current pain intensity (numerical rating scale from 0 to 10, where 0 = no pain at all, and 10 = maximum pain imaginable), pain interference from the brief pain inventory (BPI; de Andres Ares et al., 2015; Keller et al., 2004), the short version of the pain catastrophizing scale (PCS-4; Bot et al., 2014; Olmedilla Zafra et al., 2013) and the short version of the Tampa Scale of Kinesiophobia (TSK-11; Gómez-Pérez et al., 2011). The validated version in Spanish of the BPI is widely used for noncancer pain and its interference scale showed good reliability with a Cronbach's a of 0.93 (de Andres Ares et al., 2015). Considering that the confinement measures explicitly forbid walking outdoors, the patient representatives suggested excluding the item related to interference with "walking", hence it was not used. The PCS-4 has shown good internal consistency ($a = 0.86$) and almost perfect correlation with the long version ($r = 0.96$; Bot et al., 2014), which has been validated in Spanish (Olmedilla Zafra et al., 2013). The Spanish version of the TSK-11 has been validated and has shown good reliability and validity with a 2-factor solution, namely activity avoidance and harm (Gómez-Pérez et al., 2011).

A 30% reduction from baseline has been proposed as a minimal clinically important difference for both pain intensity and disability, particularly for low back pain (Ostelo et al., 2008; Rowbotham, 2001). Alternatively, a 10%–20% decrease in pain intensity and a one-point reduction in the BPI pain interference were recommended as cut-offs for minimally important differences in chronic pain patients (Dworkin et al., 2008). Considering the limited timeframe and the passive character of the intervention, clinically meaningful differences were only expected for pain intensity and interference, but not for pain cognitions.

2.6.2 | Secondary outcomes

Other pain variables from the second section of the questionnaire such as pain duration, frequency and perceived evolution were secondary outcomes. Perceived evolution referred to patients' self-reported perceived changes in their pain during the lockdown (before the trial) and during the trial.

The third section comprised questions on symptoms, diagnosis, treatment and exposure to COVID-19, as well as on the impact, emotional responses, fears and stresses evoked by the pandemic and associated restrictions (details available in Appendices I and II), followed by the validated version in Spanish of the Generalized Anxiety Disorder scale (GAD-7; García-Campayo et al., 2010).

2.6.3 | Access to healthcare services variables

The third section also evaluated access to healthcare services during the lockdown and the trial period. One specific question concerning access to chiropractic care was included only in the follow-up questionnaire. The answer to this question determined the group in which patients were placed: no access (Group 0), one visit (Group 1) or more than one visit (Group 2) to their chiropractor. Patients receiving care were asked to rate four dimensions of their satisfaction (hygiene, safety, effectiveness, global satisfaction) using a 1–4 Likert scale. Patients were also asked whether they had visited a healthcare professional other than their chiropractor for their pain or other reasons (at baseline and follow-up).

Included in the different sections were three instructional manipulation checks, screening questions that are known to increase the reliability of the dataset (Oppenheimer et al., 2009). These are questions similar in format, length and answers to the experimental questions. However, instead of providing experimental data, they are used as a mechanism to confirm that the participant is correctly reading the questions (Oppenheimer et al., 2009). This resulted in a total of 73 and 71 items initially and at follow-up, respectively.

2.7 | Statistical analysis

Statistical analyses were performed with Statistica (v13.3; Dell Inc.), SPSS (v25 statistical package IBM SPSS Statistics) and the PROCESS module for SPSS (v3.3; Hayes, 2017). A value of $p < 0.05$ was used as a threshold to determine statistical significance.

For all demographical variables, means and standard deviations or percentages from the total samples were calculated. Separate Chi-Square analyses were used to compare categorical variables between groups. To measure the influence of access to chiropractic care, changes in all pain-related variables (Section 2) as well as those of fear/

TABLE 3 Pain and questionnaire baseline characteristics of participants in the study

	Whole sample (*n* = 385)	Experimental groups		
Characteristics		Group 0 (*n* = 99)	Group 1 (*n* = 177)	Group 2 (*n* = 109)
Pain variables				
Mean pain intensity 0−10 (SD)	5.2 (2.2)	5.1 (2.1)	5.1 (2.1)	5.6 (2.2)
Pain worsened during the lockdown, *n* (%)	249 (65)	55 (56)	111 (63)	83 (76)
Chronic pain (≥3 months), *n* (%)	267 (69)	80 (81)	112 (63)	75 (69)
Treatment modified because of restrictions (%)	274 (71)	65 (66)	126 (71)	83 (76)
Questionnaire scores				
Mean pain interference 0–60 (SD)	17.5 (15.1)	15.1 (13.7)	16.7 (14.9)	20.1 (16.1)
Mean PCS-4 score 0–16 (SD)	6.6 (3.3)	6.7 (3.2)	6.2 (3.2)	7.4 (3.4)
Mean TSK-11 score 11–44 (SD)	25.7 (5.6)	25.5 (5.5)	25.1 (5.8)	26.7 (5.5)
Mean GAD score 0–21 (SD)	5.3 (4.2)	6.2 (4.1)	4.4 (4.1)	6.0 (4.4)

Note: Data are absolute values and standard deviation (SD) for pain intensity and questionnaire scores, or number of participants and percentages (%).

Abbreviations: GAD, Generalized Anxiety Disorder scale; PCS-4, Pain Catastrophizing Scale 4 items; TSK-11, Tampa Scale of Kinesiophobia 11 items.

stress and anxiety linked to the pandemic (Section 3) over time were compared between experimental groups using mixed model ANOVAs. Equality of variance was assessed by using the Brown-Forsythe test (Brown & Forsythe, 1974). To control for potential interactions of pain duration and access to another healthcare professional, these were both introduced as covariates in separate covariance analyses. Significant interactions were decomposed by using Bonferroni-corrected planned comparisons (three comparisons) to test a priori hypotheses. We hypothesized that patients with access to care, independent of the number of encounters, experience reductions in pain intensity and interference compared to patients without. Furthermore, we hypothesized that pain cognitions, pandemic-related stress and emotions would improve for patients visiting their chiropractor. Effect sizes are expressed as partial eta squared values (η^2_p). Small effect size is considered when η^2_p values ≥0.01, medium when $\eta^2_p \geq 0.06$ and large when $\eta^2_p \geq 0.14$. Correlation coefficients (Pearson's *r*) were calculated for all numerical coprimary and secondary outcomes, at baseline and follow-up. These analyses were conducted to generate hypotheses regarding which coprimary or secondary variables may act as mediators of the changes in pain intensity and interference. The results of the correlation analyses are available in Figure S2.

In order to examine the mediatory role of pain catastrophizing in the relationship between the change in pain intensity ratings and the change in pain interference, a simple moderation analysis (model 4 of Hayes) was used (Hayes, 2017). In this model, the influence of the predictor variable (change in pain intensity) over the outcome (change in pain interference) is mediated by the mediator variable (pain catastrophizing). Furthermore, Hayes' model 7 (moderated mediation) was used to test the moderating role of baseline pain intensity in the mediatory

relationship between change in pain ratings and pain catastrophizing (PCS). In this model, the moderating variable (baseline pain intensity) moderates the relationship between the predictor and the mediator (Hayes, 2017). Another mediation analysis was performed to test the mediatory effect of PCS on the relationship between fear of movement at baseline and change in pain intensity ratings.

3 | RESULTS

3.1 | Demographics

All demographical data for the whole sample and for each individual group are summarized in Table 1. The final sample of 385 participants was comprised of 99 patients who reported receiving no care (Group 0), 177 patients reportedly accessing chiropractic care on one occasion (Group 1) and 109 patients visiting their chiropractor more than once (Group 2). Mean baseline scores in pain-related variables for all participants and groups are available in Table 3.

3.2 | Coprimary outcomes

3.2.1 | Pain intensity

Mixed ANOVAs for pain intensity ratings with TIME as the within-subjects factor and GROUP (access to care) as the between-subjects factor revealed a significant main effect of TIME ($F_{(1,382)} = 90.97$, $p < 0.001$, $\eta^2_p = 0.19$). Homogeneity of variances was respected for baseline and follow-up data ($p > 0.95$ for both). For the whole sample, mean pain intensity significantly decreased 1.23 points

FIGURE 2 Pain intensity ratings at baseline and follow-up by the group. Pain intensity was reported at baseline and follow-up on a numerical rating scale from 0 to 10 in Groups 0, 1 and 2. Between-group and within-group statistical significance was obtained via Bonferroni-corrected planned comparisons of mixed ANOVAs. *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$
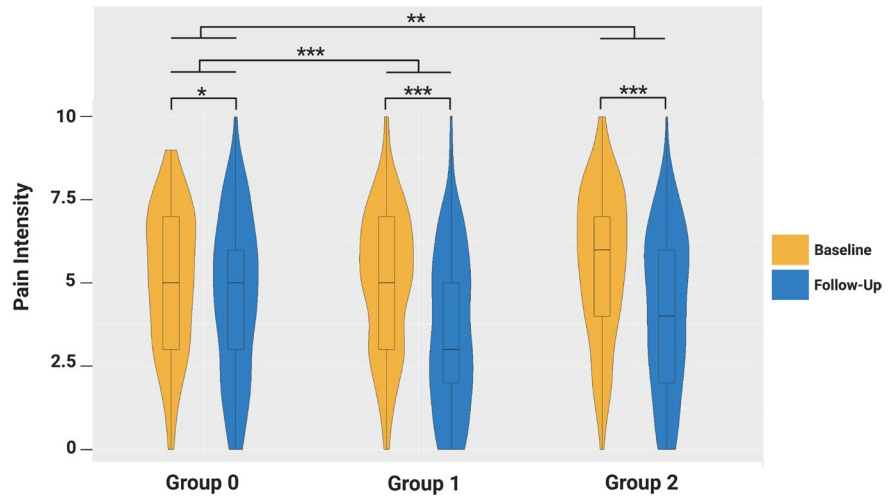
over time [95% confidence interval (CI) -1.46 to -1.0]. Pain intensity decreased by 0.53 (-0.97 to -0.08), 1.53 (-1.88 to -1.17) and 1.38 (-1.77 to 0.98) points in Groups 0, 1 and 2, respectively. There was a significant TIME x GROUP interaction ($F_{(2,382)} = 6.46$, $p = 0.002$, $\eta^2_p = 0.03$). Planned comparisons used to describe this interaction revealed a significant difference in the evolution over time when comparing Group 0 to both Groups 1 and 2 ($F_{(1,382)} = 12.26$, $p = 0.002$ and $F_{(1,382)} = 7.25$, $p = 0.02$, respectively). However, no differences were found over time between Groups 1 and 2 ($F_{(1,382)} = 0.29$, $p = 1.0$). Figure 2 provides a graphic representation of these results.

3.2.2 | Pain interference with activity

Pain interference showed a negative main effect of TIME ($F_{(1,382)} = 14.17$, $p < 0.001$, $\eta^2_p = 0.04$). Variances were not significantly different between groups ($p = 0.08$ and $p = 0.17$ at baseline and follow-up, respectively). There was a significant TIME × GROUP interaction ($F_{(2,382)} = 7.30$, $p < 0.001$, $\eta^2_p = 0.04$). Planned comparisons showed that interference was significantly different over time when comparing Group 0 to Group 1 ($F_{(1,382)} = 12.79$, $p = 0.001$) and to Group 2 ($F_{(1,382)} = 10.04$, $p = 0.005$), but not between Groups 1 and 2 ($F_{(1,382)} = 0.01$, $p = 1.0$). Interference scores showed a mean increase in 1.34 points for Group 0 (95% CI -1.06 to 3.75), and a mean reduction in 4.8 points for Group 1 (-6.98 to -2.62) and 4.68 points for Group 2 (-7.13 to -2.23). See Figure 3 for a depiction of these results.

3.2.3 | Pain catastrophizing and fear of movement (Kinesiophobia)

Mixed ANOVAs showed a significant main effect of TIME for PCS and TSK ($F_{(1,382)} = 58.24$, $p < 0.001$, $\eta^2_p = 0.13$;

$F_{(1,382)} = 4.10$, $p = 0.04$, $\eta^2_p = 0.01$, respectively). For both variables, the variances were homogenous at baseline and follow-up (all $p > 0.3$). Because gender differences in catastrophizing have been extensively reported in the literature (Sullivan et al., 2000), the PCS scores were tested for gender differences with the use of one-way ANOVA. The scores were higher for women than for men though not significant (6.7 vs. 6.4 at baseline, $p = 0.32$; 5.8 vs. 5.4 at follow-up, $p = 0.22$).

Only TSK was influenced by exposure to interventions (TIME × GROUP: $F_{(2,382)} = 4.29$, $p = 0.01$, $\eta^2_p = 0.02$). Planned comparisons revealed that TSK scores did not have a significantly different evolution when comparing no exposure to one ($F_{(1,382)} = 5.44$, $p = 0.06$), however, it was the case for multiple exposures ($F_{(1,382)} = 7.83$, $p = 0.02$). No differences were found between both groups exposed ($p = 1.0$). Group 0 showed an increase in 0.47 points (95% CI -0.27 to 1.22), Group 1 a decrease in 0.68 points (-1.22 to -0.13) and Group 2 in 1.06 points (-1.89 to -0.22). Results are shown in Figure 4 and correlations between these coprimary outcomes are represented in Figure S2.

3.3 | Influence of pain duration and access to other healthcare services

Patients were classified as acute or chronic according to their self-reported symptom duration (<3 and ≥3 months, respectively). The sample classified as 'chronic' showed significantly higher levels of pain catastrophizing ($F_{(1,379)} = 12.39$; $p < 0.001$) and kinesiophobia ($F_{(1,379)} = 9.25$; $p = 0.003$). In order to determine whether pain duration was a factor influencing the evolution of participants allocated to different groups, it was introduced as a covariate in a set of separate ANCOVAs. Introducing pain duration did not result in significant effects on the interactions TIME × GROUP × PAIN DURATION (pain intensity: $F_{(2,379)} = 2.86$, $p = 0.06$, $\eta^2_p = 0.06$;
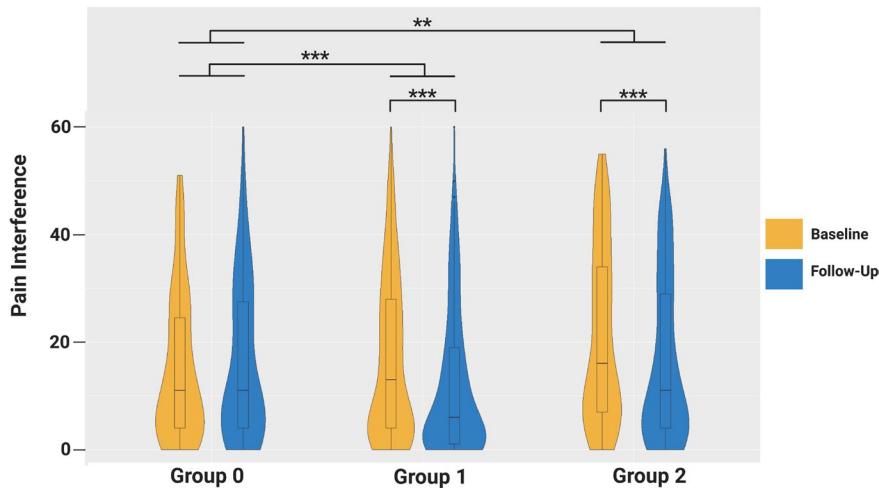
FIGURE 3 Pain interference at baseline and follow-up by the group. Pain interference was reported at baseline and follow-up from 0 to 60 according to the modified brief pain inventory in Groups 0, 1 and 2. Between-group and within-group statistical significance was obtained via Bonferroni-corrected planned comparisons of mixed ANOVAs. *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$
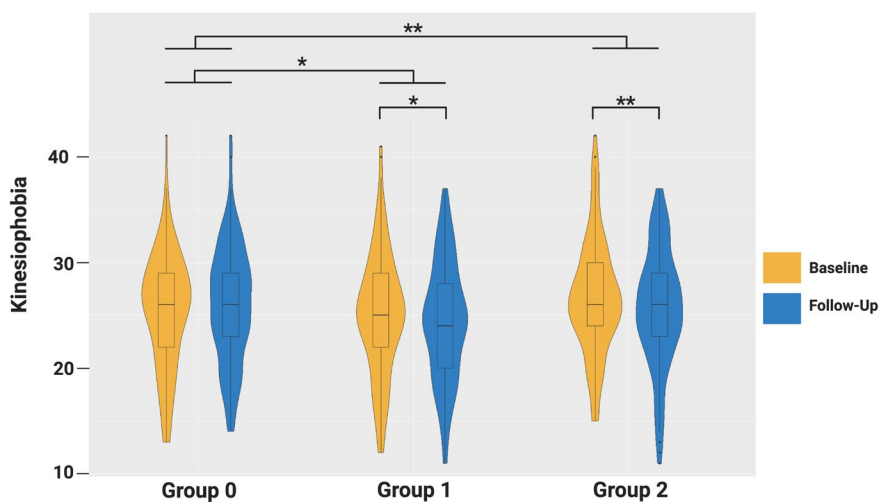

FIGURE 4 Fear of movement at baseline and follow-up by the group. Scores for the short version of the Tampa Scale of Kinesiophobia were reported at baseline and follow-up from 11 to 44 in Groups 0, 1 and 2. Between-group and within-group statistical significance was obtained via Bonferroni-corrected planned comparisons of mixed ANOVAs. *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$

pain interference: $F_{(2,379)} = 0.21$, $p = 0.81$, $\eta^2_p = 0.001$; kinesiophobia: $F_{(2,379)} = 1.35$, $p = 0.26$, $\eta^2_p = 0.01$).

During the trial, some participants reported visiting another healthcare professional (HCP) for their pain (12%, 9% and 8% of patients in Groups 0, 1 and 2, respectively). No significant interactions TIME × GROUP × HCP were observed for pain interference ($F_{(2,379)} = 0.46$, $p = 0.6$, $\eta^2_p = 0.002$) or kinesiophobia ($F_{(2,379)} = 0.73$, $p = 0.5$, $\eta^2_p = 0.004$). Accessing another HCP only had a significant influence on pain intensity (interaction: $F_{(2,379)} = 4.6$, $p = 0.01$, $\eta^2_p = 0.02$). Interestingly, patients visiting another professional did not have statistically significant pain reduction (−1.75 to 0.75, 95% CI), whereas patients only visiting their chiropractor did (−2.16 to −1.32, 95% CI).

3.4 | Mediation effects by pain catastrophizing

The mediatory effect of baseline pain catastrophizing (PCS) on the relationship between change in pain

intensity (predictor) and change in pain interference between pre- and post-test (outcome variable) was assessed (Figure 5A). The indirect effect of change in pain intensity on change in pain interference was found to be statistically significant ($b = 0.144$, $0.032 < \text{CI} < 0.291$). Furthermore, testing moderated mediation using Hayes model number 7 (Hayes, 2017) showed that the relationship between the difference in pain intensity and PCS was moderated by the intensity of pain the individual had at baseline ($F_{(1,381)} = 5.70$, $p = 0.02$). The moderation effect suggests that when an individual has a lower pain rating at baseline, a reduction in pain is associated with lower pain catastrophizing. Correspondingly, an increase in pain amongst those with high intensity at baseline is associated with high pain catastrophizing (Figure 5B).

Next, the mediatory role of baseline pain catastrophizing in the relationship between baseline fear of movement and change in pain ratings was investigated. The overall model with change in pain intensity as the dependent variable was significant ($R^2 = 0.039$, $F_{(3,381)} = 5.17$, $p = 0.002$). Only the indirect effect of fear of movement on pain was

Mediation effects by pain catastrophizing

(a)

(b)

(c)   Mediation effects by pain catastrophizing (women)

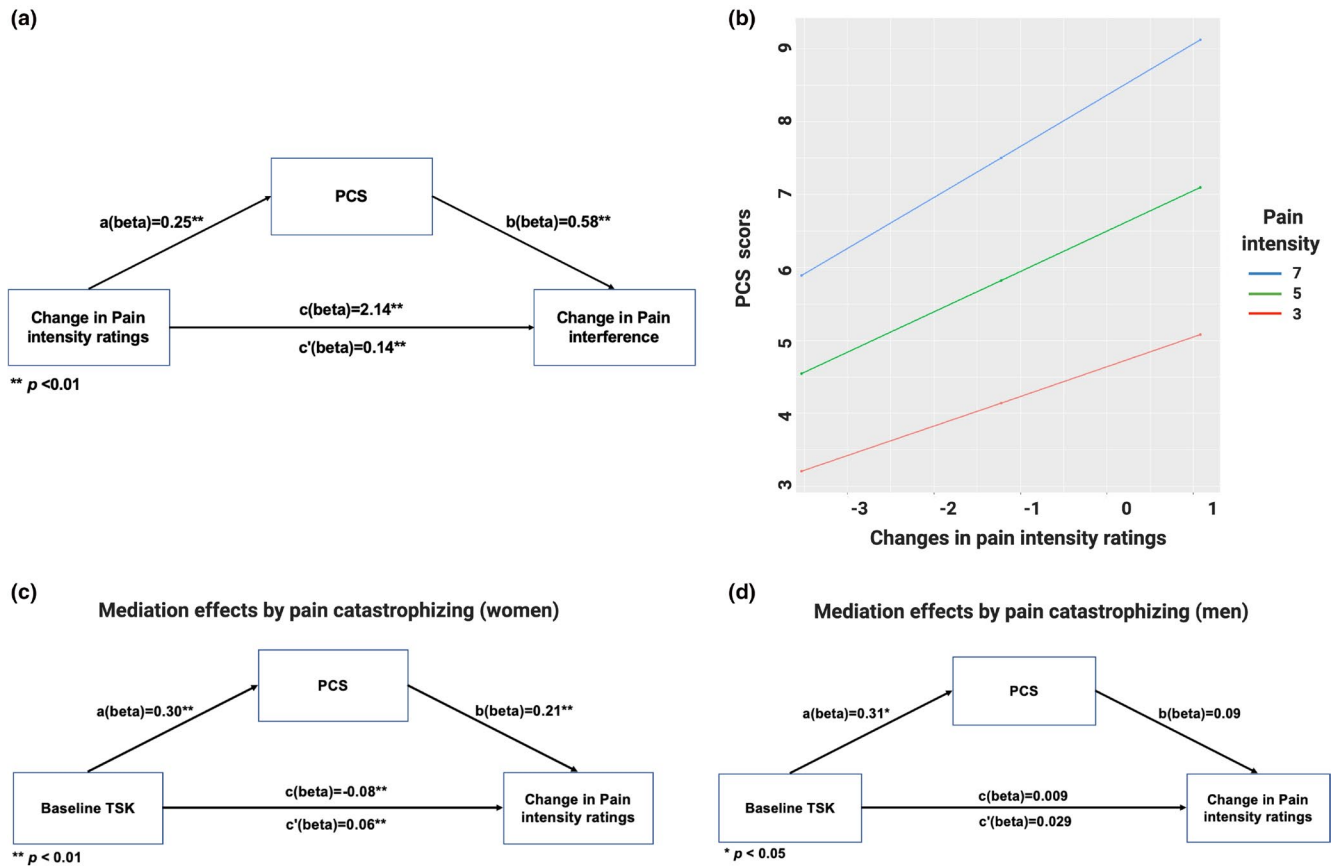**(d)**   Mediation effects by pain catastrophizing (men)

FIGURE 5 Mediation effects by pain catastrophizing. Mediatory effect of pain catastrophizing (PCS) on the relationship between changes in pain intensity ratings and in pain interference (a), moderating role of pain ratings at baseline in the relationship between pain catastrophizing and change in pain ratings (b). For patients with lower pain intensity at baseline (3/10, red line), low levels of PCS were associated with larger reductions in pain intensity. For patients with higher baseline pain intensity (~7/10, blue line), higher PCS scores were associated with pain increases. Mediatory effects of pain catastrophizing in the relationship between fear of movement (TSK) and changes in pain intensity ratings in women (c) and men (d). *$p < 0.05$; **$p < 0.01$

significant ($0.022 < \text{CI} < 0.085$). When gender was included in the above-mentioned model, there was a trend towards significance when PCS was the outcome variable ($p = 0.057$). Therefore, the analysis was repeated for each gender separately. Amongst women, the indirect effect of PCS in the relationship between TSK and changes in pain intensity was significant (Figure 5C; $0.024 < \text{CI} < 0.097$) but not amongst men (Figure 5D; $-0.022 < \text{CI} < 0.096$).

A subsequent moderation analysis was performed with the change in pain intensity as the outcome variable for analysis, and fear of harm ('harm' subscale of the TSK) as a moderator variable. The model in the full sample showed that the interaction between harm and initial pain intensity was not significant. When the model was tested amongst those visiting their practitioner more than once, the interaction between harm and initial pain intensity showed a trend towards significance ($F_{(1,105)} = 3.75$, $p = 0.055$). Contrarily, the observed effect was not significant or close to significant in the other two groups. For

Group 2 exclusively, the conditional effect of all three levels of the moderator was significant. Individuals with higher pain intensity at baseline and higher harm scores had less reduction in pain at follow-up, whereas those with similar pain ratings at baseline but lower levels of harm had more pain reduction (more than 1.7 times compared to the high harm group). There was not such a difference between individuals with low baseline pain intensity.

3.5 | Secondary outcomes

3.5.1 | Perceived evolution

Patients rated their perceived evolution during the lockdown period and at the completion of the study. During the lockdown period, two out of three patients (65%) reported that their pain had worsened. After completion of the trial, the pain had improved or was gone in 61% and

77% of patients accessing care once and more than once, respectively. The proportion of patients improving was significantly lower ($\chi^2 = 39.8$, df $= 2$, $p < 0.001$) in patients without access to care (34%).

3.5.2 | Pandemic-related emotional profile

Mixed ANOVAs showed a significant main effect of TIME for general anxiety ($F_{(1,382)} = 19.27$, $p < 0.001$, $\eta^2_p = 0.05$), which decreased in the trial period (95% CI -0.98 to -0.38). However, there was no significant interaction by GROUP ($F_{(2,382)} = 1.65$, $p = 0.19$).

A set of questions assessed the degree (from 0 to 10) to which emotions were evoked by the pandemic (sadness, worry, loneliness, anger/rage, helplessness, anxiety, surprise, relief and hope). Of the emotions reported, only *Hope* showed a significant interaction of TIME with GROUP ($F_{(2,382)} = 3.79$, $p = 0.02$, $\eta^2_p = 0.02$). The assumption of variance equality was met ($p > 0.3$ at baseline and follow-up). Changes in the degree that this emotion was reported significantly differed when comparing Group 0 to Group 1 only: $F_{(1,382)} = 7.27$, $p = 0.02$ (Group 0 vs. Group 2: $p = 0.8$; Group 1 vs. Group 2: $p = 0.4$). *Hope* only increased for participants in groups receiving care once (0.29–1.32, 95% CI); patients in the other two groups did not experience significant changes (-0.85 to 0.27 for Group 0 and -0.41 to 0.83 for Group 2, 95% CI).

Concerning the questions on pandemic stress and/or fear, only stress in the face of the COVID-19 pandemic showed significant evolution over time ($F_{(1,382)} = 9.90$, $p = 0.002$, $\eta^2_p = 0.03$) and a trend for significance by group ($F_{(2,382)} = 2.95$, $p = 0.054$, $\eta^2_p = 0.015$). The variances were homogenous between groups at baseline and follow-up ($p = 0.06$ and $p = 0.14$, respectively). Despite not finding significant differences between groups, a significant pre–post decrease (-1.16 to -0.31, 95% CI) in stress from COVID-19 was seen for Group 2 but not for the rest (-0.39 to 0.35 for Group 0 and -0.64 to 0.02 for Group 1, 95% CI). Correlations between the numerical secondary outcomes are illustrated in supplemental Figure S2.

Patients with access to chiropractic care rated their satisfaction with different aspects of care on a Likert scale (1–4) as follows: hygiene 3.53–3.74, safety 3.51–3.72, effectiveness 3.48–3.70 and overall satisfaction 3.46–3.68 (all 95% CI).

4 | DISCUSSION

This pragmatic non-randomized trial evaluated access to in-person chiropractic care at the end of the most stringent phase of lockdown taking place in Spain during the spring of 2020. When lockdown measures were eased, accessing care rapidly decreased pain intensity, interference with activity and fear of movement. Pain catastrophizing was identified as the mediator of the relationships between these variables. Patients visiting their chiropractors in this period experienced a significant increase in feelings of hope with regards to the COVID-19 pandemic. Satisfaction with care was high (~3.6/4 overall) and none of these results seemed to be influenced by exposure to other healthcare professionals or pain management services.

To redistribute and prioritize healthcare resources during COVID-19, access to and provision of services were limited or delayed (Lazzerini et al., 2020; Minhas et al., 2020). Restricting access to care forced patients to change their treatment, leading to increased pain intensity and interference (Fallon et al., 2020; Hruschak et al., 2021; Lacasse et al., 2021; Nieto et al., 2020; Page et al., 2021). Correspondingly, two-thirds of our patients reported aggravation of their pain during the lockdown. In the context of COVID-19 social distancing, self-perceived increases in pain intensity and interference were independently predicted by catastrophizing (Fallon et al., 2020; Hruschak et al., 2021). In the present study, pain catastrophizing also emerged as an important factor explaining the relationship between pain intensity and interference. This is aligned with previous data on the mediating role of catastrophizing on disability/interference (Hirsh et al., 2011; Marshall et al., 2017). Individuals' cognitions about pain affect their perception of how it interferes with daily activities (Sullivan et al., 2001). However, the relationship between pain and catastrophizing is not a direct one. Our findings supported that severity at baseline moderates this relationship: higher baseline pain intensity and catastrophizing were associated with pain aggravation after exposure. Indeed, state pain catastrophizing may be influenced by a person's experience of pain (Sturgeon & Zautra, 2013).

These findings add support to the premise that pain intensity and catastrophizing may influence levels of physical activity (Zhaoyang et al., 2020). It was proposed that catastrophizing also mediates the relationship between pain and fear (Marshall et al., 2017). This is compatible with the findings of our second mediation analysis. Fear of movement influenced changes in pain intensity indirectly through pain catastrophizing. Kinesiophobia has been associated with higher pain intensity and disability, predicting the evolution of the latter (Luque-Suarez et al., 2019). High scores, particularly in the harm subscale, were linked to low levels of physical activity (Elfving et al., 2007), while reducing kinesiophobia could stimulate engagement in physical activity for patients with back pain (Luning Bergsten et al., 2012). Currently, the promotion of physical activity is a public health priority (Damiot et al.,

2020; Pinto et al., 2020; Sallis et al., 2020; Stamatakis & Bull, 2020), particularly as inactivity is associated with a higher risk for severe COVID-19 (Sallis et al., 2021). In the present study, fear of movement was significantly reduced after longer exposure to hands-on care. Though this may have influenced the patients' degree of engagement in physical activity, this variable was not assessed. Activity levels may explain augmented pain during the lockdown (Fallon et al., 2020; Yoshimoto et al., 2021) and may change in response to care or vice versa. This variable should be monitored and controlled for in future studies.

Our results are in line with literature supporting that pain catastrophizing and fear of movement modulates treatment efficacy (Flink et al., 2010; Wertli, Burgstaller, et al., 2014; Wertli, Rasmussen-Barr, et al., 2014). Participants were mainly exposed to manual therapy, for which the mediators of treatment success are poorly understood. Pain relief from spinal manipulation was found to partly rely on influencing psychological variables including fear of movement (Ellingsen et al., 2018; Williams et al., 2007). Catastrophizing may play an important role, but the direction of the effect remains unclear (Bishop et al., 2015). It was found not only to moderate changes in pain sensitivity (Alonso-Perez et al., 2017) but also to increase the chances of response to manual therapy (Verhagen et al., 2010). The current study provides evidence for pain catastrophizing as a mediator of the relationships between kinesiophobia, changes in pain intensity and in pain interference.

Kinesiophobia, particularly the harm subscale of the TSK-11, showed a tendency to decrease the likelihood of individuals with more intense pain at baseline to benefit from access to care. This is consistent with high levels of fear-avoidance beliefs decreasing the likelihood of responding favourably to spinal manipulation (Childs et al., 2004; Cleland et al., 2007) and greater pain intensity moderating the response to it (Schellingerhout et al., 2008). However, a recent systematic review did not find these effects to be clinically meaningful for patients with chronic low back pain (de Zoete et al., 2021).

There is currently little data on the effects of reintroducing specific services and novel initiatives to counteract the consequences of delaying the provision of care for non-COVID conditions (Carrillo-de-la-Pena et al., 2021). Previous evidence supports that the introduction of chiropractic services significantly reduces pain and disability (Garner et al., 2007; Goertz et al., 2018; Prater et al., 2020). In the present investigation, hands-on chiropractic care resulted in minimal clinically important differences for both outcomes (approaching 30% from baseline), particularly after the first visit. Exposure to additional visits or other healthcare services did not yield better outcomes. This may be explained by a strong influence of in-person

care during the lockdown on psychological factors. Modulation of distressing factors such as fear, anxiety and beliefs may contribute to the short-term clinical benefits of spinal manipulation (Williams et al., 2007). Similarly, feelings of hope were leveraged after the first encounter and stress diminished after multiple interactions. These changes likely reflect the influence of contextual factors linked to hands-on care in times of high uncertainty (Kaptchuk et al., 2020) and stress associated with the pandemic (Taylor et al., 2020).

In the context of COVID-19, the effect of touch, context and therapeutic alliance associated with chiropractic care may be particularly relevant for individuals with a specific psychological profile (Bishop et al., 2015). These individual differences should be considered when planning patient access to care during restrictions. A careful selection process may be necessary to prioritize care provision for patients who will benefit more from in-person access, as opposed to those who may wait or find alternatives, such as remote interventions. Telehealth services offer a safer alternative to in-person care during times when social distancing is pivotal (Eccleston et al., 2020). It remains to be determined whether they provide equivalent benefits and levels of satisfaction (Carrillo-de-la-Pena et al., 2021).

The interpretation of the study results is limited by the lack of treatment randomization. We did not consider it ethical to assign a specific treatment after 2 months of strict lockdown, as it could further delay care for participants with more urgency (higher pain intensity, interference or anxiety) or increase the exposure of those at higher risk of infection. It is possible that some patients declined to receive treatment if they perceived that the risks outweighed the potential benefits amidst the pandemic. Cluster randomization was not deemed feasible because of different barriers or accelerators influencing the re-opening scenario for each clinic, such as economic factors, personnel, infrastructure and personal protective equipment availability. Instead, the recruitment process was pseudo-randomized, attempting to reduce sampling bias. However, this does not mean that the experimental design is devoid of other biases. It is possible that participants in the groups receiving care were more likely to be lost to follow-up if the results did not meet their expectations. This arises as a high risk for attrition bias (Nunan et al., 2018), which was moderated by using a mixed model analysis (Bell et al., 2013). Other limitations come from the conditions during the pandemic. A pragmatic trial with self-reported online data was deemed the most appropriate design to provide 'real-world' data (Christian et al., 2020; Gartlehner et al., 2006), while ensuring social distancing. This offered a short window of opportunity to measure the rapid effects of access to chiropractic care,

during the 2 weeks that made up the initial phase of lock-down easing.

To our knowledge, this is the first study to measure the impact on pain conditions of access to a healthcare service that was limited because of restrictions and made available anew in the midst of the COVID-19 pandemic. This provided a unique setting to evaluate the effects of accessing chiropractic services—of limited access during the pandemic—on pain and psychological variables. The sample (covering the majority of the Spanish territory) and the mediation analyses suggest potential benefits of hands-on care mediated by pain catastrophizing and moderated by baseline pain intensity and kinesiophobia. The provision of in-person chiropractic care under strict regulations concerning safety and hygiene may be considered to mitigate some of the negative consequences of the pandemic on patients with pain. However, individual differences in pain perception and cognitions should be examined in order to effectively prioritize access to care during the COVID-19 pandemic.

CONFLICT OF INTEREST

None declared.

AUTHOR CONTRIBUTIONS

CG-M, ZD and AOdM contributed to conceive and plan the overall trial design. The questionnaires were developed by CG-M, ZD, FMC-B, AK and AOdM. CG-M, FMC-B and AOdM contributed to the administration of questionnaire trials and data collection, CG-M and AK performed the statistical analyses, AOdM is the principal investigator, IMF the guarantor of statistical quality. CG-M wrote the first version of the manuscript. EL contributed to manuscript writing and editing. All the authors reviewed the manuscript. The team met regularly during the trial period and contributed as a whole to discussions of the data.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

APPENDIX I

Initial questionnaire sections and items

Section 1: Demographic data (9 items)

Item 1	Age
Item 2	Gender
Item 3	Marital status
Item 4	Number of people sharing household
Item 5	Has any household member been diagnosed with COVID-19?
Item 6	Education level
Item 7	Region in Spain
Item 8	Diagnosed chronic co-morbidities
Item 9	Informed consent

Section 2: Pain-related outcomes (30 items)[a]

Item 10	Pain location(s)
Item 11	Higher pain intensity in a numerical rating scale (0–10)
Item 12	Pain duration (in months)
Item 13	Pain frequency
Item 14	Pain evolution during lockdown
Items 15–20	Pain interference (6 items, 0–10, out of a total of 60)
Item 21	Changes in pharmacological treatment for pain during lockdown
Item 22	Changes in non-pharmacological treatment for pain during the lockdown
Item 23	Would you have visited your chiropractor during lockdown if available?
Item 24	Date of initiation of chiropractic care
Items 25–28	Pain catastrophizing scale, short version (4 items, 0–4, out of a total of 16)
Items 29–39	Tampa Scale of Kinesiophobia, short version (11 items, 1–4, out of a total of 44)

Section 3: Psychosocial impact of COVID-19 (31 items)[a]

Item 40	COVID-19 diagnosis
Item 41	COVID-19 symptoms
Item 42	Contact with COVID-19 cases
Item 43	Visits to healthcare professionals (for COVID-19 or pain) in the previous 2 weeks
Item 44	If affirmative, detail which professional(s)
Item 45	Current employment status
Item 46	Changes in employment status during the lockdown
Item 47	Restrictions which had more direct impact
Items 48–56	Degree to which emotions are experienced with regards to the pandemic (9 items, 0–10): Sadness, Worry, Loneliness, Anger, Helplessness, Anxiety, Surprise, Relief, Hope
Items 57–63	Degree to which the pandemic or related situations evoke stress (7 items, 0–10): pandemic-related stress, restrictions-related stress, own's health stress, fear of economic difficulties, fear of food shortage, fear of resources shortage, loved ones' health stress
Items 64–70	General Anxiety Disorder scale (7 items, 0–3, out of a total of 21)

[a] A total of three instructional manipulation checks were introduced in the form of three screening questions.

APPENDIX II

Follow-up questionnaire sections and items

Section 1: Demographic data (7 items)	
Item 1	Age
Item 2	Gender
Item 3	Marital status
Item 4	Number of people sharing household
Item 5	Has any household member been diagnosed with COVID-19?
Item 6	Education level
Item 7	Region in Spain
Section 2: Pain-related outcomes (31 items)[a]	
Item 8	Higher pain intensity in a numerical rating scale (0–10)
Item9	Pain evolution in the previous 14 days
Item 10	Pain frequency in the previous 14 days
Items 11–16	Pain interference (6 items, 0–10, out of a total of 60)
Item 17	Changes in pharmacological treatment for pain in the previous 14 days
Item 18	Changes in non-pharmacological treatment for pain in the previous 14 days
Item 19	Have you visited your chiropractor in the previous 14 days?
Items 20–23	If affirmative, satisfaction with hygiene, safety, efficacy and global satisfaction (4 items, 1–4)
Items 24–27	Pain catastrophizing scale, short version (4 items, 0–4, out of a total of 16)
Items 28–38	Tampa Scale of Kinesiophobia, short version (11 items, 1–4, out of a total of 44)
Section 3: Psychosocial impact of COVID-19 (30 items)[a]	
Item 39	COVID-19 diagnosis
Item 40	COVID-19 symptoms
Item 41	Contact with COVID-19 cases in the previous 14 days
Item 42	Visits to *other* healthcare professionals (for COVID-19 or pain) in the previous 2 weeks
Item 43	If affirmative, detail which professional(s)
Item 44	Changes in employment status in the previous 14 days
Item 45	Restrictions which had more direct impact in the previous 14 days
Items 46–54	Degree to which emotions are experienced with regards to the pandemic (9 items, 0–10): Sadness, Worry, Loneliness, Anger, Helplessness, Anxiety, Surprise, Relief, Hope
Items 55–61	Degree to which the pandemic or related situations evoke stress (7 items, 0–10): pandemic-related stress, restrictions-related stress, own's health stress, fear of economic difficulties, fear of food shortage, fear of resources shortage, loved ones' health stress
Items 62–68	General Anxiety Disorder scale (7 items, 0–3, out of a total of 21)

[a] A total of 3 instructional manipulation checks were introduced in the form of 3 screening questions.