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Mindful Self-Compassion program for chronic pain patients: A randomized controlled trial

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Abstract

Background: Although evidence-based psychological treatments for chronic pain (CP) have been demonstrated to be effective for a variety of outcomes, modest effects observed in recent reviews indicate scope for improvement. Self-compassion promotes a proactive attitude towards self-care and actively seeking relief from suffering. Consequently, more compassionate people experience better physical, psychological and interpersonal well-being.

Methods: We conducted a single-blind, randomized, controlled trial to examine the effects of a Mindful Self-Compassion program (MSC) on relevant clinical outcomes in patients with CP. Patients were randomly assigned to one of the two intervention arms: MSC or cognitive-behavioural therapy (CBT). The protocols of both intervention arms were standardized and consisted of a 150-min session once a week during 8 weeks formatted to groups of no more than 20 participants. The primary outcome was self-compassion, measured with the Self-Compassion Scale (SCS). The secondary outcomes were other pain-related scores, quality-of-life measures, and anxiety and depression scores.

Results: In all, 62 and 61 patients were assigned to the MSC and CBT groups, respectively. The MSC intervention was more effective than CBT for self-compassion (average treatment effect [ATE] = 0.126, $p < 0.05$). The secondary outcomes, pain acceptance (ATE = 5.214, $p < 0.01$), pain interference (ATE = −0.393, $p < 0.05$), catastrophizing (ATE = −2.139, $p < 0.10$) and anxiety (ATE = −0.902, $p < 0.05$), were also favoured in the experimental arm (MSC). No serious adverse events were observed.

Conclusions: Mindful Self-Compassion is an appropriate therapeutic approach for CP patients and may result in greater benefits on self-compassion and emotional well-being than CBT.

Significance: This randomized controlled trial compares the novel intervention (MSC program) with the gold standard psychological intervention for CP (CBT). MSC improves the levels of self-compassion, a therapeutic target that is receiving attention since the last two decades, and it also improves anxiety symptoms, pain interference and pain acceptance more than what CBT does. These results provide empirical support to guide clinical work towards the promotion of self-compassion in psychotherapeutic interventions for people with CP.

1 | INTRODUCTION

Evidence-based psychological theories and treatments to manage chronic pain (CP) have shifted from 'first-wave' behavioural approaches (Fordyce, 1976) to 'second-wave' cognitive-behavioural approaches (McCracken & Turk, 2002) and then to 'third-wave' – mindfulness, compassion (Gooding et al., 2020; Kabat-Zinn et al., 1986) and contextual-behavioural approaches (Hayes et al., 2006; McCraken, 2005).

Regardless of the wave, psychological interventions for CP primarily target improvements in physical, emotional, social and occupational functioning rather than the resolution of pain (Sturgeon, 2014). Cognitive-behavioural therapy (CBT), which is considered the 'gold-standard' psychological treatment for CP (Häuser et al., 2010), tries to do so by reducing distressing psychological symptoms, targeting maladaptive behavioural and cognitive responses to pain, and addressing social contingencies that modify reactions to pain (Day et al., 2012). Third-wave interventions, including acceptance-based and mindfulness-based interventions (MBIs), focus on promoting behaviours guided by important life values instead of mitigating pain. They foster acceptance and change the relationship between the person and his experiences. According to this framework, this relationship sustains psychological distress more than the symptoms themselves do (Hayes et al., 2006).

Although all these approaches, especially the ones of the second and third waves, improved CP outcomes, such as pain severity, disability and mood disturbance, the improvements were only moderate. These modest effects, ranging from small to medium in size, as observed in recent meta-analyses, indicate scope for improvement (Harrison et al., 2017; Hilton et al., 2017; Veehof et al., 2011; Williams et al., 2012).

Mindfulness-based interventions have evolved from the Mindfulness-Based Stress Reduction (MBSR) program developed for people with chronic conditions, including CP (Kabat-Zinn, 1982), to more specific programmes based on mindfulness for CP, such as Mindfulness-Based Pain Management (Cusens et al., 2009). Furthermore, specific programmes that highlight the importance of the core components of mindfulness, like the Mindful Self-Compassion (MSC) program, have also emerged (Germer & Neff, 2019).

Compassion is defined as 'a sensitivity to the suffering of self and others, with a deep commitment to alleviate it' (Neff, 2003a). Particularly, self-compassion promotes a proactive attitude towards self-care and seeking relief from suffering (Neff, 2003a). Consequently, more compassionate people demonstrate better physical (Brion et al., 2014), psychological (MacBeth & Gumley, 2012) and interpersonal well-being. Self-compassion might help confront the fear of pain, buffer difficult emotions (e.g. rage, shame and helplessness) and aid in accepting pain-related disabilities (Smith & Osborn, 2007).

Compassion-based interventions for CP promote positive emotional outcomes (Montero-Marín et al., 2018). A recent study suggested that when emotional functioning is an important outcome besides daily functioning in CP, it may be beneficial to add self-compassion, alone or as a component in other therapies (Davey et al., 2020).

However, compassion-based interventions have rarely been described well and barely been standardized; randomized controlled trials (RCTs) on these interventions are scarce (Kirby et al., 2017).

The aim of the present RCT was to compare the effectiveness of the MSC (Germer & Neff, 2019) and CBT (Kovacs & Moix, 2011; McCracken & Turk, 2002) programmes on the basis of the primary outcome (self-compassion) and secondary outcomes (pain acceptance, pain interference, pain intensity, catastrophizing, anxiety and depressive symptoms, and quality of life [QoL]) in a group of adult patients with CP.

2 | METHODS

2.1 | Design and participants

The main objective of this study was to compare the effectiveness of the MSC program and CBT on the basis of the self-compassion outcome in a group of patients with CP. To that end, a parallel group, single-blind (evaluator), randomized (1:1 ratio), controlled (vs. active comparator) trial was implemented. We considered two intervention arms (the MSC course and CBT) and two assessment points (baseline and post-intervention).

An active control was selected because recent systematic reviews have mentioned the lack of studies with 'head-to-head' comparisons between MBIs and cognitive-behavioural therapies (Khoo et al., 2019); and this is an important knowledge gap to be addressed. Moreover, investigators working in the field of compassion have claimed that compassion-based interventions and investigations in the area are still in their infancy with only small-scale RCTs (often with a non-active comparator) being performed. Therefore, they recommend conducting RCTs that have adequately powered sample sizes and controls that are not waitlists or treatments as usual, but active comparisons, such as between MBI, ACT or CBT (Kirby et al., 2017). CBT was chosen as the active control because it is a well-established and prevalent psychological intervention for CP in the field (Khoo et al., 2019). When conducting such active comparisons, it is important to clearly describe the protocols of the interventions to determine the differences between the interventions and measurements that examine the process changes unique to the intervention. In this

regard, the MSC program, among all the compassion-based interventions, is firmly standardized and easy to compare to CBT and to study differences and commonalities on mechanisms of the changes.

The eligible participants were users of a Chronic Pain Liaison Program that was coordinated by the Mental Health Department (MHD) of a public general hospital in Madrid (Spain). On average, over 450 patients enrolled in the programme every year. Most of them were referred from the hospital's CP unit and community mental health centres of the catchment area. The recruitment period was from February 2017 to October 2018.

Patients with the first appointment in the CP unit at least 3 months before the enrolment; ≥18 years of age; with a score ≥8 on the anxiety and/or depression subscales of the Hospital Anxiety and Depression Scale (HADS); diagnosed with adjustment disorder, dysthymia or major depressive disorder according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; and with signed informed consent forms were included in the study. The following patients were excluded: diagnosed with intellectual disability and/or any type of cognitive impairment, psychotic and/or manic symptoms and self-harm or suicidal ideation at the time of the study, and with previous formal training on mindfulness. Withdrawal criteria were as follows: participant's decision, hospitalization in a psychiatric unit or a worsening clinical condition identified by the researchers or the participant's attending physician/s.

The convenience sample of care providers consisted of one psychiatrist and one art therapist for MSC, and four clinical psychologists for CBT. The MSC therapists were trained and certified by San Diego University (USA), and the CBT therapists were experienced clinical psychologists specifically trained on CBT for CP. All therapists had wide experience in the field of CP. Both interventions followed standardized intervention manuals.

This study adhered to the tenets of the Declaration of Helsinki, SPIRIT 2013 (Chan et al., 2013) and CONSORT 2010 statements (Moher et al., 2012). Our institutional review board approved the trial (identifier 4,757). The study protocol was prospectively registered in December 2016 (ClinicalTrials.gov identifier NCT03386422) and retrospectively modified twice (March 2019 and May 2020).

2.2 | Measures

Participants completed a sociodemographic-clinical questionnaire (baseline) and a paper-and-pencil battery of instruments (baseline and post-intervention). Assessments included measures of pain interference, pain intensity, emotional distress, QoL, self-compassion, catastrophizing and pain acceptance. The instruments were selected in line with the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT; Dworkin et al., 2005).

2.2.1 | Baseline sociodemographic-clinical questionnaire

The following information was collected at baseline: gender, age, marital status, education level and employment status. In addition, relevant clinical variables, such as personal medical history, years of CP and medical visits because of the pain in the last 3 months, were recorded.

2.2.2 | The primary outcome

Self-compassion: The Self-Compassion Scale (SCS; Neff, 2003b) was a self-reported instrument that consisted of 26 items including statements, such as 'I am kind to myself when I am experiencing suffering', 'when I see aspects of myself that I don't like I get down on myself' and 'when things are going badly for me, I see the difficulties as part of life that everyone goes through'. The patients were asked to rate to what extent they experienced these feelings or situations on a 5-point Likert-type scale, where 1 was 'almost never' and 5 'almost always'. The final scores ranged from 1 to 5, with higher values indicating greater self-compassion. The higher scores were associated with lower negative effects, and lower disabilities and catastrophizing among people with CP (Costa & Pinto-Gouveia, 2013). The Spanish version of the SCS had good internal consistency ($\alpha = 0.87$) and test–retest stability ($r = 0.92$; Garcia-Campayo et al., 2014).

2.2.3 | Secondary outcomes

Pain interference

The Brief Pain Inventory (BPI) 'interference' subscale (Cleeland & Ryan, 1994) measured how much pain interferes with daily aspects, such as mobility or social activities. It included 7-point Likert-type items that can be scored from 0 ('does not interfere') to 10 ('completely interferes'). IMMPACT recommends its use as a measure of functioning in clinical trials (Dworkin et al., 2005). The Spanish version of the BPI had good psychometric properties and the interference subscale, in particular, presented high internal consistency ($\alpha = 0.89$) and acceptable test–retest reliability ($r = 0.77$; Badia et al., 2003).

Pain intensity

The Pain Visual Analogue Scale (McCormack et al., 1988) measured the intensity of the pain experienced. It consisted of a horizontal line divided into 10 equal parts that range

from '0 = no pain' to '10 = greatest pain ever experienced'. Participants indicated the number in the horizontal line that best reflects their level of pain. The scale had good test–retest reliability ($r = 0.87$) for CP (Boonstra et al., 2008).

Anxiety and Depression Symptoms

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) was a 14-item self-reported instrument designed for clinical populations with physical symptoms or conditions. It explored the symptoms of anxiety (7 items) and depression (7 items) experienced during the last 7 days with a 4-point Likert scale. Two final scale scores were calculated, one for the anxiety subscale (from 0 to 21 points) and one for the depression subscale (from 0 to 21 points). Higher values indicated more severe symptoms. The HADS accurately discriminated between depressed and non-depressed CP patients (Rusu et al., 2012). The Spanish version was reliable, with $\alpha = 0.83$ for the anxiety subscale and $\alpha = 0.87$ for the depression subscale (Vallejo et al., 2012).

QoL

The 36-item Health Survey (SF-36; Ware & Sherbourne, 1992) was a self-reported instrument that explored eight domains of QoL, namely physical functioning, physical role, body pain, general health, vitality, social functioning, emotional role and mental health. IMMPACT recommended its use as a measure of QoL in pain clinical trials (Dworkin et al., 2005). Two summary components (physical and mental) have been developed from its eight original dimensions (Vilagut et al., 2005). The Spanish version had an adequate internal consistency ($\alpha = 0.71$–0.94, except for the social functioning subscale whose α was 0.45) and acceptable test–retest reliability ($r = 0.58$–0.99; Alonso, 1995).

Pain catastrophizing

The Pain Catastrophizing Scale (PCS; Sullivan et al., 1995) was a 13-item measure that explored pain-related catastrophizing, including rumination, magnification and helplessness. Participants rated each item from 0 ('not at all') to 4 ('all the time'), based on how often they experienced a certain thought or feeling. The final scale score ranged from 0 to 52 points, where higher scores indicated greater catastrophic thinking in response to pain. The Spanish version of the scale had an adequate internal consistency (>0.7 for the total scale and subscales) and test–retest reliability (>0.7 for the total scale and subscales; García-Campayo et al., 2008).

Pain acceptance

The Chronic Pain Acceptance Questionnaire (CPAQ) was a 20-item self-reported measure assessing acceptance of pain (McCracken et al., 2004). The instrument explored (a) how much a person engaged in life activities *even when experiencing pain* and (b) how much a person disengaged from his or her attempts to control and/or avoid experiencing pain. Participants rated each item on a 7-point Likert scale, from 0 ('never true') to 6 ('always true'). The final scale score ranged from 0 to 48; higher scores indicated greater acceptance of pain. The Spanish version of the scale showed good internal consistency ($\alpha = 0.82$ for the activity engagement component and $\alpha = 0.78$ for the pain willingness component; Menéndez et al., 2010).

2.3 | Interventions

The intervention programmes (MSC and CBT) were conducted following two standardized treatment protocols (see below). Both of them consisted of a 150-min session (plus homework between sessions) once a week during 8 weeks formatted to groups of no more than 20 participants. The two programmes were mutually exclusive; the MSC did not include exercises that changed disruptive thoughts and beliefs and the CBT did not include mindfulness techniques or yoga exercises. Table 1 presents an overview of the programmes.

2.3.1 | MSC

Mindful Self-Compassion is a protocol-standardized intervention aimed at increasing mindfulness and self-compassion and reducing the suffering associated with experiential avoidance. It was designed and protocolized by Neff and Germer (Germer & Neff, 2019; Neff & Germer, 2013). It is not specific for CP. Adherence to the standard MSC protocol was strict, without specific reference to pain as a source of suffering.

The central components of the MSC were formal meditation together with formal and informal self-compassion practices aimed at developing cognitive, behavioural and physical abilities to soothe and comfort oneself when distressed. The outline of the programme was as follows: (a) general introduction and a review of self-compassion (what it is, and what it is not), (b) foundational knowledge and the practice of mindfulness, (c) application of self-compassion in various aspects of life and the practice of self-kindness, (d) recognition of the inner critic voice and development of a compassionate inner voice, (e) the importance of living in accordance with core values, (f) development of skills to deal with difficult emotions, like shame, (g) development of skills to deal with challenging interpersonal relationships and (h) development of skills to relate to positive aspects of oneself and to one's life with appreciation, including working on thankfulness.

2.3.2 | CBT

This was based on the Kovacs and Moix's protocol manual (Kovacs & Moix, 2011) and focused on training participants to

TABLE 1 Outline of the MSC and CBT sessions

Session number	MSC	CBT
1	• Discovering MSC • Soothing touch informal practice • Self-compassion break informal practice	• Psychoeducation • Introducing CBT
2	• Practicing mindfulness • Affectionate breathing • 'Soles of the feet' informal practice • 'Here-and-Now stones' informal practice	• Understanding the vicious circle: strain–pain–strain • Relaxation: ◦ Progressive muscle relaxation ◦ Diaphragmatic breathing
3	• Practicing loving-kindness • Awakening our hearts exercise • Compassion/loving-kindness meditation for a loved one • Finding loving-kindness phrases informal practice	• Attention techniques: ◦ Distraction ◦ Visualization • Presenting dysfunctional thoughts topic: ◦ ABC model ◦ About cognitive bias and dysfunctional thoughts
4	• Discovering your compassionate voice • Self-compassion/loving-kindness Meditation for ourselves • Motivating ourselves with compassion versus self-criticism exercise • 'Compassionate Letter to Myself' informal practice	• Working with dysfunctional thoughts: ◦ Working with diaries ◦ Detecting cognitive bias and dysfunctional thoughts ◦ Training strategies to change thoughts cognitive discussion
5	• Living deeply • Giving and receiving compassion meditation • 'Discovering Our Core Values' exercise • 'Living with a Vow' informal practice • 'Compassionate listening' informal practice	• Psychoeducation on emotions ◦ Explaining the relationship between difficult emotions and pain • Emotion regulation exercises ◦ Identifying difficult emotions and its Relation to pain ◦ Distance from unpleasant emotions
6	• Meeting difficult emotions • Strategies for meeting difficult emotions • 'Soften-Soothe-Allow' informal practice • Topic on the emotion of shame	• Interpersonal abilities • Working with interpersonal problems • Assertiveness
7	• Exploring challenging relationships • Compassionate friend meditation • 'Meeting Unmet Needs' exercise • 'Self-Compassion Break in Relationships' informal practice • 'Compassion with Equanimity' informal practice	• Working on life values and behavioural goals • Time scheduling: ◦ including enjoyable activities ◦ and self-care time
8	• Embracing your life • Compassion for self and others meditation • Cultivating happiness: 'Savouring' and 'Gratitude' informal exercises • 'Self-appreciation' exercise • Closing 'What Would I Like to Remember?'	• Education about paced physical activity • Education about body postures to prevent damage and pain • Relapse prevention

Abbreviations: CBT, cognitive-behavioural therapy; MSC, Mindful Self-Compassion.

manage their pain. Furthermore, we included CBT techniques most commonly practiced and studied for CP (Otis, 2007): (a) psychoeducation about CP and the relationship between thoughts, emotions and physical reactions; (b) relaxation and breathing techniques (abdominal breathing and progressive muscle relaxation); (c) cognitive restructuring, instruction and practice of changing dysfunctional thoughts (including catastrophizing) and common beliefs among individuals with CP (e.g. inability to control pain, hurt equals harm); (d) psychoeducation on emotions and how to regulate them; (e) interpersonal abilities; (f) attention techniques, such as distraction and visualization exercises; (g) life values, behavioural goals, time scheduling (including pleasure activities) and self-care time and (h) paced physical activity and education about body postures to prevent pain.

Both interventions were offered as a supplement to usual care, which included primary care follow-up, drug therapy, physical therapy and/or surgical procedures.

2.4 | Procedure

First, one of the researchers (APT) went over the records of the Chronic Pain Liaison Program to identify outpatients who had been visiting the department for more than 3 months. Then, she excluded patients who were under 18 years. The remaining records were of eligible participants. The team tried to contact all of them to inform them of the study. Participants who were interested were given an appointment where they were requested to fill in the informed consent form and the self-administered HADS and participate in a semi-structured diagnostic interview. Participants who met all the inclusion criteria were asked to take a brief clinical interview. After considering the exclusion criteria, a unique identifier was assigned along with completing the rest of the baseline assessment, either during this or the next scheduled visit. Once the baseline assessment was completed, the participants were informed about the date, time and location of the interventions. Neither the result of the allocation process nor the information regarding the study hypothesis was revealed until the day before the first session.

The recruitment stopped either the day before the intervention started or once the maximum number of participants per randomization ($n = 40$) was reached, whichever was earlier. Then, one of the authors (RM), who neither took part in the enrolment of the participants nor was present in the intervention group, randomly allocated each identifier to one of the treatment groups (ratio 1:1). The sequence was obtained through the TeamMaker™ software (http://chir.ag/projects/team-maker/) and no restrictions (i.e. blocking) were applied. Once randomized, the participants were contacted and informed about the assigned treatment (they were not blinded to the type of intervention). Post-treatment assessments were conducted by a research assistant (CRG), who was blinded to the treatment allocation for 7 days after the last session. This procedure was repeated at each randomization.

2.5 | Sample size calculation

To detect the medium effect size ($f^2 = 0.15$) on the primary outcome (SCS) with two predictors (treatment group and baseline scores), 73 participants were required for $\alpha = 0.05$ (two-tailed) and $1 - \beta = 0.90$. Considering an attrition rate of 20%, we required a sample size of at least 88 participants.

2.6 | Statistical analysis

Appropriate descriptive statistics were calculated (percentages, medians, means and standard deviations) depending on the variables' distributions. Further analyses utilizing goodness-of-fit tests were conducted to check the probability distributions of continuous variables.

To identify the baseline differences in relevant variables, the Pearson's chi-squared test was conducted for categorical and ordinal variables, and independent samples *t* tests were conducted for continuous variables (where the distribution was not normal, the Mann–Whitney *U* test was conducted).

To estimate the comparative average treatment effect (ATE) on the primary and secondary outcomes, generalized estimated equation (GEE) modelling was used (the post-treatment score was the dependent variable and the treatment group was the independent variable). The pre-treatment score was introduced as a covariate, even if the two groups were equivalent at baseline. The final ATE estimators (*B*) were obtained, along with their 95% confidence intervals. An exchangeable working correlation structure was introduced because it was assumed that the correlation between any two measurements was the same for each individual. For these types of longitudinal data, GEE models are recommended because they allow for within-subjects' observations to be correlated and for such correlation structures to be introduced in the model (Zeger & Qaqish, 1988).

Additionally, between-group and within-group effect sizes (standardized mean difference [SMD]) for all outcomes have been included.

The main analyses were conducted on all randomized participants (intention-to-treat). If values were missing either at random or completely at random, expectation-maximization imputation techniques were used. Per-protocol sub-analyses were also carried out. All statistical analyses were performed using SPSS version 21.0 (IBM Inc.).

3 | RESULTS

A total of 251 eligible participants were evaluated over the study period (18 months, 6 randomizations). Among them, 159 met the inclusion criteria, and 123 completed the baseline assessment and were randomized. However, 120 received the intervention (attended at least one session) and 89 were assessed for the primary outcome (SCS) at follow-up (MSC: $n = 42$, CBT: $n = 47$). Figure 1 depicts the flowchart of the participants.

Participants' characteristics and baseline outcomes are presented in Table 2. Most of the participants were women (87.8%). One-third of the sample included highly educated people (university degree), and only 22% of the participants were working at the time of enrolment. The participants rated the intensity of their pain with a mean of 7.5 points (out of 10), and most of them were diagnosed with adjustment disorder (66.7%). Baseline characteristics and outcomes were equivalent in both the groups.

Two statistical analyses were conducted. The first one was an intention-to-treat analysis with the imputation of missing data (expectation-maximization method). The second one was a per-protocol analysis. Table 3 presents the main results

of the study. In both analyses, ATEs were higher in the experimental arm.

Between-group and within-group SMDs are provided in Table 4.

3.1 | Primary outcome

Average treatment effects on the primary outcome (self-compassion) in the intention-to-treat (ITT) analyses favoured MSC with 95% confidence intervals.

The per-protocol analysis also favoured MSC over CBT on the basis of the primary outcome.

3.2 | Secondary outcomes

Average treatment effects on the secondary outcomes, pain interference, anxiety symptoms and pain acceptance, in the ITT analyses, favoured MSC with 95% confidence intervals.

Results also suggest trends in that MSC might be more effective in reducing pain interference, pain catastrophizing and anxiety symptoms, and improving pain acceptance ($p < 0.10$).

The per-protocol analysis demonstrated that MSC produced greater effects compared to CBT on pain interference, pain catastrophizing, anxiety and depressive symptoms, and pain acceptance.

No adaptations of MSC or CBT were required. No major adverse events (i.e. hospitalization in a psychiatric unit or visits to the emergency department because of psychological distress) were detected during the study period.

4 | DISCUSSION

In accordance with our hypotheses, MSC was superior to CBT in its effects on the primary (self-compassion) and most of the secondary outcomes (pain interference, anxiety and pain acceptance). Furthermore, the per-protocol analysis showed that MSC had a greater effect on depression symptoms too.

4.1 | Primary outcome: self-compassion

Regarding the primary outcome, in this study, it was found that MSC was more effective than CBT for improving

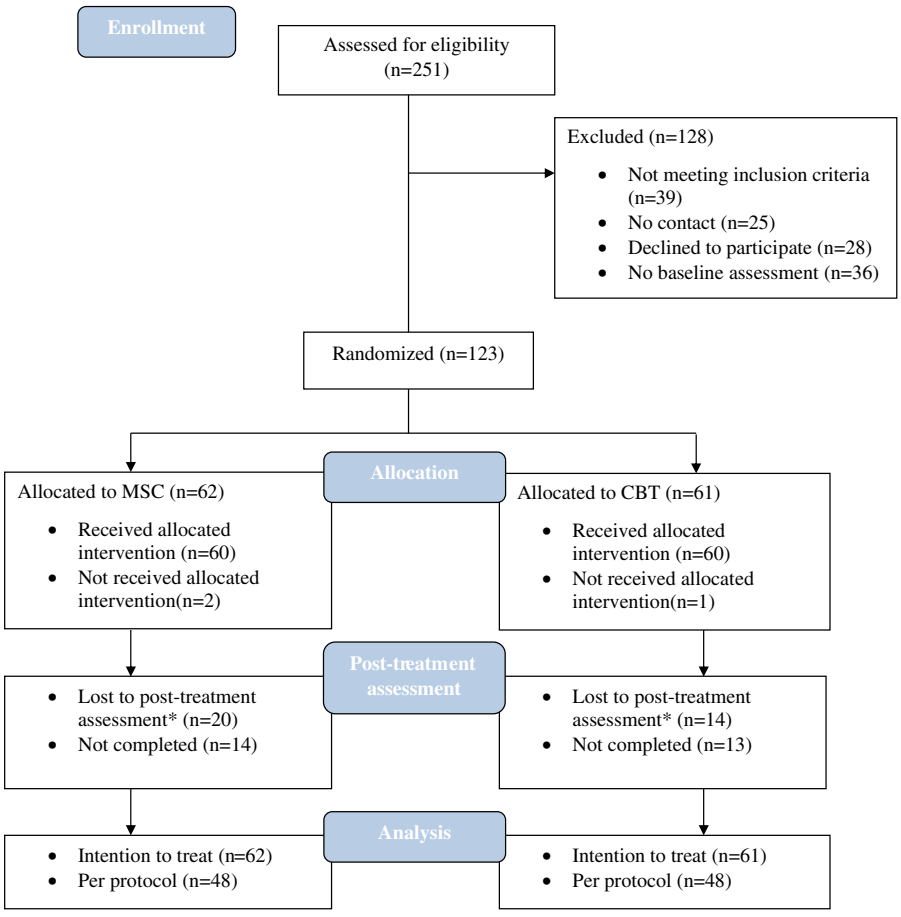

FIGURE 1 Participant flowchart. *Primary outcome. CBT, cognitive-behavioural therapy; MSC, Mindful Self-Compassion

TABLE 2 Sociodemographic and clinical characteristics at baseline

	MSC ($n = 62$)	CBT ($n = 61$)	Total sample ($n = 123$)	Hypothesis testing (MSC vs. CBT)
Age (years), *M* (*SD*)	48.29 (10.17)	49.25 (11.39)	48.76 (10.75)	$t(121) = -0.491$, $p = 0.624$[a]
Gender, *n* (%)				$\chi^2(1) = 0.740$, $p = 0.390$[b]
Women	56 (90.3)	52 (85.2)	108 (87.8)	
Men	6 (9.7)	9 (14.8)	15 (12.2)	
Level of education, *n* (%)				$\chi^2(2) = 2.744$, $p = 0.433$[b]
Primary degree	6 (9.7)	5 (8.2)	11 (8.9)	
Secondary degree	37 (59.7)	34 (55.7)	71 (57.7)	
University degree	19 (30.6)	22 (36.1)	41 (33.3)	
Job status, *n* (%)				$\chi^2(4) = 0.609$, $p = 0.962$[b]
Employed	13 (21)	14 (23.0)	27 (22)	
Housework	7 (11.3)	6 (9.8)	13 (10.6)	
Unemployed	7 (11.3)	5 (8.1)	12 (9.8)	
Retired	9 (14.5)	9 (14.8)	18 (14.6)	
Sick leave or disability	25 (41.9)	28 (45.9)	53 (43.1)	
Medical visits in the last 3 months, *n* (%)				$\chi^2(3) = 0.751$, $p = 0.861$[b]
None	2 (4.5)	1 (2)	3 (3.2)	
1	3 (6.8)	5 (9.8)	8 (8.4)	
2–5	12 (27.3)	14 (27.5)	26 (27.4)	
>5	27 (61.4)	31 (60.8)	58 (61.1)	
Duration of pain (in months), *n* (%)				$\chi^2(2) = 4.046$, $p = 0.132$[b]
6–12 months	5 (8.1)	1 (1.6)	6 (4.9)	
1–3 years	11 (17.7)	17 (27.9)	28 (22.8)	
>3 years	46 (74.2)	43 (70.5)	89 (72.4)	
Attrition, *n* (%)	13 (21.0)	14 (23.0)	27 (22.0)	$\chi^2(1) = 0.029$, $p = 0.865$[b]
DSM-5 diagnosis, *n* (%)				$\chi^2(2) = 0.306$, $p = 0.858$[b]
Adjustment disorder	42 (67.7)	40 (65.6)	82 (66.7)	
Major depressive disorder	8 (12.9)	10 (16.4)	18 (14.6)	
Dysthymia	12 (19.4)	11 (18.0)	23 (18.7)	
Primary outcome, *M* (*SD*)				
Self-compassion (SCS) *(0–5)*	2.72 (0.58)	2.62 (0.43)	2.67 (0.51)	$t(113) = 1.068$, $p = 0.288$[a]
Secondary outcomes, *M* (*SD*)				
Pain intensity (PAVS) *(0–10)*	7.52 (1.54)	7.52 (1.48)	7.52 (1.51)	$Z = -0.385$, $p = 0.701$[c]
Pain interference (BPI), *(0–10)*	6.99 (1.29)	7.11 (1.82)	7.02 (1.57)	$t(108) = -0.618$, $p = 0.788$[a]
Pain acceptance (CPAQ), *(0–156)*	39.99 (12.48)	37.64 (15.65)	38.82 (14.14)	$t(121) = 0.921$, $p = 0.359$[a]
Catastrophizing (PCS), *(0–52)*	33.36 (10.12)	35.60 (8.73)	34.47 (9.49)	$t(121) = -1.314$, $p = 0.191$[a]
Health, physical (SF-36) *(0–100)*	34.27 (7.57)	35.14 (9.02)	34.70 (8.30)	$t(121) = -0.585$, $p = 0.560$[a]
Health, mental (SF-36) *(0–100)*	23.05 (12.73)	22.39 (11.56)	22.72 (19.70)	$t(121) = 0.303$, $p = 0.763$[a]
Depression (HADS) *(0–21)*	11.51 (3.88)	11.56 (4.14)	11.53 (3.99)	$t(121) = -0.065$, $p = 0.948$[a]
Anxiety (HADS) *(0–21)*	12.72 (3.21)	12.34 (3.67)	12.53 (3.44)	$t(121) = 0.604$, $p = 0.547$[a]

Note: Italicized brackets show the score rank for each scale.

Abbreviations: BPI, Brief Pain Inventory; CBT, cognitive-behavioural therapy; CPAQ, Chronic Pain Acceptance Questionnaire; HADS, Hospital Anxiety and Depression Scale; MSC, Mindful Self-Compassion; PAVS, Pain Visual Analogue Scale; PCS, Pain Catastrophizing Scale; SCS, Self-Compassion Scale; SF-36, SF-36 Health Survey.

[a]Independent samples *t* tests (degrees of freedom in brackets).

[b]Chi-squared test of independence (degrees of freedom in brackets).

[c]Mann–Whitney's *U* test.

self-compassion (small-to-medium effect size difference). This concurs with published research in various populations, other than in CP patients, that has found compassion-based interventions to have a significant effect on self-compassion when compared with an active control (Kirby et al., 2017). Prior to this study, no specific data existed on the changes in self-compassion after interventions for CP since most recent studies in this field did not collect data on the self-compassion outcome (Carson et al., 2005; Montero-Marín et al., 2018). Given that self-compassion is an effective way to cope with life stressors, including CP (Wren et al., 2012), this result seems relevant. Self-compassionate individuals ruminate less (Odou & Brinker, 2014), are usually not perfectionists, have less fear of failures (Killham et al., 2018) and intrinsically motivate themselves with a compassionate voice to change their lives for the better (Zhang & Chen, 2016). In contrast, self-criticism, common among people with chronic medical conditions, results in poor self-care. Working on self-compassion may enhance health-promoting behaviours due in part to its link to adaptive emotions (Homan & Sirois, 2017; Sirois et al., 2015; Terry et al., 2013), even in chronic medical populations (Brion et al., 2014), including CP.

4.2 | Secondary outcomes

4.2.1 | Anxiety and depression symptoms and pain acceptance

Among the secondary outcomes, the results on pain acceptance and anxiety were remarkable; while both interventions were effective to some extent, MSC was superior to CBT in increasing pain acceptance (medium effect size difference) and reducing anxiety (small effect size difference).

The first RCTs conducted to test the effectiveness of CBT for CP found small-to-medium effect size changes in anxiety. However, subsequent meta-analyses (Morley et al., 1999; Williams et al., 2012) concluded that CBT-based programmes have no significant effect on mood and anxiety when compared with an active control. Acceptance-based interventions and MBIs have shown medium effect size reductions in anxiety symptoms after treatment (Luciano et al., 2014; Wicksell et al., 2013; Wong et al., 2011). There have been few previous studies on self-compassion-based interventions for CP, which are more relevant to our results. Montero-Marín et al. found that a compassion-based intervention (different from MSC) produced a large effect on anxiety (Montero-Marín et al., 2018).

Regarding pain acceptance, our study indicated that MSC produced better results than CBT, although acceptance had improved even after CBT (a small effect size change after treatment); this is in accordance with previous literature that has observed that MBIs increased pain acceptance (La Cour & Petersen, 2015; Turner et al., 2016). Traditionally, research is focused on pain, coping and catastrophizing as the typical action mechanisms of CBT. However, recent studies have projected acceptance also as an indicator of the benefits achieved with CBT (Åkerblom et al., 2015; Baranoff et al., 2013; Turner et al., 2016). Acceptance has been considered as one of the most relevant action mechanisms of third-wave therapies, including MBIs (Day & Thorn, 2016; La Cour & Petersen, 2015). The MSC program proved effective in increasing acceptance and reducing avoidance in a couple of earlier studies (Edwards et al., 2019; Neff & Germer, 2013). It buffered the degree to which intolerable pain sensations were experienced and immediately avoided (Shapiro et al., 2006). Despite the level of pain, lesser avoidance led to better adjustment and lesser pain interference (McCracken & Eccleston, 2005). Therefore, we hypothesized that improvement of pain acceptance may be a common result of different therapies, even beyond CBT or MBIs.

4.2.2 | Pain interference

In accordance with a recent meta-analysis (Veehof et al., 2016), MBIs reduced pain interference, as in this study, where pain `reduction was higher in MSC than in CBT. We hypothesized that MSC might regulate pain interference by working on values and facilitating people with CP to focus on and engage in valued or worthy aspects of their lives, instead of in pain and fear. This was achieved through less avoidance and more proactive behaviour when coping with difficulties.

4.2.3 | QoL, pain intensity and pain catastrophizing

No treatment effects were found in this study for pain intensity and QoL general indexes. Studies that analysed the components of QoL separately found improvements, particularly in vitality (de Jong et al., 2017; La Cour & Petersen, 2015) and physical functioning (Khoo et al., 2019). Besides, a significant reduction in catastrophizing was found in the MSC arm; previous literature has stated that self-compassion was related to low levels of pain catastrophizing (Wren et al., 2012).

In our point of view, suffering in CP may be divided into five core components: (a) struggle with cognitive aspects (high self-criticism; [Smith & Osborn, 2007; Toye et al., 2013], rumination about difficult aspects of the self, over-identification, worries about attaining personal goals and concerns about being able to fulfil one's personal and

TABLE 3 The estimated marginal means and average treatment effects (*B*) for primary and secondary outcomes at post-intervention

	Intention to treat ($n = 123$)			Per-protocol ($n = 96$)		
	MSC ($n = 62$)	**CBT ($n = 61$)**	***B*[a]**	**MSC ($n = 48$)**	**CBT ($n = 48$)**	***B*[a]**
Primary outcome						
Self-compassion (SCS) *(0–5)*	2.87 (2.64, 3.12)	2.75 (2.52, 2.98)	0.126 (–0.000, 0.252)**	2.87 (2.59, 3.16)	2.72 (2.43, 3.01)	0.152 (–0.002, 0.306)*
Secondary outcomes						
Pain intensity (PAVS) *(0–10)*	6.93 (5.04, 9.53)	7.10 (5.17, 9.76)	–0.024 (–0.082, 0.034)	7.05 (4.91, 10.14)	7.21 (5.02, 10.36)	–0.022 (–0.092, 0.048)
Pain interference (BPI), *(0–10)*	6.59 (4.99, 8.19)	6.98 (5.45, 8.51)	–0.393 (–0.760, –0.029)**	6.61 (4.61, 8.62)	7.05 (5.18, 8.91)	–0.433 (–0.876, 0.010)*
Pain acceptance (CPAQ), *(0–156)*	45.51 (–24.49, 115.51)	40.29 (–29.49, 110.12)	5.214 (1.870, 5.560)***	45.92 (–41.07, 132.92)	39.56 (–47.66, 126.79)	6.361 (2.140, 10.580)***
Catastrophizing (PCS), *(0–52)*	30.01 (–18.86, 78.88)	32.15 (–16.75, 81.05)	–2.139 (–4.596, 0.317)*	30.10 (–29.97, 90.17)	38.82 (–27.27, 92.91)	–2.791 (–5.721, 0.283)*
Health, physical (SF-36) *(0–100)*	35.76 (0.85, 70.67)	34.25 (–1.23, 69.72)	1.510 (–0.347, 3.367)	36.03 (–7.15, 79.21)	34.26 (–9.56, 78.08)	1.772 (–0.497, 4.040)
Health, mental (SF-36) *(0–100)*	25.77 (5.78, 114.84)	24.87 (5.74, 107.78)	0.035 (–0.089, 0.160)	25.91 (4.36, 153.87)	23.99 (4.19, 137.42)	0.077 (–0.075, 0.229)
Depression (HADS) *(0–21)*	10.11 (4.51, 15.71)	10.74 (4.96, 16.52)	–0.628 (–1.497, 0.241)	10.24 (3.39, 17.09)	11.23 (4.16, 18.31)	–0.993 (–2.033, 0.047)*
Anxiety (HADS) *(0–21)*	10.82 (4.67, 16.96)	11.72 (5.58, 17.86)	–0.902 (–1.770, –0.034)**	10.81 (2.92, 18.70)	11.99 (4.10, 19.89)	–1.183 (–2.262, –0.104)**

Note: Non-italicized brackets show 95% confidence intervals; italicized brackets show the score range for each scale.

Abbreviations: BPI, Brief Pain Inventory; CBT, cognitive-behavioural therapy; CPAQ, Chronic Pain Acceptance Questionnaire; HADS, Hospital Anxiety and Depression Scale; MSC, Mindful Self-Compassion; PAVS, Pain Visual Analogue Scale; PCS, Pain Catastrophizing Scale; SCS, Self-Compassion Scale; SF-36, SF-36 Health Survey.

[a]Dependent variables: SCS, PAVS, BPI, CPAQ, PCS and SF-36 (2) and HADS (2) at post-intervention; independent variable: treatment arm (MSC or CBT); covariate: SCS, PAVS, BPI, CPAQ, PCS and SF-36 (2) and HADS (2) at baseline.

*$p < 0.10$.

**$p < 0.05$.

***$p < 0.01$.

TABLE 4 Between-groups (post-treatment) and within-groups standardized mean differences (SMD)

	Between-groups[a] SMD[b]	Within-groups CBT SMD[b]	Within-groups MSC SMD[b]
Pain Interference (BPI) *(0–10)*	0.33	0.003	0.29
Pain Intensity (PVAS) *(0–10)*	0.07	0.24	0.35
Self-Compassion (SCS) *(0–5)*	0.39	0.24	0.35
Pain Acceptance (CPAQ) *(0–156)*	0.49	0.11	0.50
Catastrophizing (PCS) *(0–52)*	0.38	0.32	0.48
Physical Health (SF-36) *(0–100)*	0.10	0.06	0.15
Mental Health (SF-36) *(0–100)*	0.12	0.24	0.34
Depression (HADS) *(0–21)*	0.18	0.20	0.43
Anxiety (HADS) *(0–21)*	0.24	0.21	0.74

Note: Italicized brackets show the score range for each scale.

Abbreviations: BPI, Brief Pain Inventory; CBT, cognitive-behavioural therapy; CPAQ, Chronic Pain Acceptance Questionnaire; HADS, Hospital Anxiety and Depression Scale; MSC, Mindful Self-Compassion; PAVS, Pain Visual Analogue Scale; PCS, Pain Catastrophizing Scale; SCS, Self-Compassion Scale; SF-36, SF-36 Health Survey.

[a]Every between-groups SMD favoured MSC.

[b]SMD = (M1 − M2)/Pooled *SD*.

work-related responsibilities), (b) difficult emotions (fear of pain, fear of being criticized or seen as a burden, shame, guilt or helplessness; Purdie & Morley, 2016; Smith & Osborn, 2007), (c) unpleasant or painful bodily sensations (related to physical pain itself or to physical sensations that correlates with difficult emotions), (d) behavioural aspects (pain avoidance and general experiential avoidance of activities and events that evoke difficult emotions, which, in turn, increases disability) and (e) social disconnection, isolation and loneliness derived from the previous points. Self-compassion helps people to cope with this suffering through the following core mechanisms: (a) stimulating the soothing system related to attachment in mammals, which is a natural regulator of the threat system (Stellar & Keltner, 2014), (b) regulating the influence of the achievement system when evaluating oneself with respect to worthiness (Depue & Morrone-Strupinsky, 2005; Purdie & Morley, 2016), (c) promoting active attitudes, reducing helplessness and facilitating change providing encouragement through warm and supporting voices (Gardner-Nix, 2009; La Cour & Petersen, 2015), (d) facilitating the self-efficacy perception when approaching and managing emotions and difficulties, thereby reducing experiential avoidance, (e) promoting non-judgemental kindness, curiosity, openness, moment to moment attitude towards the whole experience (Kabat-Zinn & Hanh, 2009), especially to the experience of pain, suffering, and failures and understanding that these experiences are unavoidable and part of the human condition, thus improving connectedness (Edwards et al., 2019) and (f) facilitating the engagement in value-based activities and reducing the impact that CP has on important domains of life, rather than reducing pain intensity itself (Edwards et al., 2019).

4.3 | Strengths and limitations

Several methodological features of this study are noteworthy. Since most participants had more than 3 years of pain (72.4%), high levels of emotional distress and psychopathology (66.7% adjustment disorder, 14.6% major depressive disorder and 18.7% dysthymia), extensive histories of unsuccessful treatments in specialized units with high rates of medical visits (61.1% had visited a doctor more than 5 times in the last 3 months because of pain) and short- or long-term disability to work (43.1%), the fact that psychological treatments were effective is encouraging. To protect external validity, we tried to minimize the selection bias (i.e. not rejecting people with pending disability claims or comorbidities). Other strengths included IMMPACT-recommended outcomes, random allocation, blind outcome assessment, an active control group that has already widely demonstrated effectiveness, programmes conducted by certified MSC teachers and well-trained CBT therapists and high levels of therapy manualization to facilitate replication.

Limitations include moderate attrition rates (around 20%, in accordance with most RCTs on psychotherapeutic interventions for CP; Glombiewski et al., 2010; Luciano et al., 2014), absence of a third control non-active group or usual care, absence of follow-up and non-systematic registration of adverse events, which would have been really valuable (Sharpe, 2020). All measures were based on patient-reported outcomes. Including objective outcomes, such as return to work and ecological momentary assessment method (Garcia-Palacios et al., 2014), may more clearly reflect wider impacts and improve ecological validity.

5 | CONCLUSIONS

The results of this randomized, controlled trial comparing two interventions in adult patients with CP conducted at the MHD of a tertiary hospital suggest that both MSC and CBT have beneficial effects implemented together with standard medical management; however, MSC offers greater benefits to self-compassion, pain interference, pain acceptance, pain catastrophizing and emotional well-being than the CBT intervention.

Our results were meaningful for a specific group of CP patients: women, highly educated people, patients with CP and comorbid psychopathologies, undergoing treatment in specialized units (non-primary care units) who were referred to the Chronic Pain Liaison Program of the MHD with a prolonged history of pain, medical visits and previous treatments (following the therapeutic ladder for pain management by the OMS). These kinds of patients have few therapeutic alternatives left; MSC seems to be a very valuable therapeutic alternative when there is a great level of suffering and previous treatments have failed.

Future research may help in identifying the differences and commonalities between MSC and CBT that may promote pain-related improvements and patient characteristics that may predict better compatibility with specific treatment approaches. Both aspects are essential to establish clinical guidelines. Previous literature pointed out that self-compassion alone improved functioning in CP patients (Edwards et al., 2019). Therefore, tailoring interventions that target self-compassion more directly may be warranted in the future, even if they are not compassion-based. Psychological treatments for CP, in any form (CBT, ACT, MBSR, etc.), may improve, in particular the emotional functioning outcomes (Davey et al., 2020), with the introduction of self-compassion training and a self-compassionate attitude from the therapists.

Mindfulness-based intervention, in particular, compassion-based interventions, help in recognizing a person as worthy of compassion, respect, dignity and forgiveness, especially when facing failure, pain, discomfort, physical and/or psychological suffering. Given the emotional benefits of compassion, we would like to encourage therapists to include this component and recognize the importance of this human emotion in whatever practice or technique they adopt.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

AUTHOR CONTRIBUTIONS

APT, BRV and MTZ conceived and designed the study and collected the data. CRG and ILA collected the data. RM made randomizations and data analysis. APT, MTZ and RM wrote the paper and reviewed the successive versions of the manuscript. BRV reviewed the successive versions of the manuscript and made relevant contributions to the manuscript. MDRD made relevant contributions to the manuscript. All authors discussed the results and commented on the manuscript, and all of them read and approved the final version of the manuscript.

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