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Original article

Mindfulness-based stress reduction for chronic pain and health-related quality of life after intensive care unit discharge

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Abstract. *Aim:* To test the efficacy of a mindfulness-based stress reduction (MBSR) program on pain management and on quality of life among chronic pain patients discharged from the intensive care unit (ICU). *Methods:* A mindfulness-based stress reduction intervention, aimed at improving pain management was implemented in a sample of 43 survivors of critical illness who suffered from chronic pain at an ICU. In this observational study, data were collected before (T0= 12 months after ICU discharge) and after the adoption of a MBSR program (T1 = 10 months after intervention). The Brief Pain Inventory-Short Form (BPI-SF) and EuroQol-5 Dimension (EQ-5D) were used. *Results:* The Brief Pain Inventory showed a significant reduction in worst pain in the last 24 h ($p < .001$), least pain in the last 24 h ($p = .011$), pain on average ($p < .001$), and in terms of pain interference with mood ($p = .002$) and with sleep ($p < .001$). EQ-5D showed a significant reduction in the perception of moderate or extreme pain/discomfort ($p = .009$) and moderate to severe problems with anxiety/depression ($p = .031$). *Conclusion:* MBSR program seems to improve chronic pain intensity and to reduce the negative interference of pain on quality of life. Although the results are statistically significant, they do not appear to be clinically relevant. However, further studies with larger sample sizes and control groups are needed. (www.actabiomedica.it)

Key words: chronic pain, pain management, mindfulness-based stress reduction, intensive care units, survivors, quality of life, brief pain inventory, stress psychological, post-intensive care syndrome

Introduction

The Intensive Care Unit provides the treatment for critically ill patients experiencing organ failure and acute physiological derangement. Critical illness is now well recognized as being associated with numerous detrimental long-term consequences that can affect health-related quality of life for up to five years after ICU discharge (1). For many years, little attention has been given to the long-term consequences or complications experienced by patients after ICU discharge. Survival and mortality rates have dominated outcome measures in critical care research for decades (2). However, more recently patient-centered have become increasingly important. The long-term outcomes now more commonly investigated in critical care research now include functional capacity, various psychological factors, physical fitness, and quality of life (2). Research has shown that the majority of patients requiring intensive care experience varying degrees of pain during their stay. Importantly, recent studies reported that this pain often persists after discharge and can become

chronic if not properly treated (2). Chronic pain, defined as pain persisting for more than three months (3), is a common complication of Intensive Care Units. It has been reported in survivors of critical illnesses for many years after hospital discharge. Various studies report that the occurrence of chronic pain in survivors of Intensive Care Units (ICUs) ranges from 18% to 44% (2, 4). Psychosocial factors play key roles in pain and its associated psychosocial and physical disabilities (3, 4). In fact, four of the eight non-pharmacological treatments recommended for persistent pain include psychotherapy and mind-body components (5, 6) in addition to pharmacological treatments. One of these, Mindfulness-Based Stress Reduction (MBSR), a mind-body approach, focuses on increasing awareness and acceptance of moment-to-moment experiences, including difficult emotions and physical discomfort. MBSR is becoming increasingly popular and accessible worldwide. It is a widely disseminated and frequently cited example of mindfulness training, been shown to reduce anxiety, depression and stress (7, 8). Mindfulness-based interventions have been recognized as helpful for a range of conditions including chronic pain. However, the efficacy of the MBSR program on chronic pain management and quality of life remains unclear. A recent study compared the clinical effectiveness of the MBSR program with a multidisciplinary pain intervention (MPI) program in terms of pain intensity, pain-related distress, quality of life, and mood in patients with chronic pain (9). One randomized clinical trial of ninety-nine chronic pain patients, aged 24 to 64 years, showed a reduction in pain intensity and pain-related distress, though the differences were not statistically significant. Moreover, in chronic pain patients with arthritis**,** improvements in pain intensity and functional limitations are achieved through the MBSR program (10), with a positive impact on quality of life and psychological distress. However, patients affected by chronic headache or migraine showed a smaller improvement on pain intensity and on psychological distress in patients with fibromyalgia. These patients were taught and encouraged to meditation regularly in order to enhance the outcomes of MBSR (10). One study examined the effects of MBSR on health-related quality of life and physical and psychological symptomatology in a heterogeneous patient population (11). A total of 136 patients participated in an 8-week MBSR program and were required to practice 20 minutes of meditation daily. Pre- and post-intervention data were collected using the Short-Form Health Survey (SF-36), the Medical Symptom Checklist (MSCL) and Symptom Checklist-90 Revised (SCL-90-R). Health-related quality of life was improved as demonstrated by better scores on all indices of the SF-36, including vitality, bodily pain, role limitations due to physical health, and social functioning. Alleviation of physical symptoms was evidenced by a 28% reduction on the MSCL. Decreased psychological distress was shown by a 38% reduction on the Global Severity Index on the SCL-90-R by a 38%, a 44% reduction on the anxiety subscale, and a 34% reduction on the depression subscale. One-year follow-up revealed maintenance of initial improvements on several outcome parameters (11). Another study explored the impact of a Mindfulness-Based Stress Reduction (MBSR) intervention on people with metastatic cancer integrated in Early Palliative Care (EPC) (12). Feasibility and acceptability were assessed in 16 participants. In addition, pre-post measures of cancer pain and mood state were collected. Semi-structured, in-depth interviews were conducted with a subset of 8 participants at the end of the study and analyzed using the Interpretative-Phenomenological analysis. The results showed that the MBSR intervention help**s** patients to develop an accepting attitude towards metastatic cancer, assisting them in coping with anxiety and cancer pain. MBSR improves self-regulation of mood, fostering feelings of compassion. The MBSR program also supports participants in questioning and reconnecting with their values and spiritual beliefs (12). While several studies in the literature examine the effectiveness of MBSR programs none focus on chronic pain patients discharged from Intensive Care Units. Building on the aforementioned considerations and based on the hypothesis that psychotherapeutic interventions can positively impact patient health, this study aimed to evaluate the effectiveness of a mindfulness-based stress reduction (MBSR) program in managing pain and improving quality of life in chronic pain patients discharged from the ICU.

Methods

Design and setting

This observational study was conducted in a single ICU, where data were collected both before (T0= 12 months after ICU discharge) and after (T1= 10 months after intervention) the implementation of a Mindfulness-Based Stress Reduction program (Figure 1). The intervention involved integrating pharmacological treatment with MBSR. The study was conducted in an 8-bed adult ICU within the emergency department of a second-level hospital. It included adult patients admitted to ICU between March 2021 and July 2021, with follow-ups extended until August 15th, 2021. Common conditions treated in the ICU included acute respiratory distress syndrome (ARDS), trauma, multiple organ failure, post-operative surgical, and sepsis. Following their ICU stay, the patients were discharged to other departments within the 'Territorial Social Health Authority'. In this observational study, data were collected 12 months after ICU discharge and 10 months after the adoption of a MBSR program (2 hours per week for 8 weeks in a group format). Outcome measures included chronic pain assessed by the Brief Pain Inventory-Short Form (BPI-SF), perceived quality of life, assessed by EuroQol-5D, and pain management.

Eligibility criteria for participants

A total of 116 patients were contacted by telephone 12 months after ICU discharge. Of these, 3 patients (2.6%) declined to participate. A convenience sample of 43 patients (39.7%) with chronic non-cancer pain (CP) or who developed chronic pain after discharge was recruited for this study. Eligible participants were self-reporting patients, aged 18 years or older, who suffered from chronic non-cancer pain and had been admitted to the ICU at Lecco Hospital between March 1, 2021, and July 30, 2021. Additionally, only patients able to provide informed consent and without cognitive impairment were included. Patients with quadriplegia (from any cause), or those not

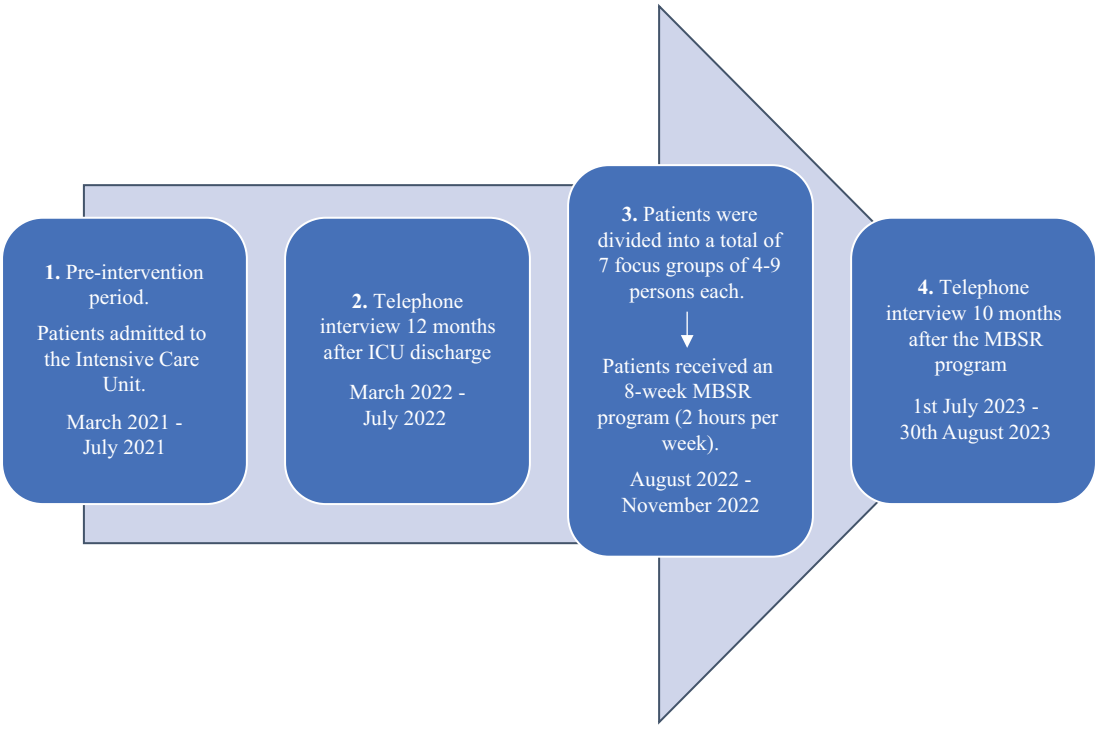

Figure 1. Timeline for implementation of the Mindfulness-Based Stress Reduction (MBSR) program.

autonomous enough to participate in the telephone interview were excluded.

Intervention

The Mindfulness-Based Stress Reduction protocol is a structured and systematic program centered around mindfulness meditation, designed to teach individuals how to take better care of themselves and live a healthier and more adaptive life (13). The official MBSR protocol was developed by Jon Kabat-Zinn at the Center for Mindfulness at the University of Massachusetts and was created with the aim of facilitating stress reduction and chronic pain management. Therefore, the specific objective of the MBSR course is to help participants reduce the level of subjective suffering and acquire and maintain greater well-being (13). Participants included in the study received usual care with drug therapy (NSAIDs, opioids, corticosteroids), treatment, and evaluations during the study period for chronic pain treatment. In addition, all 43 patients received an 8-week MBSR program (2 hours per week) in 7 groups (4-9 people each). The 8 sessions for the 7 groups were completed within a total of three months (March-July 2022) (Figure 1). In each of the 8 sessions were conducted during the 12 months after ICU discharge, a different topic was addressed, in line with the MBSR program and our research protocol: 1. Overview of mindfulness; 2. Facing difficulties; 3. Mindful breathing; 4. Staying present; 5. Allowing (letting it be); 6. Thoughts are not facts; 7. Taking care of yourself; 8. Dealing with future struggles. The contents of each session concerned: psychoeducation, exercise and homework for each theme. The original MBSR program was kept unchanged. However, we added a brief segment of psychoeducation to the first session to reflect on the distress of chronic pain and of patients suffering from it, to show how Mindfulness-Based Interventions can be helpful for it. Finally, lectures and exercises on compassion were provided to the participants. MBSR consisted of discussion and interaction among the participants in order to facilitate their learning, and of psychoeducation based on cognitive therapy and formal meditational exercises. Homework was assigned to the participants at every session, which was expected to take 20 - 45 minutes every day with a guided meditation CD. The qualified therapists of MBSR were clinical psychologists and nurses, who had at least 5 years of Mindfulness experience. All the therapists followed the intervention protocol schedule at each session to ensure homogeneity and integrity of treatment. Data were collected by two nurse researchers who are not involved in the treatment. There was no restriction on any co-interventions during the study period. However, patients were asked to refrain from participating in any type of Mindfulness-Based Interventions (MBIs) or from engaging in meditational exercises, yoga or other cognitive behavioral therapies during the study.

Primary outcome measures

The main outcome measure was chronic pain, defined as pain that persists or recurs for longer than 3 months (3). Such pain often becomes the predominant clinical problem in some patients. As such it may warrant specific diagnostic evaluation, therapy and rehabilitation. Chronic pain is a frequent condition, affecting an estimated 20% of people worldwide and it is a multifactorial condition: biological, psychological and social factors contribute to the pain syndrome (3). These data were obtained using the BPI-SF.

Secondary outcome measures

Secondary outcome measures were quality of life, intervention adherence, mindfulness skill measurement before and after the mindfulness training program, and pain treatment (i.e. opioids, non-opioids, NSAIDs, antidepressants, cortisone) and specific treatments for pain (i.e. radiofrequency).

Assessment and instrument

The study self-reported their demographic characteristics (gender, age, education, marital status) using a structured instrument developed by the research team, through private personal interviews to protect each participant's privacy, 12 months after ICU discharge during a telephone interview.

Pain occurrence, pain intensity, pain location, interference of pain with function were evaluated using

the Brief Pain Inventory–Short Form (BPI-SF) (14) 12 months after ICU discharge and 10 months after intervention during a telephone interview. We enrolled only patients suffering from chronic pain with drug therapy for at least 3 months. Patients were asked to indicate whether they felt pain (yes/no). If they did, they rated the severity of their average, least, and worst pain, ranging from 0 (no pain) to 10 (the worst pain imaginable), using the Numeric Rating Scale (NRS). Pain interference with the 7 domains of functioning was rated on a NRS from 0 (does not interfere) to 10 (completely interferes). Within the BPI-SF there is also the question: *What treatments or medications are you receiving for your pain?*

The BPI-SF has well-established validity and reliability in patients with cancer (15) or in ICU survivors (16), where it has exhibited sensitivity to change in longitudinal studies. The Italian validation was carried out by Bonezzi and colleagues in 2002 (16). We assessed the participants' Quality of Life (QOL) using the 3-level version of the EuroQol-5 Dimension (EQ-5D) introduced in 1990 by the EuroQol Group (17) 12 months after ICU discharge and 10 months after intervention during a telephone interview. The EQ-5D essentially consists of 2 pages: the EQ-5D descriptive system and the EuroQol-Visual Analogue Scale (EQVAS). The EQ-5D descriptive system comprises the following five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems, some problems, and extreme problems. The patient is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions. This decision results in a 1-digit number that expresses the level selected for that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state. The EuroQol-5D-Visual Analogue Scale (EQVAS) records the patient's self-rated health on a vertical visual analogue scale where the endpoints are labelled 'Best Imaginable Health State' and 'Worst Imaginable Health State'. The EQVAS can be used as a quantitative measure of health outcome that reflects the patient's own judgement. The Italian version was described and validated by Balestroni and Bertolotti in 2012 (18).

We used the Five Facet Mindfulness Questionnaire (FFMQ) to assess the participants' mindfulness skills (19- 20) 12 months after ICU discharge and 10 months after intervention during a telephone interview. This 39-item**,** self-administered questionnaire measures five domains of mindfulness skills – observing, describing, acting with awareness, non-judging of inner experience, and non-reacting to inner experience. This scale was used as a process measure of the intervention - to measure whether the participants have adopted mindfulness skills (19). The test consists of 39 items that measure the five facets, and the scores provide an estimate of where participants stand in terms of mindfulness and self-awareness. The subscales showed adequate internal consistency (Cronbach's alpha between 0.75 and 0.91). Responses on the scale are made on a 5-point Likert Scale, and the summation of the direct and reverse-scored items give the total score. The five facets, or key aspects of mindfulness that the test measures, act as mediators of mindful interventions and therapeutic change (21). There are two patterns of scoring involved in the Five Facet Mindfulness Quiestionnaire: i) Direct Scoring – where the items are scored according to the Likert value (for example 1 would add a score of 1 and 4 adds a value of 4) and ii) Reverse Scoring – where the items are scored backward (for example, 1 adds a score of 5, 5 adds a score of 1, 4 would mean a score of 2, and vice versa). Summation of all the direct and reverse items adds up to the total value of the scale. The FFMQ also provides an accurate judgment of the impact of any previous mindfulness practices. The development of this questionnaire was crucial, as it was one of the earliest measures that exploring the efficacy of mindfulness in overcoming real-life problems. The Italian validation was carried out by Didonna and colleagues in 2019 (20). Participants' adherence to the intervention was assessed by the frequency of attendance at the MBSR program. The patients who attended less than four (out of eight) sessions were considered dropouts, in line with the study protocol.

Ethical issues

The Introduction of the Mindfulness-Based Stress Reduction program on ICU patients was

supported by a pain management protocol, approved and implemented by Comitato Ospedale Senza Dolore (Committee Against Hospital Pain). The study protocol was in line with the Declaration of Helsinki, as revised in 2013, and was approved by the Institutional Ethics Committee (Inter-company committee of Brianza, No. 320 of 10/12/2021). All participants provided their informed written consent to participate during their ICU stay, at the follow-up visit, or at the time of discharge. Consent was obtained from the nursing staff. Only patients who had given their consent participated in the follow-up interview, which occurred 12 months after ICU discharge. Detailed history-taking, including medical history, was conducted for all participants, and written informed consent was also obtained.

Statistical methods

A descriptive analysis of all variables was conducted. Data analysis was performed blindly by a staff member who was not involved in the study and who was neither aware of its aim nor of the patient group to which the data belonged. Descriptive statistics, Standard Deviations (SD) and Means (M), and relative and absolute frequencies were calculated. Between-group comparisons were performed using the Student's T Test (ratio level variables) and Chi-Square Test (nominal variables).

The Statistical Package for the Social Sciences (SPSS) software, version 2,1 was used for the analysis of patient data (IBM SPSS Statistics, Version 21.0 Armonk, NY: IBM Corp.)

The level of significance was set at p <0 .05.

Results

Baseline participant characteristics

Forty-three patients were enrolled in our study, of which 30 (69.8%) were men, and 72% were undergoing surgery (Table 1). The mean age of the subjects interviewed was 65.1 years, with an average ICU stay of 17.9 days and an average hospital stay of 20.7 days (Table 1). Patients reported pain in a total of eight body areas. The most prevalent pain site was the

Table 1. Demographic and clinical characteristics of patients included in the study.

Characteristics	**N = 43**
Age, mean (sd) y	65.1 (± 9.3)
Gender, n (%)	
Male	30 (69.7)
Female	13 (30.3)
Anthropometric data	
Weight, mean (sd), kg	74.9 (± 10.1)
BMI, mean (sd)	27.7 (± 2.6)
BMI> 30, n (%)	14 (32.6)
ICU admission diagnosis, n (%)	
Medical	10 (23.3)
Surgical	31 (72.1)
Trauma	2 (4.6)
Level of education <15 yr, n (%)	14 (32.6)
ICU length of stay (days), mean (sd)	17.9 (±16.9)
Hospital length of stay (days), mean (sd)	20.7 (±12.8)
Use of invasive ventilation for patients, n (%)	38 (88.4)
Length of invasive mechanical ventilation (hours per patient), mean (sd)	279.18 (± 365.48)
Use of non-invasive ventilation for patients, n (%)	15 (34.9)
Length of non-invasive mechanical ventilation (hours per patient), mean (sd)	66.7 (± 100.2)
APACHE II, mean (sd)	15.25 (7.1)
APACHE II> 20, n (%)	7 (16.3)
Tracheostomy, n (%)	10 (23.2)
Advanced cardiovascular/amine support, n (%)	15 (34.9)
Renal/Dyalisis support, n (%)	4 (9.3)
Septicaemia and septic shock, n (%)	11 (25.6)
Pain locations, n (%)	
Shoulder/Upper arm Neck Ankle/Foot Knee Lower back Upper back Head Abdomen	19 (44.2) 9 (20.9) 8 (18.6) 8 (18.6) 8 (18.6) 6 (13.9) 3 (6.9) 1 (2.3)
Number of pain sites for patient, n (%) 1 2 3	 26 (60.4) 15 (34.9) 2 (4.7)

Abbreviations: SD= standard deviation; Y= year; N= number; KG = kilograms; BMI = Body Mass Index; ICU = Intensive Care Unit; APACHE II = Acute Physiology and Chronic Health Evaluation II, it is applied within 24 hours of admission of a patient to an ICU.

shoulder/upper arm (44.2% of patients), and 34.9% reported pain in two or more different sites. (Table 1).

Intervention adherence

Eight out of the 43 patients attended less than four sessions and were thus considered dropouts (dropout rate = 18.6%) 12 months after enrollment. No interviews were conducted with these eight patients 10 months after the MBSR intervention. The reasons for not participating in MBSR sessions or follow-up interviews (in line with study protocol) were health problems, family issues, issues related to caregiving and work circumstances. The mean number of sessions attended was 7.2.

The benefits of MBSR program on chronic pain

Ten months after the 8-week MBSR program (range: 298-334 days), all patients interviewed still suffered from chronic pain. Using the BPI-SF, the intervention had a significant effect on the reduction in terms of pain intensity (worst pain in the last 24 h: $t_{(34)}$ = 5.767, p < .001; least pain in the last 24 h: $t_{(34)}$ = 2.692, p = .011; pain on average: $t_{(34)}$ = 4.828, p < .001) and in pain interference (interference with mood: $t_{(34)}$ = 3.271, p = .002; interference with sleep: $t_{(34)}$ = 4.889, p < .001) 10 months after MBSR intervention (Table 2). We note that significant differences in terms of pain intensity (right now) and of pain interference with general activity, normal work, walking ability, relationship with other people and enjoyment of life did not emerge at the 10-month mark (Table 2).

No gender differences emerged from statistical sub-analysis of data (male vs female participants) in the benefits of MBSR for pain intensity or pain interference.

The benefits of MBSR program on quality of life

The MBSR program has a positive impact on participants' quality of life and it significantly reduces the perception of moderate or extreme pain/discomfort ($x_{(1)}$=6.726, p=.009) and of moderate to severe problems of anxiety/depression ($x_{(1)}$= 4.614, p= .031), assessed 10 months after intervention using the EuroQol-5D (Table 3). No significant difference emerged in the perceived quality of life assessed by EQVAS, score range

Table 2. Results of the Brief Pain Inventory in Chronic Pain-Patients before and after Mindfulness-Based Stress Reduction protocol.

BPI-SF Question	Before (n= 43)	After (n= 35)	Mean difference (SD); CI 95%	SE	p
Pain intensity (0-10), Mean (SD)					
Worst pain in the last 24 h	5.65 (0.9)	4.37 (1.0)	1.28 (1.31); (0.83, 1.73)	.222	**.001**
Least pain in the last 24 h	3.11 (0.8)	2.62 (1.3)	0.48 (1.06); (0.11, 0.85)	.180	**.011**
Pain on average	4.17 (0.7)	3.54 (0.9)	0.62 (0.77); (0.36, 0.89)	.130	**.001**
Pain right now	2.20 (1.5)	2.17 (1.1)	0.03 (2.0); (-0.66, 0.71)	.339	.993
Pain interference (0-10), Mean (SD)					
Interference with general activity	4.57 (1.2)	4.48 (1.3)	0.09 (0.8); (-0.21, 0.39)	.149	.571
Interference with mood	4.17 (1.8)	3,4 (1.8)	0.77 (1.4); (0.29, 1.25)	.235	**.002**
Interference with normal work	2.8 (2.6)	3.2 (2.2)	-0.4 (2.2); (-1-16, 0.36)	.376	.295
Interference with walking ability, Mean (SD)	4.14 (2.1)	4.25 (2.3)	-0.11 (1.2); (-0.53, 0.30)	.258	.586
Interference with relationship with other people, Mean (SD)	4.02 (2.3)	4.0 (2.0)	0.02 (1.0); (-0.31, 0.37)	.171	.869
Interference with sleep, Mean (SD)	6.05 (1.3)	4.8 (1.4)	1,25 (1.5); (0.73, 1.77)	.257	**.001**
Interference with enjoyment of life, Mean (SD)	3.42 (1.6)	3.08 (1.5)	0.34 (2.1); (-0.36, 1.05)	.350	.334

Abbreviations: BPI-SF = Brief Pain Inventory-Short Form; n= number; SD = Standard Deviation; h = hour; CI = Confidence Interval; SE = Standard Error.

Table 3. Evolution of the EuroQol-5D scores during the study before and after Mindfulness-Based Stress Reduction protocol, and the results of the Five Facet Mindfulness Questionnaire.

Dimension	Before (n=43)	After (n= 35)	*F*	p
Mobility, n (%) *	15 (34.9)	13 (37.2)	X^2= 0.043	.836
I have no problems in walking about	28 (65.1)	22 (62.8)		
I have some problems in walking about	0	0		
I am confined to bed				
Self-care, n (%) *	13 (30.2)	15 (42.8)	X^2= 1.336	.247
I have no problems with self-care	30 (69.8)	20 (57.2)		
I have some problems washing or dressing myself	0	0		
I am unable to wash or dress myself				
Usual activities, n (%) *	22 (51.2)	22 (62.9)	X^2= 1.073	.300
I have no problems with performing my usual activities	18 (41.9)	12 (34.3)		
I have some problems with performing my usual activities	3 (6.9)	1 (2.8)		
I am unable to perform my usual activities				
Pain/discomfort, n (%) *	0	0	X^2= 6.726	**.009**
I have no pain or discomfort	27 (62.8)	31 (88.6)		
I have moderate pain or discomfort	16 (37.2)	4 (11.4)		
I have extreme pain or discomfort				
Anxiety/depression, n (%) *	13 (30.2)	19 (54.3)	X^2= 4.614	**.031**
I am not anxious or depressed	27 (62.8)	13 (37.1)	*t*= -1.401	.168
I am moderately anxious or depressed	3 (7)	3 (48.6)		
I am extremely anxious or depressed	50.8 (12.5)	54.4 (15.1)		
EQVAS, Mean (SD)+				
FFMQ				
Mindfulness: nonjudging, Mean (SD)+	2.05 (0.9)	2.41 (0.7)	*t*= -2.255	**.030**
Mindfulness: describing, Mean (SD)+	2.5 (1.1)	2.77 (1.1)	*t*= -2.046	**.048**
Mindfulness: observing, Mean (SD)+	2.75 (0.8)	2.83 (0.6)	*t*= -.620	.538
Mindfulness: awareness, Mean (SD)+	2.52 (0.9)	2.94 (0.8)	*t*= -2.211	**.034**
Mindfulness: nonreactivity, Mean (SD)+	2.66 (0.6)	2.80 (1.1)	*t*= -.615	.543

* The chi-square test (X^2) was applied in calculating P values. +The *t*-test was applied in calculating P values. *Abbreviations:* N= number; SD = Standard Deviation; FFMQ = Five Facet Mindfulness Questionnaire; EQVAS= EuroQol-5D-Visual Analogue Scale.

0-100, before and after intervention (50.8 *vs* 54.4, $t_{(34)}$ = -1.401, p = .168) (Table 3). No gender differences emerged from statistical sub-analysis of data (male vs female participants) in the benefits of MBSR for perceived quality of life.

Mindfulness and its impact on the vital aspects

All participants completed the FFMQ, which assesses five facets of a general tendency to be mindful in daily life: observing, describing, acting with awareness, nonreactivity to inner experience and non-judging of inner experience. Items are rated on a 5-point Likert-type scale ranging from 1 (never or very rarely true) to 5 (very often or always true). The Five Facet Mindfulness Questionnaire, an objective test assessing mindfulness and its impact on vital aspects of life, showed a significant difference in non-judging ($t_{(34)}$ = -2.255, p= .030), describing (t(34) = -2.046, p = .048) and awareness (t(34) = -2.211, p = .034) between the

assessments taken before the intervention and those taken 10 months after the intervention (Table 3). No gender differences emerged from statistical sub-analysis of data (male vs female participants) in the benefits of MBSR for the results of FFMQ.

Effect of MBSR program on pain treatment

Pharmacological treatments at enrollment included: Opioids, NSAIDs, Antidepressants and Cortisones (Table 4). No statistically significant reductions were found in the overall use of chronic pain treatments. Among patients not using opiods or NSAIDs, we observed a reduction in average pain (BPI-SF, pain on overage: NRS= 4.3 vs 3.8, $t_{(23)}$ = 2.716, p = .012). Among patients using antidepressants, we also observed a reduction in average pain (BPI-SF, pain on overage: NRS = 3.75 vs 1.0, $t_{(3)}$ = 11.000, p = .002), 10 months after the intervention. No other statistically significant differences emerged, including comparisons between male and female participants, 12 months after enrollment (Table 4).

Discussion

In this observational study on 43 chronic pain patients discharged from the intensive care unit (ICU), the efficacy of a mindfulness-based stress reduction (MBSR) program on pain management and quality of life was evaluated. The program appeared to decrease pain intensity and its negative impact on quality of life. The intervention involved the introduction into routine clinical practice of a new pain management protocol directed at critically ill survivors. We observed a prevalence of chronic pain of 39.7%, one year after ICU discharge, 39.7%, in line which aligns with the literature reporting a prevalence of pain after an ICU stay between 24% and 41% (22-24). However, a recent study showed reported a prevalence of 54% of chronic pain in COVID-19 survivors following an ICU stay (25). The main site of pain observed in the patients was the shoulder (44%), which is lower than the 67% prevalence of ICU-related shoulder reported by Gustafson and colleagues at 6 months following hospital discharge (26). Shoulder impairment is a potential source of disability with a significant impact on upper limb function. Obviously, further research into potential mechanisms underlying shoulder impairment and potential targeted interventions to reduce the prevalence is warranted. Ten months after intervention, a significantly greater proportion of patients reported reduced pain intensity and pain interference in daily living during the follow-up interview. Although the general perception of quality of life has not improved, some dimensions of quality has shown improvement. Chronic pain has become a common problem within primary care and can negatively impact patients' lives, plus the multidimensional negative impact of chronic pain leads to poorer quality of life for patients with chronic pain compared to the general population and patients with other long-term conditions (27). Quality of life improvements often appear to be short lived, with quality-of-life gains made within the first 12 months following an intervention typically not persisting to the twenty-four-month stage (28). However, improved patient quality of life is a goal for policy makers and health and social care providers alike, and improvements should lead to positive impacts upon patient satisfaction, more timely resource allocation and lower service utilization (29). Further work around establishing a formal system to measure patient quality of life is needed, along with ensuring that the data can be used to improve patient care and satisfaction. It was interesting to explore possible gender differences in response to treatment. However, due to the relatively small sample size, this statistical subanalysis of the data (male vs female participants) was difficult to perform. The impression is that an MBSR program can be either useful or ineffective, regardless of gender. During the MBSR program, treatment sessions were designed as interactive discussions and aimed at improving the patients' well-being by explaining the interactions between pain intensity and interference, emotions, behaviour, and cognition. The patients began to conceptualize and understand their situation when they discovered the pathophysiological mechanisms that had caused their pain. The MBSR program also gave them the opportunity to express their feelings and allowed them to listen to other people within the group who were in the same situation and who shared their experiences, related to intensive

Table 4. Comparison of the effect of Mindfulness-Based Stress Reduction protocol on drug use and therapeutic treatments for chronic pain before and after.

Variable	Before (n= 43)	After (n= 35)	X^2	Mean difference (SD); CI 95%	p
Opioid, n (%)*	24 (55.8)	24 (68.6)	1.327		.249
NRS, Mean (SD)+	4.3 (0.7)	3.8 (1.1)		0.50 (0.97); (0.12, 0.95)	**.012**
EQVAS, Mean (SD)+	49.16 (13.8)	50.41 (11.9)		-1.25 (3.3); (-2.6, 0.17)	.083
Non-Opioid/NSAIDs, n (%)*	12 (27.9)	10 (28.6)	0.004		.948
NRS, Mean (SD)+	3.80 (0.4)	3.70 (0.5)		0.10 (0.31); (-0.12, 0.32)	.343
EQVAS, Mean (SD)+	56 (8.7)	57 (7.1)		-1.0 (4.6); (-4.28, 2.28)	.509
Antidepressants, n (%)*	10 (23.2)	5 (14.2)	1.000		.317
NRS, Mean (SD)+	3.75 (0.5)	1.0 (0.0)		2.75 (0.5); (1.95, 3.54)	**.002**
EQVAS, Mean (SD)+	52.5 (9.6)	62.5 (5.0)		-10 (11.5); (-28.4, 8.4)	.182
Cortisonic, n (%)*	7 (16.3)	7 (20)	0.181		.670
NRS, Mean (SD)+	4.0 (0.0)	4.66 (0.57)		-0.66 (0.57); (-2.10, 0.76)	.184
EQVAS, Mean (SD)+	45 (10.4)	48.57 (6.9)		-3.57 (8.5); (-11.4, 4.30)	.310

*The chi-square test was applied in calculating P values. +The T-test was applied in calculating P-values. *Abbreviations:* SD = Standard Deviation; N = number, NRS = Numerical Rating Scale/pain on average; EQVAS = EuroQol-5D-Visual Analogue Scale; NSAIDs = Nonsteroidal Anti-Inflammatory Drugs; CI = Confidence Interval.

care, helping them learn about solutions and coping strategies. Participants reported that the intervention provided them with new skills and new knowledge, evident through the improvement of the FFMQ scale scores in reducing pain intensity, improving quality of life, and enhancing the understanding of the role of the mind-body connection in health. These results are consistent with previous studies fostering participant support, the ability to learn effective coping strategies, and the opportunity to talk openly about feelings in a safe environment among others in a similar situation (9, 30, 31). A recent meta-analysis suggests that mind-body therapies are associated with modest improvements in pain and with small reductions in opioid dose (32). The findings of this research follow this trend. Our study did not aim to demonstrate the definitive efficacy of MBSR in reducing drug therapy. However, we observed a significant improvement in the average perception of pain among patients receiving opioids and antidepressants. With high doses of opioids, the benefit to risk relationship becomes worse and patients on high-potency opioids report more psychological impairment than those on low-potency opioids, but no advantage in pain relief (33). Some previous studies suggest that long term opioid treatment is not effective in controlling chronic pain (34, 35) and may even worsen symptoms by interfering with emotional coping and eliminating or reducing important activities associated with self-care (36). Notably, self-care is one of the dimensions of the EuroQol-5D which also identifies a close relationship between self-care and optimal quality of life.

Good adherence to the intervention was observed with 81% of included patients attending at least 7 out of 8 program sessions and all of these 35 patients then responded to interviews conducted 10 months after intervention. In general, higher adherence to medical and health interventions is associated with better outcomes. According to a recent study on the dropout rate of patients with chronic pain undergoing psychosocial intervention, this can reach about 50% with no statistical differences being found according to age, gender, etiology, employment status, but a greater dropout rate is observed among those with the lowest educational levels (37). In our study, the dropout was lower (18.6%). It is possible that, being a small group, the emotional ties formed between the patients and therapists have improved adherence.

Limitations

This study has some limitations.

The main ones are the relatively small sample size, the absence of a control group, and the fact that our data refers to a single-center study. A significant issue is the lack of controls, as the study duration (approximately one year) makes it difficult to avoid comparison with untreated patients. A formal sample size calculation was not performed prior to the study, instead, we included patients who were consecutively discharged from our intensive care unit over a five-month period (March-July 2021). Another limitation is that the loss to follow-up exceeded 15%, which may have introduced attrition bias. It is important to note that our results can only be generalized to patients discharged from the Intensive Care Unit. Additionally, we found no studies that implemented an MBSR program after intensive care for patients with chronic pain, limiting the ability to compare our findings with the existing literature.

Clinical implications

A thorough assessment of chronic pain nursing diagnoses is necessary for the development of an effective pain management plan. Nurses play a key role in the assessment of pain, due to the nature of their relationship with patients (38, 39). The patient's self-report is the most reliable information about the chronic pain experience. As pain is always subjective, a patient's report of pain should be accepted at face value in the absence of evidence to the contrary, although providers may consider other means to evaluate pain and identify causes (40). Chronic pain can cause depression and irritability, which in turn lead to insomnia and fatigue, perpetuating a cycle of irritability, depression and pain. Promoting the use of psychoeducation can offer significant benefits in managing chronic pain. The main objective is to provide participants with the opportunity to self-care skills and improve their overall quality of life. Nurses can coach the patient, encourage self-directed meditation, or provide an audio guide to help elicit the relaxation response. By practicing and applying various cognitive and behavioral self-management techniques, participants learn how to set realistic goals and manage their pain more effectively. In addition to improving pain management outcomes, psychoeducation can also promote better patient-provider communication and help reduce healthcare costs. In addition, nurses can encourage and support the patient's use of methods known to help modifying pain unless they are specifically contraindicated. Strategies may include seeking quiet and solitude, learning about their condition, pursuing interesting activities as a form of distraction, praying, or socializing.

Conclusion

The manuscript aims to demonstrate the utility of mindfulness-based stress reduction in chronic pain patients. The topic is significant because many patients often require alternative approaches to managing their pain after ICU care. The findings of this before-and-after study suggest a benefit of the Mindfulness-Based Stress Reduction program in survivors of critical illness suffering frojust m chronic pain, with an improvement in pain intensity, pain interference and quality of life. Despite the limitations of this study, MBSR program appears to alleviate chronic pain symptoms and reduce the negative impact of pain on some functional activities. Although the results are statistically significant, they may not be clinically relevant. MBSR is a promising nonpharmacologic adjunct to current pain management strategies for chronic pain patients. The study indicated that this type of intervention was well-accepted by participants and feasible when implemented in a focus-group setting. However, studies with larger samples and RCTs are needed.

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