

Effects of a Mindfulness-based Intervention on Chronic Pain Sufferers: Lessons Learned from a Replicated Single-case Design Study in an Indian Setting

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ABSTRACT

Introduction: Chronic pain is an emerging healthcare problem in India. Chronic pain is not physical pain alone it has psychological, social, and economic perspectives. The treatment modalities of chronic pain in India mostly focus on physical pain. It is important to search for an optimal-cost self-help therapy that can help the sufferer to live a meaningful life despite the chronic pain. Mindfulness, gaining popularity in the western world maybe a viable option.

Aim: To explore the preliminary effects of mindfulness on different outcome variables like pain intensity, chronic pain acceptance, anxiety and depression and World Health Organisation-Quality Of Life (WHO-QOL) in Indian chronic pain sufferers.

Materials and Methods: This replicated single-case design study was conducted at Harmony Mindfulness Centre and Kalyani ESI Hospital, Kolkata, West Bengal, India from December 2020 to May 2021. The effects of a face-to-face eight-week mindfulness based intervention were studied in six chronic pain sufferers. The quantitative variables like Numerical Rating scale (NRS), Chronic Pain Acceptance Questionnaire (CPAQ),

WHO-QOL, and Hospital Anxiety and Depression Score (HADS) were studied at three time points; pre-session, immediate post-session and six months after completion of the session. Reliable Change (RC) based on Reliable Change Index (RCI) was calculated and modulus RC i.e., $|RC| > 1.96$ was considered to be statistically significant with p-value < 0.05 . Qualitative data was collected post-session by getting written responses to a question "How did you experience the effects of this mindfulness based intervention?" The responses were categorised into five emergent themes to determine which aspect of the programme appealed to the participants the most.

Results: The pre-session variables showed significant improvement (p-value < 0.05) based on the reliability change index in post-session. The post-session improvement in the variables was maintained even at six months follow-up. Positive mental state was the most common theme marked by participant's post-session.

Conclusion: The Mindfulness-Based Intervention (MBI) has a positive impact on pain intensity, chronic pain acceptance, anxiety and depression and QOL of Indian chronic pain sufferers.

Keywords: Chronic pain acceptance, Positive mental state, Self-help therapy

INTRODUCTION

The world's nearly 30% of population suffers from pain. A global prevalence survey in 2018 found 19.3% of the Indian adult population (i.e., 180-200 billions) are suffering from chronic pain [1]. In a Vanderbilt Global pain survey, pain point prevalence was approximately 24% to 41% in the Indian cohort [2]. Chronic pain was earlier looked upon as a problem with clear pathophysiological bases, which required physical treatments such as medication, interventions, or surgery [3]. The bio-psycho-social understanding explains the dynamic interaction of physiological, psychological, and social factors resulting in the total experience of chronic pain [4]. Chronic pain affects the whole spectrum of life, ranging from personal complaints of insomnia, fatigue, mood disorders to social challenges of family, work, costs, and finances [1]. Anxiety and depression are frequent associates of chronic pain [5]. A 14.1% of Indian chronic pain patients suffer from depression [1]. Chronic pain severely deteriorates the Quality Of Life (QOL) of the sufferer [6].

Unfortunately, the treatment options in India, like medicines {Non Steroidal Anti-Inflammatory Drugs (NSAIDs)} [6], interventions, stimulations, mostly focus on the physical aspects of pain. The psycho-social complaints are grossly neglected in this part of the world [7]. Awareness about associated mental health problems and access to psychotherapies are limited. As the psychosocial complaints are not cared for, the chronic pain remains unsatisfactorily treated. The researchers felt the need for a treatment modality which

should address the psychosocial dimensions of chronic pain, be a self-help tool, and may be available at an optimal cost to the Indian chronic pain sufferers.

Kabat-Zinn J applied mindfulness to chronic pain patients of the west, and reported improvements in pain symptomology and QOL [8]. The work by Kabat-Zinn J resulted in further research with Mindfulness-Based Intervention (MBI) in the field of chronic pain. But even after an extensive search, we have not come across any study on mindfulness in the Indian chronic pain sufferers. Mindfulness may prevent dysfunctional reactions to chronic pain and can be used as a self-help tool. Mindfulness is usually conducted in group sessions so has a potential to reach out a larger section of the population at optimal cost. These factors make mindfulness a viable adjuvant treatment option for chronic pain sufferers in developing countries like India. A replicated-single-case design was chosen for this study with a small sample, as there was no previous experience with mindfulness in this study population. The aim of the present study was to see the effects of MBI on different outcome variables. This study should be looked upon as the first step to explore the effects of a MBI on chronic pain sufferers of India.

MATERIALS AND METHODS

This replicated single-case design study was conducted at Harmony Mindfulness Centre and Kalyani ESI Hospital, Kolkata, West Bengal, India from December 2020 to May 2021. An Institutional ethical

approval was obtained with number ESIH/KLY/1374/A/IEC-5. Informed consent was taken from all the participants.

Inclusion criteria: Participants with age more than 18 years and lesser than 65 years, suffering from chronic pain as main complaint, pain intensity more than 3 in 10 points NRS scale 4, the duration of chronic pain more than 3 months, no “red flags” serious symptoms and signs of pain present (e.g., cancer pain), level of education to be at least till higher secondary standard, on a stable treatment regimen for chronic pain and no plan of alteration in the next two months, not undergoing any psychiatric treatment at present, had no experience of mindfulness or meditation, willingness to attend all eight sessions of the session over two-month time were included in the study.

Exclusion criteria: Participants suffering from major co-morbidities, psychiatric diseases, and pregnancy in case of females were excluded from the study.

Study Procedure

A replicated single-case-design was chosen for the study, as this was the recommended design for the development and evaluation of new interventions [9]. Every patient was studied extensively and the quantitative variables such as pain intensity by Numerical Rating scale (NRS), chronic pain acceptance by Chronic Pain Acceptance Questionnaire (CPAQ) [10], anxiety and depression by Hospital Anxiety and Depression Score (HADS) [11], World Health Organisation-Quality Of Life (WHO-QOL) [12] was noted at three time points: before the session, at the end of the session, and after six months after completion of the session.

Subjects suffering from chronic pain, reporting to the medical institution, were informed about the study. The mindfulness session was organised by a mindfulness center, in collaboration with a medical institution. Total 15 subjects, who showed initial interest to participate, were screened in an interview. Only eight subjects fulfilled the inclusion and exclusion criteria of the study. Mindfulness was used as an adjuvant intervention and no interference was done with the existing treatment regimen of participants. Six participants attended all eight sessions while two participants were irregular and were excluded from the study. The final sample size was six and there were no controls.

The demographic data were collected before the study. The outcome measures were:

- Pain intensity which was measured using a 10-point NRS, where zero represents “no pain at all” whereas ten represents “the worst pain ever possible” [13].
- Pain acceptance was measured by the CPAQ which has 20 items consisting of the Activity Engagement and the Pain Willingness subscale. A higher score implies greater acceptance of chronic pain [11].
- QOL was measured using the WHO-QOL also designated as WHO-QRL BREF which consists of 26 items which measure four domains: physical health, psychological health, social relationships, and environment.
- Mental state of anxiety and depression was measured using HADS which is a 14-item scale with 7 items each for anxiety and depression subscales. A subscale score >8 denotes anxiety or depression. Scoring for each item ranges from zero to three [12].

Additionally, at the end of the session, qualitative data was collected by arranging a group discussion among participants and getting written responses to a question “How did you experience the effects of this mindfulness based intervention?” The responses were categorised into five emergent themes: positive mental state, acceptance, non judgemental, self-compassion and reduce stress, to determine which aspect of the session appealed to the participants the most.

Mindfulness-Based Stress Reduction Programme

The eight weeks MBI had elements from the original Mindfulness-Based Stress Reduction (MBSR) programme. The sessions were approximate two hours in duration followed by half an hour of interaction with the

participants and homework assignments. The mindfulness instructor was trained via the original MBSR programme and NHS approved mindfulness courses and has experience of teaching Mindfulness for more than two years. During the face-to-face sessions, formal meditation skills (body scan, sitting meditation, handling difficult emotions), informal meditation skills (incorporation of mindfulness in daily activities), and mindfulness attitudes (acceptance, patience, letting go, non judgemental, gratitude, compassion) were discussed and encouraged to practice. The subjects were required to do a daily formal practice of meditation of thirty minutes and maintain a logbook. The daily practice of formal, informal, and mindfulness activities was self-reported and the homework assignments were reviewed by the instructor, at the end of sessions. Any participant experiencing any discomfort or adverse effect during the session was asked to report to the instructor. A written feedback about the session was obtained from the participants at the end of the session. At six months follow-up, the questionnaires were mailed to the participants and their responses were obtained. Collection and monitoring of detailed data regarding quality of daily meditation practice during the session and post-session at six months follow-up, was outside the scope of the study.

STATISTICAL ANALYSIS

Data analysis was done using PASW®, SPSS Statistics for Windows 7® version 18.0.0 and Microsoft® Office Excel 2010. The RC based on RCI was calculated and mod RC viz., $|RC| > 1.96$ was considered to be statistically significant with p-value <0.05. The RC is a ratio which equals to the difference between a participant's pre-session and post-session scores, divided by the standard error of the difference of the measure (Sdiff).

RESULTS

The demographic data of the participants are detailed in [Table/Fig-1]. Mean score for each outcome variable in each patient were measured and compared at three time points; pre-session, immediate post-session and at six months follow-up.

Participants number / Age (years)/ Sex (M/F)	Work status	Pain description	Co-morbidities	Existing treatment regimen
1/55/F	Housewife	Suffering from Osteoarthritis for last 3 years.	No such	On simple analgesics like Paracetamol.
2/35/F	Physician	Suffering from chronic pelvic pain for last 2 years.	Hypertension, Diabetes type II, Mild Bronchial asthma, Hypothyroidism	All conservative management including analgesics, hormonal drugs tried without much effect.
3/20/M	Student	Suffering from Fibromyalgia for last 1 year.	No such	Tried Psychotherapy like Counselling. Now on Pregabalin and Nortriptyline for last 2 months without much improvement.
4/35/F	Nurse	Suffering from non specific low back pain for last 1 year.	No such	Irregularly takes non prescription analgesics for pain.
5/43/M	Operation Theater (OT) Technician	Suffering from low back pain for 3 years. Provisional diagnosis of L5-S1 disc prolapse.	Hypertension	On gabapentin and amitriptyline for last 1 year.
6/55/M	Business-man	Suffering from low back pain for last 5 years. Diagnosed as L5-S1 disc prolapse.	No such	On pregabalin and amitriptyline for last 5 years. Six months back received a caudal epidural injection. His pain intensity decreased post procedure but persisted.

[Table/Fig-1]: Description of the demography, work status, pain condition, comorbidities and treatment regime of all the participants. Quantitative data analysis

NRS

The immediate post-session mean NRS pain scores improved in all six participants (p -value<0.001 for P 1, 2, 4, 6; p -value=0.017 for P 3, 5). Mean post-session NRS scores were maintained at six month follow-up, except for participants 3,4 and 6 (p -value=0.017) [Table/Fig-2].

CPAQ

The AE (activity engagement) component showed reliable improvements immediate post-session in all participants (p -value <0.05) except participant 5; while PW (pain willingness) component improved for participant 2 (p -value=0.001) and 4 (p -value=0.002). Mean CPAQ scores were maintained at six month follow-up compared to immediate post-session improvements, except for participant 4 [Table/Fig-2].

WHO-QOL

Reliable improvement (p -value <0.05) was noted in Domains 1 and 2 for participants 1, 2 and 6 in immediate post-session when compared to pre-session. Domain 3 did not show improvement for

any participant, while Domain 4 showed improvement for participant 6 only (p -value<0.001). The improvement in WHO-QOL scores immediate post-session was maintained at six month follow-up for participants 2, 3, and 5 [Table/Fig-3].

HADS

There were reliable improvements in mean HADS (D component) scores in all participants except participant 3; while HADS (A component) was improved in all participants except participant 3 and 4. The immediate post-session improvements in mean HADS score were maintained at six months, except for HADS (A) component of participant 6 (p -value=0.036) [Table/Fig-4].

Qualitative Data Analysis:

The emergent themes from post-session group discussion were:

1) Positive mental state; 2) Acceptance; 3) Non Judgemental; 4) Self-Compassion; 5) Reduced Stress. As can be seen from the cumulative frequency histogram [Table/Fig-5], the 50th percentile (9.5) falls on #5; the 75th percentile (14.25) on #1; while #2 and #3 falls between

Test-variable	Mean NRS Pain Scores (0-10)			Reliable Change (RC) of Difference in Mean Scores and p-values		
NRS	Pre-session	Post-session	6 Month Follow-Up	Pre-session vs Post-session	Post-session vs 6 Month Follow-Up	Pre-session vs 6 Month Follow-Up
P1	7.25	4.25	4.25	RC=3.57† p-value<0.001*	RC=0.00 p-value=1.000	RC=3.57† p-value<0.001*
P2	7.75	3.25	3.25	RC=5.95† p-value<0.001*	RC=0.00 p-value=1.000	RC=5.95† p-value<0.001*
P3	4.75	3.00	4.75	RC=2.38† p-value=0.017*	RC=-2.38‡ p-value=0.017*	RC=0.00 p-value=1.000
P4	5.25	1.75	3.75	RC=3.57† p-value<0.001*	RC=-2.38‡ p-value=0.017*	RC=1.19 p-value=0.234
P5	6.25	4.00	4.00	RC=2.38† p-value=0.017*	RC=0.00 p-value=1.000	RC=2.38† p-value=0.017*
P6	4.75	1.75	4.00	RC=3.57† p-value<0.001*	RC=-2.38‡ p-value=0.017*	RC=1.19 p-value=0.234
N=6	Mean ± SD 6.00 ± 1.26	Mean ± SD 3.00 ± 0.89	Mean ± SD 4.00 ± 0.63	p-value=0.001*	p-value=0.075	p-value=0.041*
Test-variable	Mean CPAQ (AE) Scores (0-66)			Reliable Change (RC) of Difference in Mean Scores and p-values		
CPAQ Activity Engagement (AE)	Pre-session	Post-session	6 Month Follow-Up	Pre-session vs Post-session	Post-session vs 6 Month Follow-Up	Pre-session vs 6 Month Follow-Up
P1	25.75	36.75	34.25	RC=-2.33† p-value=0.019*	RC=0.63 p-value=0.528	RC=-1.69 p-value=0.091
P2	24.25	37.75	32.25	RC=-2.96† p-value=0.003*	RC=1.27 p-value=0.204	RC=-1.69 p-value=0.091
P3	24.25	34.25	27.00	RC=-2.11† p-value=0.035*	RC=1.48 p-value=0.139	RC=-0.63 p-value=0.528
P4	25.25	40.00	29.75	RC=-3.17† p-value=0.001*	RC=2.11‡ p-value=0.035*	RC=-1.05 p-value=0.294
P5	40.75	45.25	40.00	RC=-0.84 p-value=0.401	RC=1.05 p-value=0.294	RC=0.21 p-value=0.833
P6	26.75	37.00	29.75	RC=-2.11† p-value=0.035*	RC=1.48 p-value=0.139	RC=-0.63 p-value=0.528
Test-variable	Mean CPAQ (PW) Scores (0-54)			Reliable Change (RC) of Difference in Mean Scores and p-values		
CPAQ Pain Willingness (PW)	Pre-session	Post-session	6 Month Follow-Up	Pre-session vs Post-session	Post-session vs 6 Month Follow-Up	Pre-session vs 6 Month Follow-Up
P1	28.75	35.25	31.25	RC=-1.03 p-value=0.303	RC=0.68 p-value=0.496	RC=-0.34 p-value=0.734
P2	18.25	36.75	38.00	RC=-3.27† p-value=0.001*	RC=-0.17 p-value=0.865	RC=-3.44† p-value<0.001*
P3	24.00	32.00	24.00	RC=-1.37 p-value=1.170	RC=1.37 p-value=0.170	RC=0.00 p-value=1.000
P4	20.00	38.00	25.00	RC=-3.09† p-value=0.002*	RC=2.23‡ p-value=0.026*	RC=-0.86 p-value=0.390
P5	32.00	36.75	35.75	RC=-0.86 p-value=0.390	RC=0.17 p-value=0.865	RC=-0.68 p-value=0.496
P6	40.00	43.25	34.00	RC=-0.51 p-value=0.610	RC=1.54 p-value=0.123	RC=1.03 p-value=0.303

[Table/Fig-2]: Mean NRS pain scores and CPAQ scores of participants pre-session, immediate post session and 6 months follow-up with Reliable Change (RC) in mean scores in each participants as they progress from pre-session to 6 month follow-up:

* p -value<0.05 is statistically significant; †Indicates significant improvement reliable change ($|RC| >1.96$); ‡Indicates significant deterioration reliable change ($|RC| >1.96$)

Test-Variable	Mean WHO-QOL Physical Domain 1 Scores Transformed (0-100)			Reliable Change (RC) of difference in mean scores and p-values		
WHO-QOL Domain 1	Pre-session	Post-session	6 Month Follow-Up	Pre-session vs Post-session	Post-session vs 6 Month Follow-Up	Pre-session vs 6 Month Follow-Up
P1	37.67	69.00	50.33	RC=-3.29† p-value=0.001*	RC=2.01† p-value=0.044*	RC=-1.27 p-value=0.204
P2	44.00	69.00	69.00	RC=-2.65† p-value=0.008*	RC=0.00 p-value=1.000	RC=-2.65† p-value=0.008*
P3	44.00	44.00	44.00	RC=0.00 p-value=1.000	RC=0.00 p-value=1.000	RC=0.00 p-value=1.000
P4	75.00	81.33	75.00	RC=-0.63 p-value=0.528	RC=0.63 p-value=0.528	RC=0.00 p-value=1.000
P5	56.33	69.00	69.00	RC=-1.38 p-value=0.167	RC=0.00 p-value=1.000	RC=-1.38 p-value=0.167
P6	38.00	68.67	55.67	RC=-3.29† p-value=0.001*	RC=1.38 p-value=0.167	RC=-1.91 p-value=0.056

N=6	Mean±SD 49.17±14.26	Mean±SD 66.83±12.17	Mean±SD 60.50±12.31	p-value=0.022*	p-value=0.112	p-value=0.038*
Test-Variable	Mean WHO-QOL Psychological Domain 2 Scores Transformed (0-100)			Reliable Change (RC) of Difference in Mean Scores and p-values		
WHO-QOL Domain 2	Pre-session	Post-session	6 Month Follow-Up	Pre-session vs Post-session	Post-session vs 6 Month Follow-Up	Pre-session vs 6 Month Follow-Up
P1	56.33	81.00	69.00	RC=-3.87 [†] p-value<0.001*	RC=1.86 p-value=0.063	RC=-2.01 [†] p-value=0.044*
P2	50.00	75.00	69.00	RC=-3.87 [†] p-value<0.001*	RC=0.93 p-value=0.352	RC=-2.94 [†] p-value=0.003*
P3	43.67	43.67	43.67	RC=0.00 p-value=1.000	RC=0.00 p-value=1.000	RC=0.00 p-value=1.000
P4	63.00	81.00	62.67	RC=-2.79 [†] p-value=0.005*	RC=2.79 ⁺ p-value=0.005*	RC=0.00 p-value=1.000
P5	69.00	81.33	81.33	RC=-1.86 p-value=0.063	RC=0.00 p-value=1.000	RC=-1.86 p-value=0.063
P6	69.00	69.00	56.33	RC=0.00 p-value=1.000	RC=2.01 [†] p-value=0.044*	RC=2.01 [†] p-value=0.044*
Test-Variable	MEAN WHO-QOL Social Domain 3 Scores Transformed (0-100)			Reliable Change (RC) of Difference in Mean Scores and p-values		
WHO-QOL Social Domain 3	Pre-session	Post-session	6 Month Follow-Up	Pre-session vs Post-Session	Post-session vs 6 Month Follow-Up	Pre-session vs 6 Month Follow-Up
P1	50.00	56.00	50.00	RC=-1.18 p-value=0.238	RC=1.18 p-value=0.238	RC=0.00 p-value=1.000
P2	44.00	50.00	50.00	RC=-1.18 p-value=0.238	RC=0.00 p-value=1.000	RC=-1.18 p-value=0.238
P3	31.00	31.00	31.00	RC=0.00 p-value=1.000	RC=0.00 p-value=1.000	RC=0.00 p-value=1.000
P4	81.00	81.00	81.00	RC=0.00 p-value=1.000	RC=0.00 p-value=1.000	RC=0.00 p-value=1.000
P5	69.00	69.00	69.00	RC=0.00 p-value=1.000	RC=0.00 p-value=1.000	RC=0.00 p-value=1.000
P6	56.00	56.00	56.00	RC=0.00 p-value=1.000	RC=0.00 p-value=1.000	RC=0.00 p-value=1.000
Test-Variable	Mean WHO-QOL Environmental Domain 4 Scores Transformed (0-100)			Reliable Change (RC) of difference in mean scores and p-values		
WHO-QOL Environmental Domain 4	Pre-session	Post-session	6 Month Follow-Up	Pre-session vs Post-session	Post-session vs 6 Month Follow-Up	Pre-session vs 6 Month Follow-Up
P1	69.00	69.00	75.00	RC=0.00 p-value=1.000	RC=-1.07 p-value=0.284	RC=-1.07 p-value=0.284
P2	69.00	69.00	75.00	RC=0.00 p-value=1.000	RC=-1.07 p-value=0.284	RC=-1.07 p-value=0.284
P3	56.33	56.33	50.00	RC=0.00 p-value=1.000	RC=1.07 p-value=0.284	RC=1.07 p-value=0.284
P4	69.00	75.00	69.00	RC=-1.07 p-value=0.284	RC=1.07 p-value=0.284	RC=0.00 p-value=1.000
P5	62.67	68.67	69.00	RC=-1.07 p-value=0.284	RC=0.00 p-value=1.000	RC=-1.07 p-value=0.284
P6	50.00	69.00	69.00	RC=-3.39 [†] p-value<0.001*	RC=0.00 p-value=1.000	RC=-3.39 [†] p-value<0.001*

[Table/Fig-3]: Mean WHO-QOL domain 1,2,3,4 scores of participants post-session, immediate post session and 6 months follow-up with Reliable Change (RC) in mean scores of each participants as they progress from pre-session to 6 month follow-up:

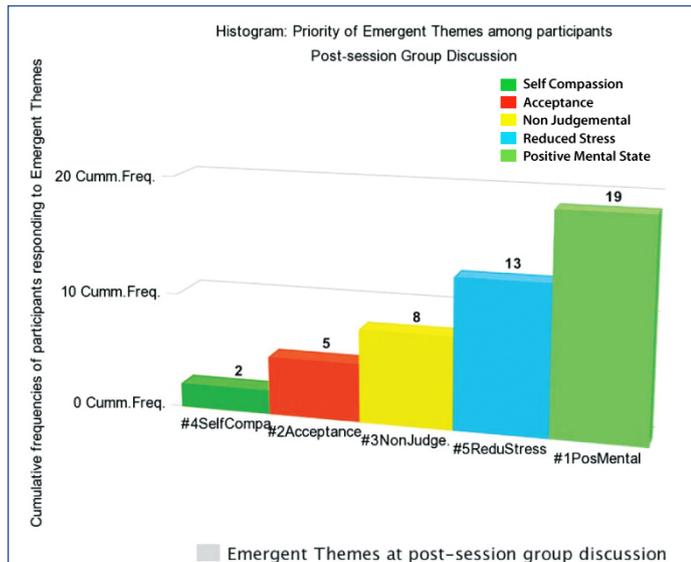
* p-value <0.05 is statistically significant; [†]Indicates significant improvement reliable change ($|RC| > 1.96$); [‡]Indicates significant deterioration reliable change ($|RC| > 1.96$)

Test-variable	Mean HADS Depression Scores (0-21)			Reliable Change (RC) of Difference in Mean Scores and p-values		
HADS (Depression)	Pre-session	Post-session	6 Month Follow-Up	Pre-session vs Post-session	Post-session vs 6 Month Follow-Up	Pre-session vs 6 Month Follow-Up
P1	6.25	2.25	3.25	RC=2.40 [†] p-value=0.016*	RC=-0.60 p-value=0.548	RC=1.80 p-value=0.072
P2	8.75	1.00	1.75	RC=4.81 [†] p-value<0.001*	RC=-0.60 p-value=0.548	RC=4.21 [†] p-value<0.01*
P3	8.75	7.75	3.75	RC=0.60 p-value=0.548	RC=2.40 [†] p-value=0.016*	RC=3.01 [†] p-value=0.002
P4	7.25	1.00	4.00	RC=3.61 [†] p-value<0.001*	RC=-1.80 p-value=0.072	RC=1.80 p-value=0.072
P5	7.25	1.00	1.00	RC=3.61 [†] p-value<0.001*	RC=0.00 p-value=1.000	RC=3.61 [†] p-value<0.01*
P6	12.75	6.00	7.25	RC=4.21 [†] p-value<0.001*	RC=-0.60 p-value=0.548	RC=3.61 [†] p-value<0.01*
N=6	Mean± SD 8.50± 2.51	Mean± SD 3.17± 3.06	Mean ± SD 3.50 ± 2.07	p-value=0.003*	p-value=0.741	p-value=0.001*
Test-variable	Mean HADS Depression Scores (0-21)			Reliable Change (RC) of Difference in Mean Scores and p-values		
HADS (Anxiety)	Pre-session	Post-session	6 Month Follow-Up	Pre-session vs Post-session	Post-session vs 6 Month Follow-Up	Pre-session vs 6 Month Follow-Up
P1	10.25	4.25	6.00	RC=2.51 [†] p-value=0.012*	RC=-0.83 p-value=0.406	RC=1.67 p-value=0.095
P2	12.75	4.00	6.75	RC=3.76 [†] p-value<0.001*	RC=-1.25 p-value=0.211	RC=2.51 [†] p-value=0.012*
P3	15.00	14.00	15.00	RC=0.41 p-value=0.682	RC=-0.41 p-value=0.158	RC=0.00 p-value=1.000
P4	5.00	2.00	3.00	RC=1.25 p-value=0.211	RC=-0.41 p-value=0.158	RC=0.83 p-value=0.406
P5	11.75	2.00	2.00	RC=4.81 [†] p-value<0.001*	RC=0.00 p-value=1.000	RC=4.81 [†] p-value<0.001*
P6	14.25	4.75	10.25	RC=3.76 [†] p-value<0.001*	RC=-2.09 [†] p-value=0.036*	RC=1.67 p-value=0.095

[Table/Fig-4]: Mean HADS depression and anxiety scores of participants pre-session, immediate post-session and 6 months follow-up with Reliable Change (RC) in mean scores of each participants as they progress from pre-session to 6 month follow-up:

*p-value <0.05 is statistically significant; [†]Indicates significant improvement reliable change ($|RC| > 1.96$); [‡]Indicates significant deterioration reliable change ($|RC| > 1.96$)

the 25th percentile (4.75) and the 50th percentile. The priority of emergent themes among the participants were #1>#5>#2=#3>#4. Positive mental state followed by Reduced Stress were the most prominent themes selected by the participants.



[Table/Fig-5]: Representation of qualitative data by histogram showing priority of emergent themes in post-session group discussion.

Regarding the effects of MBI, there has been an overall improvement in outcome scores from pre-session to post-session, with $RC > 1.96$, (p -value < 0.05). In contrast, there has a modest improvement of scores at 6 months follow-up compared to pre-session. The scores somewhat decrease at six months follow-up compared to post-session but there were maintained from the post-session highs for a majority of the participants. No discomfort or adverse effects were reported by the participants during the conduct of eight weeks MBI to six months follow-up.

DISCUSSION

The aim of the study was to see the effects of MBI on a small sample of patients, using the replicated single case study design. An overall improvement in pain intensity, chronic pain acceptance, anxiety and depression, WHO health-related QOL from pre-session to Post-session, most of them being RCs with $|RC| > 1.96$, (p -value < 0.05) with sustained improvement in some aspects even at six months follow-up was found. The individual variation in participant's response may be attributed to the concept of mindfulness. Mindfulness encourages paying increased attention to body and pain, in contrast to the natural habit of Indian sufferers to avoid and ignore pain and this may have created some ambiguity in results. The interpersonal differences were acceptable and within our expectations.

This study results were to some extent comparable to a study which found significant improvement in pain acceptance and physical function, compared to pain scores and QOL [14]. The finding of a significant decrease in pain intensity (measured by NRS) with Mindfulness, was in contrast with a study on 109 patients which found more significant effects on anxiety and depression, mental QOL (psychological well-being), and pain acceptance, sustainable up to a six months follow-up [15]. One very important aspect of this research work was to note the changes in psychosocial relationship of the sufferer with chronic pain. A significant increase in CPAQ (in two subsets of Activity engagement and Pain willingness) [16] suggested improvements in physical, social, emotional as well as work-related functioning in the participants. By using WHO QOL, authors wanted to measure the well-being of sufferers. The psychological well-being along with the overall QOL were being significantly improved in almost all participants which is comparable to results are seen in another study [17]. This research found significant decreases in both Anxiety (A) and Depression (D)

subsets of HADS in the participant's post-session which correlates with other research works on psychological well-being [18,19]. A qualitative analysis of emergent themes in a group discussion of the question "How did you experience the effects of this Mindfulness based intervention?" also reinforces the "positive mental state" that the session generated in the participants.

The rationale for choosing Mindfulness as an intervention in the study was that it is an effective behavioural intervention in self-regulation for chronic pain patients [8]. Several scientific research works were carried out and a theoretical model of the mechanisms of MBIs for chronic pain management was suggested [20]. The dimensions of pain catastrophising and pain acceptance [21], were found to be affected by mindfulness in individuals with chronic low back pain [22]. Mindfulness-based pain relief is associated with orbito-frontal and rostral anterior cingulate cortex, regulation of low-level nociceptive neural targets (thalamus and primary somatosensory cortex) [23]. Several mindfulness programme directed specifically to chronic pain management were developed [24]. Systemic reviews and meta-analysis concluded that Mindfulness improves pain, depression symptoms, and QOL [17,25], and can be good alternatives to traditional cognitive behavioural treatments in chronic pain management [26]. American College of Physicians has included MBSR as a modality for the treatment of chronic low back pain, in their practice guidelines [27].

Mindfulness is yet to be studied extensively in the Indian population, as evident from the scarcity of scientific research work. The researchers have not come across any study with MBI and chronic pain in the Indian population. A few studies in Indian context, mentions its use in perinatal grief [28], stress-relief in pregnant [29], or stress management in coronary heart disease patients [30].

Lessons learned from this study may be useful in further research. Mindfulness appears to be a relatively novel concept for the participants but well acceptable as evident from written comments post-session. Two out of initial eight participants were irregular and did not complete the two months programme; shorter versions of the session or options of viewing recordings of sessions may increase participant compliance. A lot of sufferers could not join the session due to physical disability, so provision of online modes of learning may be useful. The use of MBI as an adjuvant therapy (and not as a stand-alone therapy) in chronic pain sufferers appears more rational as it involves complex human learning, interactions, and execution. A detailed cost-analysis was beyond scope but the concept of group sessions may optimise the cost of execution in developing countries like India. The positive mental state and stress reduction aspect of mindfulness may have additional benefits in the mentally stressed Indian population [31]. In spite of the shortcomings, the present study provides important observations and lessons to carry forward in Indian context.

Limitation(s)

The sample size was small and lacked a control group. All the parameters were self-reported by the participants, which had its own limitations. Participants had a basic education level which can affect understanding of mindfulness concepts. A detailed documentation of daily meditation practice and change in medications during the session was not available to the researchers. None of the measures of Mindfulness, like the Kentucky Inventory of Mindfulness Skills [32], or the Mindful Attention Awareness Scale [33], could be included in the present study.

CONCLUSION(S)

The mindfulness based intervention has a positive influence on pain intensity, chronic pain acceptance, anxiety and depression and QOL of Indian chronic pain sufferers. Further larger scale trials will be required to substantiate the results.

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PLAGIARISM CHECKING METHODS: ^[Jain H et al.]

- Plagiarism X-checker: May 31, 2021
- Manual Googling: Sep 29, 2021
- iThenticate Software: Oct 14, 2021 (8%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **May 30, 2021**Date of Peer Review: **Sep 10, 2021**Date of Acceptance: **Oct 05, 2021**Date of Publishing: **Nov 01, 2021**