Brief Communication

Effects of a mindfulness-based intervention on pain intensity, disability and quality of life of chronic low back pain patients: A randomised study

INTRODUCTION

The lifetime prevalence of low back pain was 66% among Indians (2022).[1] Chronic low back pain (CLBP) is multifactorial and refers to non-specific localised back pain below the costal margin and above the inferior gluteal folds with a duration of >3 months. CLBP was previously treated only with medicines and invasive procedures, but the newer bio-psycho-social model demands a multimodal treatment approach.

Mindfulness is defined as 'the awareness that arises on paying attention in a particular way on purpose, in the present moment, and nonjudgmentally' and has been used as a group behavioural intervention.[2] The initial mindfulness-based stress reduction (MBSR) modules evolved into equally effective brief mindfulness-based intervention (MBI) modules. The mechanism of pain relief in mindfulness involves higher-order (rostral anterior cingulate cortex) regulation of lower nociceptive targets (thalamus and primary somatosensory cortex).[3,4]

The study's primary objective was to determine an MBI's effectiveness in pain intensity, disability, and quality of life. The secondary objective was to observe the effects on stress, anxiety, depression, pain acceptance, pain catastrophising and mindfulness characteristics in the Indian population. We hypothesised that mindfulness will improve pain intensity, disability and quality of life.

METHODS

This randomised controlled trial (RCT) was conducted from August 2023 to February 2024. Written informed consent was obtained from all the participants to enrol them in the study and use the patient data for research and educational purposes. An Institutional Ethics Committee clearance (KPCMCH/IEC/2023/135, dated 10 July 2023) was obtained, and the trial was registered with Clinical Trials Registry-India (CTRI/2023/08/056037, https://ctri.nic.in/). The study was carried out following the principles of the Declaration of Helsinki, 2013 and good clinical practice.

Patients of age 18–65 years, suffering from CLBP >3 months, had a definitive provisional diagnosis of CLBP (excluding infection, neoplasm, metastasis, etc.), had an intensity of pain of numerical rating scale (NRS) >4 and were on a stable treatment regimen were recruited. Patients with previous experience with mindfulness, patients suffering from uncontrolled systemic diseases, patients with a history of back surgery and patients with pain in other parts of the body, like fibromyalgia, were excluded from the study.

The principal investigator randomised [sequence produced through the Statistical Package for the Social Sciences (SPSS) software's random selection procedure] the patients as per the random sequence to Group U (usual care) or Group M (mindfulness). The allocation concealment was done using a set of sealed envelopes chosen by the participants. Those who attended at least three of five sessions were retained in the study. The usual medical treatment regimen of the patients [receiving medicines like paracetamol (650 mg thrice a day), pregabalin 75 mg, amitriptyline 10 mg, etc.] was continued, and mindfulness or usual care was used as an additional therapy.

A five-session version of the MBSR programme was chosen [Table 1]. The programme was conducted by a pain physician trained via the original MBSR programme (https://www.ummhealth.org/center-mindfulness) and with teaching experience of more than four years. The participants maintained a daily practice log of home practice, which was monitored by the teacher, and regional language was used in most of the communication. Group U attended sham sessions and practised relaxation exercises (mindfulness concepts were excluded). Any participant experiencing any adverse effects was taken care of by a neuro-psychiatrist.

The demographic characteristics were noted. The outcome variables were assessed using a self-assessment questionnaire at three time points: pre-programme, post-programme and six months from the start of the programme. The primary outcome parameters were pain intensity, disability and quality of life. The pain intensity was measured using the 11-point NRS, disability by the 10-item Oswestry Disability Index (ODI) and quality of life with 26 items World Health Organization (WHO) quality of life (WHO QOL 100) scales. The secondary parameters stress, anxiety and depression were measured using the Depression Anxiety and Stress Scale-21 items

(DASS 21) and pain acceptance was measured by the Chronic Pain Acceptance Questionnaire-8 (CPAQ 8). Pain catastrophising was measured by a 13-item pain catastrophising scale (PCS), and different aspects of mindfulness were measured by the 14-item Freiburg Mindfulness Inventory (FMI).

Sample size calculation was made with a standard deviation (SD) of 1.86 for the difference in pain intensity (from a study by Carrie E Brintz *et al.*)[5] With a power of 80% to find the difference using repeated measures analysis of variance (RM ANOVA) with a type I error (α) of 5%, the calculated minimum total sample size was 184 (or 184/2 = 92 in each group). Initially, 200 patients were screened (anticipated attrition of 10%). SPSS statistics software version 18.0 (IBM Corporation, Armonk, NY, USA) was used. The statistical test used for age [expressed as mean (SD)]

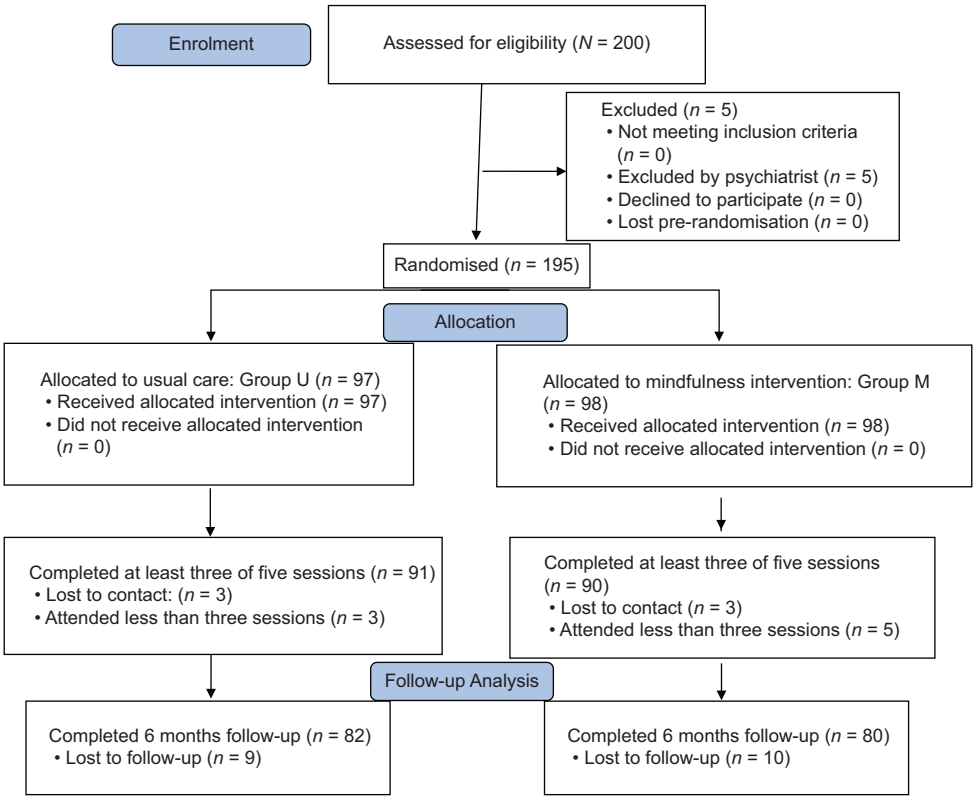

Figure 1: Consolidated Standards of Reporting Trials flow diagram

Table 1: Mindfulness (and usual care) intervention details and demographic profile

Variable (pre-session)	Group U (*n*=97)	Group M (*n*=98)	Comparison between Group M and Group U
Age mean (SD)	49.28 (5.89)	48.74 (5.97)	*t*=0.6366 df=195 *P*=0.525
Gender: Male/Female, *n* (%)	72 (74.23)/ 25 (25.77)	69 (70.41)/ 29 (29.59)	χ^2=0.355, df=1, *P*=0.551
Intervention details			
Each mindfulness session: duration 1.5 h, 40 participants in each group, daily home practice of 20 min, session contents mentioned below:			
Session 1. Introduction to mindfulness (practice: mindfulness of breathing)			
Session 2. Mindfulness and use in chronic LBP (practice: body scan)			
Session 3. Application of mindfulness to deal with pain catastrophising and to increase chronic pain acceptance (practice: mindfulness of pain areas)			
Session 4. Interrupting the cycle of pain to suffering: moving forwards with acceptance and self-compassion (practice: self-compassion)			
Session 5. Sum up of all learnings (review of all practices)			
The control group participants attended similar sessions. In these sham sessions, topics on self-care, pain education and relaxation exercises were discussed and practised. The mindfulness concepts were deliberately excluded. These sessions remained non-specific to qualify as an active intervention			

CI=confidence interval, LBP=low back pain, SD=standard deviation, n=number of patients

Table 2: Comparison of study parameters

Variable	Group U			Group M			Comparison in of Group U versus Group M	Comparison of PV (pre vs. post vs. FU)	Comparison of PV of Group M and Group U in pre-session (×1), post-session (×2) and follow-up (×3) (RM ANOVA multiple comparison with Bonferroni correction) (corrected α=0.05/3=0.0167)			Observed effect size (η^2) and treatment effect size (η_p^2)
	Pre (*n*=97)	Post (*n*=91)	FU (*n*=82)	Pre (*n*=98)	Post (*n*=90)	FU (*n*=80)	MS *F*-statistic (df_1, df_2) *P*	MS *F*-statistic (df_1, df_2) *P*	(x1−x2) *F*- statistic Crit. val. *P*	(x1−x3) *F*- statistic Crit. val. *P*	(x2−x3) *F*- statistic Crit. val. *P*	η^2 and η_p^2
Primary outcome variables												
NRS												
Mean (SD)	7.206 (0.815)	7.252 (0.708)	7.243 (0.639)	7.020 (1.015)	5.455 (0.961)	5.850 (0.887)	159.156	28.802	0.753	0.557	0.196	η^2=0.086
95% CI	[7.04–7.37]	[7.1–7.4]	[7.1–7.38]	[6.82–7.22]	[5.25–5.66]	[5.65–6.05]	186.492	33.749	56.193	33.211	4.945	η_p^2=0.112
							(1, 532)	(2, 532)	5.783	5.785	5.788	(medium)
							0.000*	1.588e-14*	4.851e-13**	1.803e-8**	0.026	
ODI												
Mean (SD)	36.845	40.450	37.304	37.346	26.055	27.850	7524.924	1070.997	3.804	4.461	0.657	η^2=0.017
95% CI	(4.029)	(3.482)	(3.992)	(4.913)	(5.013)	(5.109)	34.549	4.917	4.502	65.625	0.1169	η_p^2=0.018
	[36.03–37.66	[39.72–41.18]	[36.43–38.18]	[36.36–38.33]	[25–27.11]	[26.71–28.99]	(1, 532)	(2, 532)	5.783	5.785	5.788	(small)
							7.341e-9*	0.007*	0.034	8.993e-15*	0.732	
WHO QOL							1328.171	489.033	3.113			
Domain 1	33.237	33.450	32.512	33.541	39.588	35.750	11.296	4.159	6.924	0.7214	2.391	η^2=0.015
Mean (SD)	(10.780)	(9.024)	(8.617)	(12.548)	(12.675)	(9.850)	(1, 532)	(2, 532)	5.783	0.4033	4.671	η_p^2=0.015
95% CI	[31.06–35.41]	[31.57–35.33]	[30.62–34.41]	[31.02–36.06]	[36.93–42.24]	[33.56–37.94]	0.0008322*	0.01613*	0.008856**	5.785	5.788	(small)
										0.5258	0.03136	
WHO QOL												
Domain 2	29.402	30.131	30.256	29.051	35.244	31.825	566.082	559.315	3.448	1.805	1.643	η^2=0.025
Mean (SD)	(9.125)	(8.438)	(6.794)	(10.744)	(9.762)	(7.944)	6.918	6.835	11.935	3.635	3.276	η_p^2=0.025
95% CI	[27.56–31.24]	[28.37–31.89]	[36.03–37.66]	[28.76–31.20]	[33.20–31.75]	[30.06–33.59]	(1, 532)	(2, 532)	5.783	5.785	5.788	(small)
							0.008779*	0.001172*	0.0006144**	0.05737	0.07117	
WHO QOL												
Domain 3	29.783	28.153	30.963	25.887	33.877	29.475	0.3256	516.250	3.174	2.403	0.771	η^2=0.018
Mean (SD)	(10.568)	(8.252)	(9.887)	(10.671)	(10.971)	(9.148)	0.003	4.952	8.627	4.952	0.531	η_p^2=0.018
95% CI	[27.65–31.91]	[26.43–29.87]	[28.79–33.14]	[23.75–28.03]	[31.58–36.17]	[27.44–31.51]	(1, 532)	(2, 532)	5.783	5.785	5.788	(small)
							0.9555	0.007394*	0.003518**	0.02669	0.466	
WHO QOL												
Domain 4	32.618	31.670	29.646	32.112	35.556	32.200	358.908	230.241	0.845	1.456	2.302	η^2=0.012
Mean (SD)	(8.268)	(6.095)	(5.705)	(10.545)	(8.793)	(7.541)	5.108	3.277	0.827	2.685	7.808	η_p^2=0.012
95% CI	[30.95–34.28]	[30.44–32.94]	[28.39–30.9]	[30.00–34.23]	[33.71–37.4]	[30.52–33.88]	(1, 532)	(2, 532)	5.783	5.785	5.788	(small)
							0.02421*	0.0385*	0.363	0.102	0.005496**	

Contd...

Table 2: Contd...

Variable	Group U			Group M			Comparison in of Group U versus Group M	Comparison of PV (pre vs. post vs. FU)	Comparison of PV of Group M and Group U in pre-session (×1), post-session (×2) and follow-up (×3) (RM ANOVA multiple comparison with Bonferroni correction) (corrected α=0.05/3=0.0167)			Observed effect size (η^2) and treatment effect size (η_p^2)
	Pre (*n*=97)	Post (*n*=91)	FU (*n*=82)	Pre (*n*=98)	Post (*n*=90)	FU (*n*=80)	MS *F*-statistic (df1, df2) *P*	MS *F*-statistic (df1, df2) *P*	(x1−x2) *F*- statistic Crit. val. *P*	(x1−x3) *F*- statistic Crit. val. *P*	(x2−x3) *F*- statistic Crit. val. *P*	η^2 and η_p^2
Secondary outcome variables												
Pain acceptance												
Mean (SD)	16.793	16.681	16.743	16.663	24.233	22.687	2444.246	722.336	3.708	2.951	0.757	η^2=0.094
95% CI	(3.994)	(3.756)	(3.687)	(4.385)	(5.199)	(4.796)	112.484	33.241	56.679	38.067	2.501	η_p^2=0.111
	[15.99–17.6]	[15.9–17.46]	[15.93–17.55]	[15.78–17.54]	[23–14,25.32]	[21.62–23.75]	(1, 532)	(2, 532)	5.783	5.785	5.788	(medium)
							0.000*	2.487e-14*	3.915e-13**	1.874e-9**	0.114	
Pain catastrophising												
Mean (SD)	36.195	35.824	35.804	36.234	26.844	29.650	3145.728	1176.909	4.856		1.406	η^2=0.120
95% CI	(5.185)	(4.710)	(4.879)	(4.665)	(5.194)	(4.658)	113.291	42.3854	74.719	3.450	6.984	η_p^2=0.137
	[35.15–37.24]	[34.84–36.8]	[34.73–36.88]	[35.29–37.17]	[25.74–27.93]	[28.61–30.69]	(1, 532)	(2, 532)	5.783	40.413	5.788	(medium)
							0.000*	0.000*	1.11e-16**	5.785	0.008**	
										6.355e-10**		
DASS-S												
Mean (SD)	18.237	18.252	17.987	18.265	12.933	13.325	1348.717	422.718	2.643	2.566	0.077	η^2=0.110
95% CI	(3.268)	(3.013)	(3.256)	(3.625)	(1.964)	(1.798)	133.168	41.737	58.955	52.601	0.0761	η_p^2=0.135
	[17.58–18.9]	[17.63–18.88]	[17.27–18.7]	[17.54–18.99]	[12.52–13.34]	[12.93–13.72]	(1, 532)	(2, 532)	5.783	5.785	5.788	(medium)
							0.000*	0.000*	1.439e-13**	2.607e-12**	0.782	
DASS-A												
Mean (SD)	17.494	17.769	18.000	17.704	13.244	13.737	993.866	231.192	2.080	1.704	0.375	η^2=0.063
95% CI	(3.485)	(2.925)	(3.348)	(3.932)	(2.399)	(2.220)	89.353	20.785	33.746	20.583	1.585	η_p^2=0.072
	[16.79–18.2]	[17.16–18.38]	[17.26–18.74]	[16.92–18.49]	[12.74–13.75]	[13.27–14.23]	(1, 532)	(2,532)	5.783	5.785	5.788	(medium)
							0.000*	2.034e-9*	1.349e-8**	7.837e-6**	0.208	
DASS-D												
Mean (SD)	11.072	10.967	11.182	11.214	8.800	9.125	223.998	81.701	1.254	0.976	0.277	η^2=0.074
95% CI	(1.821)	(1.642)	(1.722)	(2.280)	(1.530)	(1.353)	65.466	23.878	39.210	22.646	2.662	η_p^2=0.082
	[10.71–11.44]	[10.63–11.31]	[10.8–11.56]	[10.76–11.67]	[8.48–9.12]	[8.82–9.43]	(1, 532)	(2, 532)	5.783	5.785	5.788	(medium)
							3.997e-15*	1.172e-10*	1.051e-9**	2.844e-6**	0.103	
FMI												
Mean (SD)	22.577	22.362	22.768	22.836	27.133	25.750	899.644	210.441	2.027	1.533	0.494	η2=0.033
95% CI	(4.051)	(3.728)	(3.507)	(4.705)	(5.577)	(5.100)	42.401	9.918	17.445	10.574	0.991	η_p^2=0.035
	[21.76–23.39]	[21.59–23.14]	[22.00–23.54]	[21.89–23.78]	[25.96–28.3]	[24.61–26.89]	(1, 532)	(2, 532)	5.783	5.785	5.788	(small)
							1.723e-10*	0.000059*	3.687e-5**	0.00125**	0.320	

Group M=mindfulness group, Group U=usual care group. Data are expressed as mean (standard deviation) (95% confidence interval). **P*-values of RM ANOVA are significant at $P<0.05$. ***P*-values of multiple comparison by Bonferroni correction are significant at $P<0.0167$. η^2=effect size, η_p^2=treatment effect size, ANOVA=analysis of variance, CI=confidence interval, Crit. Val. = critical value, DASS=Depression, Anxiety and Stress Scale (S=stress, A=anxiety, D=depression), df=degrees of freedom, *F*=*F* statistic of RM ANOVA, FMI=Freiburg Mindfulness Inventory, FU=follow-up, M=mindfulness, MS=mean square, NRS=numerical rating scale, ODI=Oswestry disability Index, PV=pooled variance, RM ANOVA=repeated measures analysis of variance, SD=standard deviation of the mean, U=usual care, WHO QOL=World Health Organization Quality of Life scale, n=number of patients

was an unpaired *t*-test, and for gender (expressed as a percentage) was a Chi-square of independence. For the other outcome parameters, the statistical test was RM ANOVA (Bonferroni model). The normality of data was tested using the Shapiro–Wilk Test and results were presented in mean (SD) and percentage format. $P < 0.05$ was considered statistically significant for RM ANOVA results, and $P < 0.0167$ was statistically significant with Bonferroni correction. The F distribution (named after Ronald Fisher) derived from the quotient of two Chi-square distributions was used to interpret RM ANOVA results.

RESULTS

The flow diagram is summarised [Figure 1]. The baseline demography were comparable between the groups [Table 1]. The primary outcome parameters showed a significant difference both between Group M and Group U and between treatments (pre-session vs. post-session vs. follow-up) in NRS ($F = 56.193$, $P = 4.851e\text{-}14$), ODI ($F = 65.625$, $P = 8.993e\text{-}15$) and WHO QOL domain 1 and 2. Regarding the secondary outcome parameters, results of RM ANOVA showed a significant difference between Group M and Group U and between treatments (pre-session vs. post-session vs. follow-up) in almost all the parameters. Participants reported no adverse effects during sessions [Table 2].

DISCUSSION

In Group M (mindfulness), pain intensity (NRS), disability index and quality of life (in domain 1,2) significantly improved post-session and were mainly sustained in follow-up. Stress, anxiety, depression, pain acceptance and pain catastrophising (effect size medium) showed significant improvement post-session and were mainly sustained in follow-up.

Our study's findings were congruent with those of previous studies. Anheyer *et al.*[6] found mindfulness to decrease pain intensity. An RCT by Morone *et al.*[7] showed it to reduce disability in the elderly with CLBP. A systemic review found MBIs to reduce pain intensity,[8] while another found it to improve depression and quality of life (along with pain).[9] A systemic review found mindfulness to improve pain acceptance,[10] while a study found it to decrease pain catastrophising.[11] In the Indian context Patil[12] mentioned its use in CLBP, and Banth and Ardebil[13] used mindfulness in Iranian female patients and found it to reduce pain severity and improve quality of life.

Limitations include the study being a single-centre trial, the outcome variables being self-reported, the per-protocol format of analysis, significant loss of participants in follow-up, heterogeneity of received medical treatment and non-calculation of cost-effectiveness of the therapy.

CONCLUSION

Mindfulness had a positive impact on pain intensity, disability and quality of life of Indian chronic low back pain patients.

Acknowledgement

We are indebted to Dr. Satyaki Basu and Dr. Subhashis Saha for their support in this research.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared upon request.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Submitted: 01-Apr-2024
Revised: 25-Jul-2024
Accepted: 13-Aug-2024
Published: 14-Sep-2024

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Quick response code	Website: https://journals.lww.com/ijaweb
	DOI: 10.4103/ija.ija_361_24

How to cite this article: Pal A, Mukhopadhyay P, Bhattacharyya D, Ray S. Effects of a mindfulness-based intervention on pain intensity, disability and quality of life of chronic low back pain patients: A randomised study. Indian J Anaesth 2024;68:915-20.