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Original Research Article

Effects of a mindfulness based intervention on mental well-being and quality of life in Indian adults: an early attempt for integration into community clinical practice

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ABSTRACT

Background: In India, the burden of mental ill-health is ever increasing. There is an urgent requirement for the implementation of interventions to prevent psychosocial problems from getting manifested as psychiatric diseases. The researchers see potential in mindfulness, an evidence-based group therapy popular in Western countries. This study shares a ground-level experience with an eight-week face-to-face mindfulness-based intervention. The aim was to see the effects of mindfulness on anxiety, depression, and quality of life in Indian adults.
Methods: Participants were randomized into two groups (n=74): group M participated in the mindfulness program while group C attended placebo sessions. The Hospital anxiety and depression score (HADS) for anxiety and depression and WHO quality of life (WHO QOL 100) were measured pre-program and post-program. Statistical analysis used was the paired and unpaired t-Test and one-way ANOVA for the outcome variables.
Results: The HADS-A (anxiety) and HADS-D (depression) improved with p=0.0001 and p=0.0003 with the practice of mindfulness. In the mindfulness group, domains 1, 2, and 4 of WHO quality of life also improved post-session with p<0.0001 when compared to the control group.
Conclusions: Mindfulness improved the anxiety, depression, and quality of life of Indian adults. Mindfulness holds initial promise for integration into community clinical practice. This study being an early attempt, further studies will be needed before widespread implementation in the country.

Keywords: Mindfulness-based intervention, Indian adults, Anxiety, Depression, Quality of life

INTRODUCTION

Mental ill-health is among the leading cause of non-fatal disease burden in India.[1] Mental well-being is of critical importance and without mental health, there can be no true physical health.[2] In India, nearly 150 million need active mental interventions. The mental ill-health burden is on the increase due to the growing awareness and recognition in the societies, changing lifestyles, and biological vulnerabilities.[3] Mental infirmity sometimes creates a lifelong impact and result in a poor quality of life. In the Indian context, the clinical practice or the delivery of mental health services are mostly limited to secondary or tertiary levels of health care. A huge treatment gap exists as the preventive evidence-based options are limited.[4] A recent survey emphasized the importance of the implementation of preventive interventions at the community level.[1] Integration of community-based interventions with the existing setup will have the potential to reduce this treatment gap.[5] And most of the preventive interventions are only theoretical-based, its' high time for practical application of

interventions to improve the mental health of the Indian community.[6] These evidence-based interventions will be the entry points to mainstream healthcare.

Mindfulness has been integrated into the mainstream health care of Western countries since the 1970s.[7] Mindfulness was defined by Kabat-Zinn as "the awareness that arises when paying attention on purpose, in the present moment, and non-judgmentally".[8] Mindfulness was first implemented in a clinical setting as a group program called the mindfulness based stress reduction (MBSR). MBSR gave way to Mindfulness based interventions (MBIs) that are structured, practical-oriented, flexible, and modified for application in different community settings. Subsequent research found Mindfulness to reduce psychological symptoms, increase subjective well-being, and improve behavioural regulation.[9] But India has major social and cultural differences from the West and the experience with mindfulness is limited. After an extensive search, nominal research with mindfulness can be traced in the non-clinical Indian population. The researchers in this study focus on the prevention of psychosocial problems of anxiety and depression prevalent in Indian societies from getting manifested as diseases. Mindfulness sessions have the advantage of being conducted in a group without the involvement of psychiatric specialists/experts. India has already a shortage of specialists with 0.75 psychiatrists per 100,000, too meagre a resource for the whole population.[10] Mindfulness sessions are not a replacement for established psychological/psychiatric therapies but can be a valuable addition to preventive mental health services. This study shares a ground-level experience with the practical application of mindfulness in an Indian community. It aims to see the impact of an eight-week face-to-face MBI on anxiety, depression (measured by Hospital anxiety and depression score; HADS) and quality of life (measured by WHO quality of life score; WHO-QOL 100) of apparently healthy Indian adults. The researchers formulate a hypothesis that Mindfulness will positively affect the anxiety, depression, and quality of life of the participants post-program.

METHODS

Study design and setting

The prospective randomized controlled study was conducted by a medical institution based in West Bengal, India. It collaborated with a mindfulness centre to organize the face-to-face mindfulness program. The study period was March to August 2021. Institutional ethical clearance was obtained and written informed consent was taken from all participants. The trial was registered in the clinical trial registry of India.

Sample size calculation

Despite an extensive search, any previous data in the Indian setting with HADS and WHO-QOL 100 was not found. The sample size was calculated based on non-Indian studies, on the assumption of a standard deviation (SD) of 11.53 and 3.365 of the expected difference of mean HADS and WHO QOL 100 from the previous non-Indian studies, with a power of >80% to detect this difference using Paired-t test, Unpaired-t test and one-way ANOVA, with type I error (α) of <5%.[11,12] The calculated minimum sample size came out as 28 each using HADS and 38 each using WHO-QOL score. Hence, we planned our study with 80 participants divided into 2 groups of 40 each. Information about the study was spread in the community and interested participants contacted the study-co-ordinator. Eighty participants were screened by the researchers, based on written responses to a questionnaire based on inclusion and exclusion criteria.

Inclusion and exclusion criteria

Inclusion criteria were age between 18 to 65 years, no major diagnosed physical illness, not undergoing any psychological therapy or any plans of it during the study period, no any significant drug history, level of education more than higher secondary standard with a basic understanding of English and have to be a resident of India. Exclusion criteria were; diagnosed psychiatric illness, previous experience with mindfulness or meditation. The selected participants were subjected to an interview with a clinical psychologist to exclude any major psychological illness that has escaped initial screening. There was a provision for referral to psychiatric specialists and those subjects were not included in the study. Total 80 participants were randomized into 2 groups; mindfulness (group M) and control group (group C), 40 in each group. Randomization was done using Random Number Tables of By Rand Corporation, USA©1955. Six participants in group C did not complete the pre-session formalities of data submission and were excluded from the study. The 40 candidates of group M were further sub-divided into two separate batches of 20 participants each and they participated in the MBI, on different days of the week. The 34 candidates in the control group attended "placebo" sessions. These placebo sessions involved instructions about self-care, of similar duration (where Mindfulness exercises and concepts were deliberately avoided) and were conducted by the same instructor. Candidates of the control group were later offered to join the MBI after the study period, which is beyond the scope of the present discussion. Attendance in at least six out of eight sessions was considered to be criteria of completion of the program. All candidates in group M and in group C completed the program. Final sample size was (n=40) for group M and (n=34) for group C (Figure 1).

Intervention

The 8 week MBI was a reflection of the original 8 week Mindfulness-based stress reduction (MBSR) program. The program consisted of an orientation session and eight main sessions, one session each week. The duration of the sessions was approximate two hours. The all-day silent retreat was not included. The mindfulness instructor was

trained via the original MBSR course and other affiliated courses and had experience teaching Mindfulness for more than two years. The language of communication was English but the local language was used for some parts for better understanding. During the face-to-face sessions, formal meditation skills (body scan, sitting meditation), 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 bring in 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, mindfulness activities and the homework assignments were monitored by the instructor. The group C participants doing placebo sessions maintained a similar schedule (excluding the Mindfulness exercises and concepts). Any participant experiencing any discomfort or adverse effect during the programme was asked to report to the instructor.

Outcome variables

Demographic data (age, sex) was collected at the beginning of the study. In addition, quantitative variables HADS and WHO QOL were measured at two time points; pre-session and post-session.[9,13]

HADS

This scale was deliberately chosen as it is a reliable tool for community-level research work to screen anxiety and depression in primary care medical practice. HADS consists of a fourteen-item scale with seven items each for anxiety and depression subscales. Scoring for each item ranges from zero to three. A subscale score >8 denotes anxiety or depression.

WHO QOL 100

WHO QOL focuses on physical and mental health and the functional performance of individuals. WHO QOL has 4 domains: physical health (7 items), psychological health (6 items), social relationships (3 items), and environment (8 items), after computing the scores, they were transformed to a 0-100-scale.

Any participant experiencing any discomfort was requested to report to the instructor. The overall experience of the participants post-program was noted as a subjective measure to serve as an indirect measure of acceptability of the mindfulness program in the study population.

Statistical analysis

Data of WHO-QOL and HADS were treated as continuous. Data were tested for equality of variance using Levene's test. Normality was confirmed using Shapiro-Wilk test. The analysis of continuous data was performed using Paired and Unpaired t-test and One-way ANOVA. Baseline characteristics (age, sex) were tested using the Un-paired t-test and Chi-square (χ^2) test respectively. The statistical software used was SPSS Statistics for Windows 7® version 18.0.0 (Chicago, IL 60606-6412) and GraphPad Prism® InStat version 5.0. (California 92037-3219), Microsoft® Office Excel 2010 (Washington: Microsoft) was used to draw the Figures. Results were presented as mean (SD) and percentage format, $p<0.05$ was considered statistically significant.

RESULTS

Baseline characteristics

Out of 80 participants enrolled, 40 participated in the mindfulness intervention (Group M) and 34 acted as controls (Group C) (Figure 1). Baseline demographic characteristics (age, sex) were similar between the participants (Group M) and controls (Group C) (Table 1).

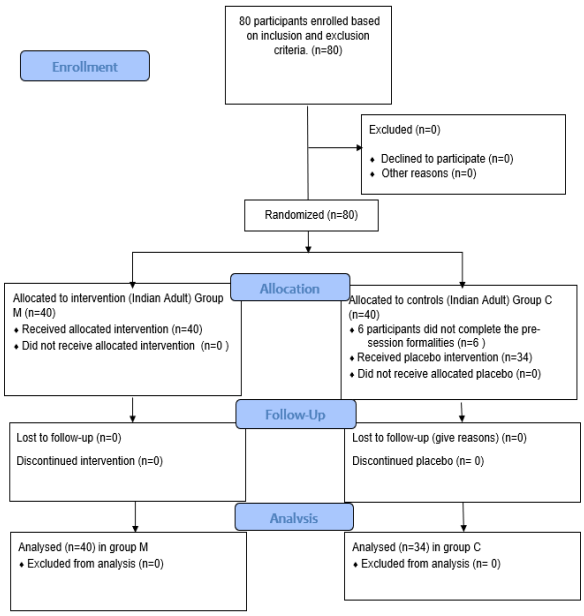

Figure 1: Consort 2010 flow diagram of participants in the study.

HADS

The HADS was grouped into pre-session and post-session scores for each group (group M and group C). By Unpaired t-test, the mean scores in group M when compared to group C (post-session) differed significantly in HADS-A (anxiety) and HADS-D (depression) with $p<0.0001$ and $p=0.0003$ respectively. By Paired t-test, the mean scores in post-session differed significantly only in group M compared to respective pre-session scores with $p<0.0001$ in both HADS-A and D (Table 1). The above tests were followed up by one-way ANOVA which also showed that HADS Scores were also significantly lower in post-session group M compared to other scores in HADS-A and D with $p=0.000$.

Table 1: Representation of demography (age, sex), WHO QOL (4 domains), HADS (anxiety and depression) of the study participants.

Groups		Group M (n=40) Mean (SD)/ N (%)	Group C (n=34) Mean (SD)/ N (%)	Unpaired t test p value	ANOVA	
					F statistic	P value
Basic characteristics	Age (years)	49.70 (10.49)	50.20 (10.66)	0.8398		
	Sex	M=14 (35.00) F=26 (65.00)	M=15 (44.12) F=19 (55.88)	0.4233		
WHO-QOL	**Domain1**					
	Pre-session	61.8 (13.51)	61.26 (11.86)	0.8568	9.0185	<0.0001
	Post-session	73.37 (10.51)	61.97 (12.57)	<0.0001		
	Paired t-test p value	<0.0001	0.1032			
	Domain2					
	Pre-session	55.95 (9.89)	54.82 (10.30)	0.6323	17.5359	<0.0001
	Post-session	69.05 (11.38)	54.47 (9.89)	<0.0001		
	Paired t-test p value	<0.0001	0.5351			
	Domain 3					
	Pre-session	58.8 (16.25)	58.5 (15.47)	0.9357	1.3815	0.2509
	Post-session	64.72 (15.26)	60.26 (13.68)	0.1932		
	Paired t-test p value	<0.0001	0.4585			
	Domain 4					
	Pre-session	62.17 (8.24)	61.38 (7.28)	0.666	5.3147	0.0017
	Post-session	68.55 (10.75)	62.47 (8.76)	0.0103		
	Paired t-test p value	<0.0001	0.4732			
HADS	**Anxiety**					
	Pre-session	7.77 (3.10)	8.17 (3.20)	0.5968	15.3467	<0.0001
	Post-session	4.15 (2.63)	7.38 (2.75)	<0.0001		
	Paired t-test p value	<0.0001	0.1034			
	Depression					
	Pre-session	6.75 (3.55)	7.23 (3.69)	0.5952	8.0994	0.0001
	Post-session	3.77 (3.43)	6.61 (2.95)	0.0003		
	Paired t-test p value	<0.0001	0.1115			

WHO-QOL 100 scores

The WHO-QOL scores were grouped into pre-session and post-session scores for each group (group M and group C). By Unpaired t-test, the mean post-session scores in Group M when compared to group C differed significantly in domain 1,2 and 4 of WHO-QOL with p<0.0001 in domain 1,2 and p<0.0103 in domain 4. By Paired t-test, the mean post-session scores of group M differed significantly compared to respective pre-session scores with p=0.0001 in all domains of WHO-QOL (Table 1).

The above tests were followed up by one-way ANOVA which also showed that WHO-QOL scores were also significantly higher in post-session Group M compared to other scores in domain 1,2 and 4 with p<0.0001 in domain 1,2 and p=0.0017 in domain 4. There were no significant differences in mean scores of domain 3 WHO QOL in group M when compared to group C. One-way ANOVA result within domain 3 WHO-QOL was also not significant. No discomfort or side effect was reported by any participant during the program.

DISCUSSION

The results of the study support the hypothesis formed. The MBI caused a significant improvement in anxiety (p<0.0001) and depression (p=0.0003) components of post-session HADS scores, compared to the control group. Mindfulness significantly improved the physical (p<0.0001), psychological (p<0.0001), and environmental (p=0.0103) domains of WHO QOL with not much effect in the social domain as compared to the control group.

The improvements in the psychological domain of WHO QOL and the effects on anxiety and depression components of HADS indicate the positive impact of Mindfulness on the mental wellbeing of the participants. Mindfulness appears to be culturally acceptable as evident from written comments of participants post-program. The effects on anxiety and depression are comparable to prior research work from other countries. Previous studies found Mindfulness to be effective on anxiety and depression in Spanish university students and Danish women.[14,15] The significant positive impact on anxiety and depression perhaps reflects the huge burden

of underlying sub-clinical mental diseases in the Indian community.[5] A previous study found mindfulness interventions targeted at subclinical symptoms of mental disorders to be more beneficial.[16] The impact of Mindfulness on WHO QOL is consistent with results in Taiwanese and Iranian patients and in patients with Parkinson's disease.[12,17,18] A few Indian studies mention its application in specific domains like to treat depression in diabetes mellitus, to lower intraocular pressure, use in gastro-oesophageal reflux patients and in pregnant women, but the experience with the non-clinical population in a clinical setting are minimal.[19-23]

In India the problems related to mental health are multi-dimensional. There are a lot of myths and stigmas associated with mental health problems.[24] This leads to improper utilization of existing mental health services.[25] So community-based interventions are to play a pivotal role in clinical practice in the near future.[26] There is a lack of practical implementation of evidence-based preventive models in the Indian scenario.[27] Mindfulness appears to have a few additional advantages as a preventive intervention in the Indian context. The mindfulness-based interventions are available within the community itself. Perhaps a shift from individual therapies to group-based therapies may help in increasing the acceptability. Moreover, it can reach out to a large number of people at a point of time, beneficial for a populous country like India.

The mindfulness concepts and exercises though completely new to Indian participants were well understood and accepted by the participants. The difficulties faced in this early study were to keep the participants' commitment going for a period of two months, maintain interest in the control group, and problems faced by debilitated participants in physical attendance. But the delivery of programs at the community level was a welcome step to overcome the stigma and unwillingness to go to formal mental health setups. These programs acted as referrals to the mainstream mental healthcare system breaking the current trend of seeking professional help as the last resort.

Mindfulness is only an additional tool and not a panacea to multi-level mental health problems in the Indian context. Individuals with a diagnosed psychiatric illness need to be treated by psychiatric specialists and no one doubts this notion. The researchers neither promote mindfulness as a one-size-fits-all intervention for all subclinical psychological issues nor claim any superiority over other evidence-based therapies.[28,29]

Comparison with other standard therapies was beyond the scope of this study. The motive behind this research work was only to explore the practical implementation of mindfulness in community clinical practice in the Indian context. These type of evidence-based preventive interventions at the community level will be the effective access point to secondary and tertiary mental care.

Limitations

Limitations of this study include self-reporting of variables by participants, no use of active intervention (only placebo sessions) in comparison groups, and no scope of follow-up post-intervention. The participants showed interest to participate, which may have influenced the results. HADS used in this early study is a basic screening tool with limitations to reflect mental wellbeing. None of the specific measures of mindfulness, nor other outcome variables reflecting well-being, can be included in the study.

A cost analysis was not performed so inference on the low cost of the intervention cannot be drawn. The study was conducted in an urban/semi-urban community setup, so the cultural acceptability of Mindfulness may not be generalized to multiple and diverse communities throughout the country. The study recruited participants who had a basic education level with a nominal understanding of English, so no opinion can be formed about the understanding of mindfulness at lower education levels.

Despite the limitations, this early study is a stepping stone towards the integration of mindfulness in the existing mental health care infrastructure. Mindfulness group programs are rational entry points to mainstream medical care in a community where medical help is sought as the last resort. But proper integration into clinical practice will be a long process involving standardization, training, quality-control, planned implementation, and cost analysis through further research.

More extensive research on mindfulness will deepen the knowledge of its applications in different socio-cultural perspectives and different clinical or non-clinical settings. Creating more research evidence and translating those evidence into practice will be the future direction.

CONCLUSION

Mindfulness shows initial promise as a preventive community-based intervention to improve anxiety, depression, and quality of life of Indian adults. This study opens up the possibilities of integration of Mindfulness into community clinical practice and this needs to be substantiated by further research.

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