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Original Research Article

An online mindfulness-based intervention influences the health-related quality of life of Indian children and adolescent during COVID-19 pandemic: a randomized controlled trial

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ABSTRACT

Background: COVID-19 pandemic is endangering the psychosocial health of Indian children and adolescent. The psychosocial morbidity can get manifested as psychiatric diseases if not addressed properly. This study aims to see the effects of an online Mindfulness-based intervention on the health-related quality of life (HRQoL) of apparently healthy but 'vulnerable' children in Indian community, during the COVID-19 pandemic.
Methods: A randomized controlled trial with 43 children and one of their interactive parents as participants from the community. An online eight-week Mindfulness program was selected as the psychosocial intervention. 22 participants in group M attended the Mindfulness program (parents in group PM) while 21 participants in group C attended placebo sessions (parents in group PC). The quantitative measure was the HRQoL, measured by the KIDSCREEN10 questionnaire. Qualitative data was in form of a response to a question "Which aspect of the mindfulness program appealed to you the most from your child's perspective?" The post-program parent responses were analyzed on basis of some emergent themes. The statistical analyses used were independent samples t-test, Chi-square test and one-way analysis of variance (ANOVA) for the outcome variables.
Results: The KIDSCREEN10 score significantly improved (p value <0.0001) in the cases (group M and PM), compared to the control groups. 'Calm' and 'focus' were the prominent emergent themes, reported by the parents post-program.
Conclusions: The online mindfulness-based intervention positively impacts the health-related quality of life of Indian children and adolescents during the COVID-19 pandemic. The results need to be substantiated by further studies.

Keywords: Mindfulness, Children and adolescent, Health-related quality of life, COVID-19 pandemic

INTRODUCTION

The psychosocial health of children and adolescent is a global problem.[1] The COVID-19 pandemic added immediate and long-term psychosocial challenges to Indian children.[2] More than 37 crore children (0-14 years) in India were facing adjustment problems due to the COVID-19 pandemic.[3] They were been forced into newer difficulties of social isolation, lack of physical activities, interrupted formal education, and a probable increase in abuse and insecurity.[4] COVID-19 pandemic deteriorated children's health-related quality of life (HRQoL) in terms of weight gain, sleep, and screen time.[5] This apparently healthy population is becoming extremely "vulnerable" which needs to be seriously addressed during the pandemic and post-pandemic.[6] Unfortunately, in India, this major concern lacks priority and research work with children are few and far between. In the present context, community-

based paediatric psychosocial intervention models are the need of the hour.[3] The interventions have to be time-limited, culturally acceptable, avoiding direct in-person interactions and have to be useful even in the resource-restricted setting. The online mode of delivery will be preferred during the pandemic as it avoids direct person-to-person contact, has wide accessibility using electronic devices, and can be delivered at optimal costs. At the Indian community level, the availability and application of online evidence-based preventive psychosocial group intervention for children are practically non-existent.

Mindfulness has been an integral part of the healthcare system in the West to reduce stress, improve mental health and increase subjective well-being in adults.[7] Mindfulness-based group interventions can be delivered online and can act as a preventive additional well-being tool for children at the community level. Mindfulness has already been used as an adjunct therapy for children with a wide range of physical and mental health problems.[8] The Indian general pediatric population has major sociocultural differences from the West, and the experience with Mindfulness remain limited.

This study is a preliminary attempt to introduce online Mindfulness in Indian paediatric community during the challenging times of the COVID-19 pandemic. The prevailing psychosocial distress may get manifested as psychiatric diseases if not taken care of in this tender age. The researchers formulate a hypothesis that mindfulness will improve the HRQoL, reflected by KIDSCREEN10 scores of the children. This study may be considered the first step to provide some baseline preliminary data at the community level to inspire further research.

METHODS

This prospective randomized controlled trial was planned involving children of age 8 to 14 years and one interactive parent. This age group was intentionally chosen as preadolescence and adolescence is a time of major developmental changes, is an ideal age for targeting wellbeing.[9] The study period was February to May 2021. The study was conducted by Kalyani ESI hospital, West Bengal, India in collaboration with a mindfulness centre which acted as a community venue. The participants were local residents of a metropolitan city in India. An ethical approval was taken from the institutional ethical committee and the study was registered in the clinical trials registry of India.

The sample size was calculated based on the assumption of a standard deviation (SD) of 2.18 of the expected difference from the previous studies, with a power of >80% to detect this difference using Tukey HSD all pair comparison test with type I error (α) of <5%.[10] The calculated sample size came out as 20 in each group.

The parents in the local community were informed about the study. Interested parents contacted the study coordinator. The 50 initial requests of participation were screened based on inclusion and exclusion criteria. Inclusion criteria were: child age 8 to 14 years, school going with normal learning abilities, participant has access to electronic device, not suffering from any medical disease, not undergoing any physical or mental treatment, no developmental delays noted by the parents, no recent history of suffering from COVID-19 infection in last 2 months, the participant child and parent is a resident of India, and participant should be able to understand and communicate in simple English. Exclusion criteria were: suffering from any known psychiatric illness, severe attention deficit or behavioral problems, and previous experience with mindfulness. The 43 screened candidates were further scheduled for a personalized online interview by a pediatric clinical psychologist to find any major learning disability or psychological problem in any participants. No such condition was found, and all the screened participants were included in the study.

The 43 children selected were randomized using random number tables of by Rand Corporation, USA©1955 to group M (cases) and group C (controls) with 22 children in group M and 21 children in group C respectively. One parent of each participant, designated as the interactive parent, was allocated in group PM and PC respectively. Group M participated in an eight-week online mindfulness program while group C served as a control. For group C participants' similar "placebo" sessions were organized in the study period, with the same instructor, of the same duration but without involving the concepts and exercises of mindfulness. Group C was later given an option to participate in the mindfulness program, after the end of the present study, which is beyond the scope of the present discussion (Figure 1). Informed consent was obtained from the parents via emails.

The online mindfulness-based intervention selected was influenced by the Mind UP program, popular in Western countries.[11] The program had elements from the original mindfulness-based stress reduction program (MBSR). Minor modifications were made in the program for a better understanding of the Indian pediatric population. The online sessions were conducted live through an App that could be downloaded on any electronic device. The language of communication was mostly English but explanations were given in local language whenever needed. The mindfulness instructor was trained through the original MBSR course, NHS-approved digital mindfulness course, and has experience of teaching mindfulness for more than two years. An orientation session was organized, to engage the children, built a rapport with the instructor, and give an overview of the whole program. The eight main sessions were of one-hour duration. The sessions focussed to bring mindfulness in daily activities and practicing optimism, gratitude, perspective-taking, and kindness. The doubts of the participants were clarified by virtual interactions at the end of the sessions. A lot of emphasis was given on home practicing of the mindfulness exercises, under the

supervision of the parents. The interactive parent updated the home practice daily through an App which was monitored by the instructor.

All the data was collected via emails, made available with the principal investigator, and can be shared on request. The demographic data were noted for both the group M and C and also group PM and PC before the program. The quantitative outcome measure was the self-reported children and parent KIDSCREEN10 questionnaire (reflecting children HRQoL) before and after the completion of the program. HRQoL focuses on different domains of physical health, psychological health, social health, and role performance. KIDSCREEN10 was deliberately chosen as it can be easily understood. The focus of the researchers was the wellbeing of apparently healthy children and not on specific measures of mental states of stress, anxiety, and depression. The wellbeing of children has multiple perspectives and HRQoL reflects some of the perspectives.[12] KIDSCREEN10 is an internationally developed, easy to administer, reliable, and valid tool of HRQoL, appropriate for age 8 to 14 years.[13]

In addition, qualitative data were collected in form of written parent responses to the question "Which aspect of the mindfulness program appealed to you the most from your child's perspective?" at the end of the program. The group PM participants (parents of group M participants) were requested to mail written responses to this question. The parents were requested to mark the most appropriate responses based on maximum improvement noted post-program if any and emergent themes were formed. The concept behind the collection of this qualitative data was to expand the understanding of the effect of mindfulness in this particular study population, which may give directions to future research. The overall experience of the cases (children and their parents) was noted via mail as written comments post-program to serve as an indirect measure of acceptability of the online mindfulness program in this community. Any adverse effects noticed were asked to report to the instructor.

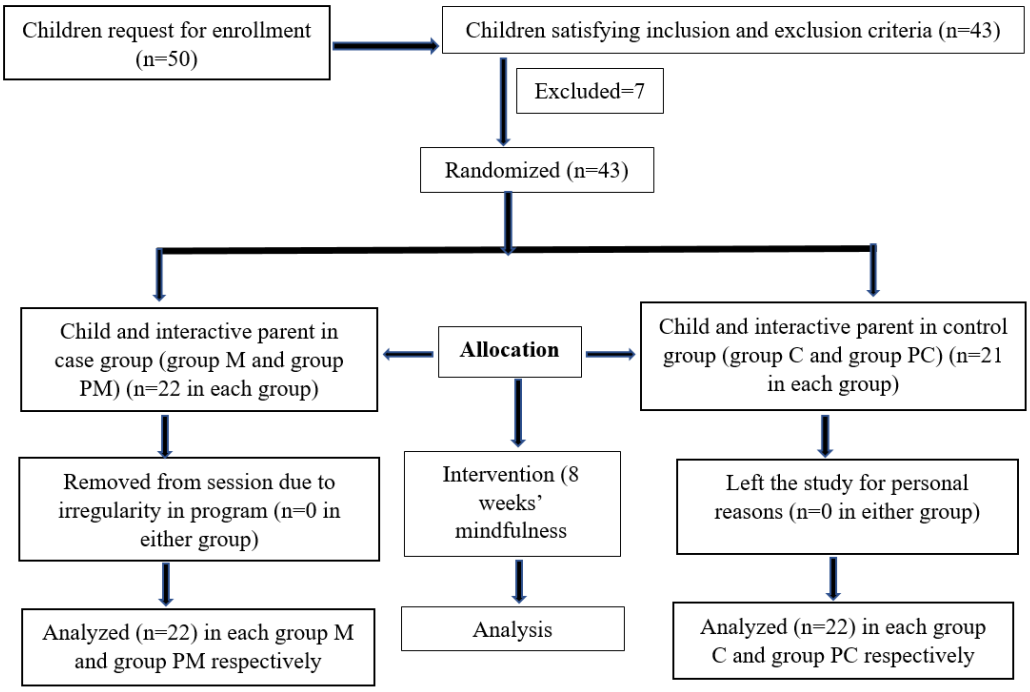

Figure 1: Consort 2010 flow diagram of progress through phases of the randomized trial.

Statistical analysis

Data of KIDSCREEN10 score 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 Tukey HSD all pair test. Baseline characteristics (age, sex) were tested using independent samples t-test and Chi-square (χ^2) test respectively. One-way ANOVA was done to compare all KIDSCREEN10 scores between all groups. The statistical software used was predictive analytics software (PASW®), statistical package for the social sciences (SPSS) statistics for Windows 7® version 18.0.0 (Chicago: SPSS Inc.) and GraphPad Prism® InStat version 5.0. (California: GraphPad Software Inc.). 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. Qualitative data of emergent themes was arranged in ascending order of frequencies; the cumulative frequencies were calculated as depicted by cumulative frequency histogram and the themes above the median were taken as major themes.

RESULTS

Baseline characteristics

22 children and their interactive parent as cases (group M and PM) and 21 children and their interactive parent as controls (group C and PC) completed the study. Baseline characteristics (age, sex) were similar between children and their interactive parent in cases (group M) compared to the controls (group C) (Table 1).

Analysis of quantitative data

KIDSCREEN-10 scores

The KIDSCREEN-10 scores were grouped into 8 groups based on pre and post program records in each group (group Mpre, Mpost, PMpre, PMpost, Cpre, Cpost, PCpre, PCpost). The mean scores in (group Mpost) and (Group PMpost) [post-session in child and interactive parent group] differs significantly from the rest of 6 groups with one-way ANOVA result F (7, 164)=115.5101 with p<0.0001 (Table 2).

The above test was followed-up by Tukey HSD all pair test which revealed that KIDSCREEN-10 scores were also significantly higher in children of cases group post-session (group Mpost) when compared with the children in controls group post-waiting period (group Cpost); (Q=21.7642, p<0.0001) (Table 2). KIDSCREEN-10 scores were also significantly higher in interactive parent of cases post-session (group PMpost) when compared with the interactive parent in controls group post-waiting period (group PCpost); (Q=22.9053, p<0.0001). KIDSCREEN-10 scores among pre-session child (p=0.9249) and interactive parent group (p=0.8548) was not significant compared to their respective controls. Also, pre-session and post-session KIDSCREEN-10 scores were not significant when responses of the children were compared with their corresponding interactive parent.

Table 1: Representation of children and parents characteristics (age, sex) and Kidscreen-10 scores in different groups [results are represented in mean (SD) and percentage format].

Groups	Age in years (mean (SD))	Sex, (n (%))	KIDSCREEN-10 Score (mean (SD))	
Group M, n=22	10.81 (1.94)	M=12 (54.55) F=10 (45.45)	Group Mpre (n=22)	28.91 (3.43)
			Group Mpost (n=22)	44.77 (2.54) **
Group PM, n=22	42.77 (3.23)	M=8 (36.36) F=14 (63.64)	Group PMpre (n=22)	29.68 (2.98)
			Group PMpost (n=22)	45.45 (2.61) **
Group C, n=21	10.76 (1.76)	M=12 (57.14) F=9 (42.86)	Group Cpre (n=21)	29.00 (3.56)
			Group Cpost (n=21)	29.95 (3.51)
Group PC, n=21	42.90 (3.25)	M=7 (33.33) F=14 (66.67)	Group PCpre (n=21)	29.33 (3.05)
			Group PCpost (n=21)	29.85 (3.41)

**P<0.0001 (group Mpost versus Cpost) and (group PMpost versus PCpost); group Mpre: Kidscreen-10 scores of children in cases group M pre-session; group Mpost: scores of children in cases group M post-session; group PMpre: scores of parents of children in cases group PM pre-session; group PMpost: scores of parents of children in cases group PM post-session; group Cpre: scores of children in controls group C pre-waiting period; group Cpost: scores of children in controls group C post-waiting period; group PCpre: scores of parents of children in controls group PC pre-waiting period; group PCpost: scores of parents of children in controls group PC post-waiting period

Table 2: Representation of the types of statistical tests done, test results along with the p values for age, sex and KIDSCREEN-10 scores in different groups.

Variable/s	Type of test	Groups compared	Test statistic	P value
Age	Independent samples t-test	Group M (n=22) versus group C (n=21)	t= 0.0884 df=41	P=0.9300
		Group PM (n=22) versus group PC (n=21)	t=0.1315 df=41	P=0.8960
Sex	Chi-square test	Group M (n=22) versus group C (n=21)	X^2=0.0294 df=1	P=0.8638
		Group PM (n=22) versus group PC (n=21)	X^2=0.0433	P=0.8349
KIDSCREEN-10 Score	One way ANOVA	Group Mpre, Mpost, PMpre, PMpost, Cpre, Cpost, PCpre, PCpost	F=115.5101 df=(7,164)	P<0.0001**
	Tukey's HSD post-hoc test	Group Mpre (n=22) versus Cpre (n=21)	Q=0.1335	P=0.9249
		Group Mpost (n=22) versus Cpost (n=21)	Q=21.7642	P<0.0001**
		Group PMpre (n=22) versus group PCpre (n=21)	Q=0.5118	P=0.8548
		Group PMpost (n=22) versus group PCpost (n=21)	Q=22.9053	P<0.0001**
		Group Mpre (n=22) versus group PMpre (n=22)	Q=1.1482	P=0.6885

Variable/s	Type of test	Groups compared	Test statistic	P value
		Group Mpost (n=22) versus group PMpost (n=22)	Q=1.0131	P=0.7073
		Group Cpre (n=21) versus group PCpre (n=21)	Q=0.4839	P=0.8659
		Group Cpost (n=21) versus group PCpost (n=21)	Q=0.1383	P=0.9238

** The p values are statistically significant; group classifications of KIDSCREEN-10 scores are as per Table 1

Qualitative data: emergent themes

Five emergent themes were formed (focus, calm, optimism, gratitude, and responding to difficult situations) representing the different aspects of the child's nature/behaviour thought to be affected by the mindfulness program.

Post-session group discussion with group PM showed that calm and focus were the main emergent themes with cumulative frequencies above 32 (median) (Figure 2).

No adverse effect reported by any participant.

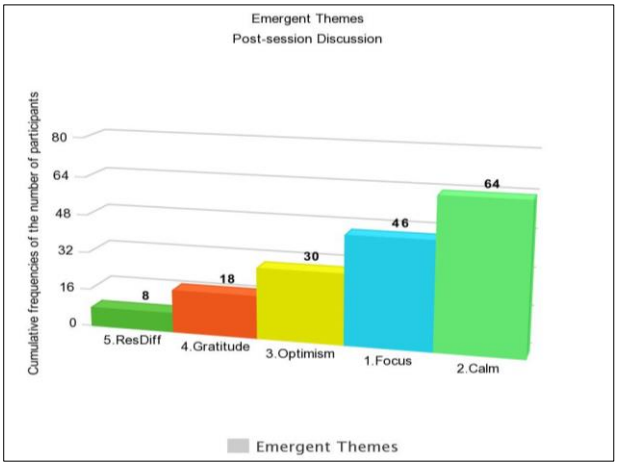

Figure 2: Cumulative frequency histogram of emergent themes from post-session responses of the parents of group M (i.e. group PM).

DISCUSSION

The results support the hypothesis that Mindfulness will improve the KIDSCREEN10 scores of the participants who attended the program. KIDSCREEN10 scores significantly improved (p value <0.0001) in the cases (group M and PM) post-session, when compared to their respective controls (group C and PC). Mindfulness may have helped the children to develop "calm" and "focus" more as per the qualitative data analysis. Future studies will throw more light on the change in these behavioral aspects. Mindfulness appears to be acceptable to Indian children as indirectly evident from written subjective comments of the participants' post-program.

In our study, the influence of mindfulness on HRQoL of children is comparable to previous study results. A study on Hispanic children noted that mindfulness significantly affects their quality of life.[14] Another study found mindfulness to decrease emotional and behavioral problems in low-income adolescents.[15] A research work comments that current evidence is in favor of mindfulness for improving the health and well-being of children and adolescents.[16] A meta-analysis reinforces the efficacy of using mindfulness-based interventions for improving the mental health and wellbeing of youth.[17] Mindfulness appears to influence the HRQoL of Indian children in this study, irrespective of the sociocultural difference with the West.

The study had several positive aspects. Any child in the community who expressed interest to participate was given a chance (provided they fulfilled the inclusion and exclusion criteria). The online sessions could be attended from the home even during the pandemic times. The children were congenial with the online format, as it was the commonest format used by most schools during the pandemic. The mindfulness concepts and exercises were communicated in a simple way for easy understanding of the children. The children understood the concepts well as evident from the interactions and post session parents' comments. Any doubts faced were cleared at the end of sessions.

The challenges faced were to keep track of daily practice of children, to collect data from parents post program, and to continuously motivate the children to complete the program. Arrangement of small tokens of appreciation (via parents) for the children, and commitment to mail certificates on successful program completion perhaps helped in 100% retention of the participants.

The psychosocial impact of COVID-19 on children is multidimensional, so an elaborative strategic plan of action involving multiple levels is needed.[6] Mindfulness alone will not be able to address all the different aspects of this huge problem but can definitely act as an additional tool of wellbeing. Mindfulness helps in coping by using practical examples; simple breathing exercises, relaxation techniques, and positive self-talk. Mindfulness reinforces the importance of human virtues like kindness, compassion, and patience to make the children understand their role in society in times of crisis.[18] Many of the other psychosocial interventions are individualized therapies, require formal institutional set-ups and involvement of specialists. In new-age digital India, the majority of the population having access to electronic devices and the schools were operating online due to COVID-19 pandemic. So, an online mindfulness group program will have additional advantage of extensive reach at a point of time, can be easily implemented in a community setting,

and can be executed with minimal resources. A study conducted by same group of researchers found online mindfulness to decrease stress in Indian adults during COVID-19 pandemic.[19] But studies on healthy Indian paediatric population except a few with dissociative disorders, or anxiety, remains unavailable or extremely limited.[20,21]

This study is an initial attempt with several limitations. The sample population including the parents showed interest to participate which may have influenced the results. The participants were school-going children of a metropolitan city with access to electronic devices, so the results cannot be generalized to the rural or under-privileged children of the country. The self-reported KIDSCREEN10 scores must have limitations in reflection of the HRQoL. KIDSCREEN10 was developed in western countries and its experience with the Asian population is limited.[22] HRQoL was the only outcome variable studied, multiple variables reflecting different aspects of wellbeing or cognitive-behavioral aspects or child/adolescent mindfulness scales could not be included in this study.[17,23,24] The sample size was comparatively small with no scope of follow-up after some time interval, so the usefulness and long-term effects in larger community remain undetermined.

In spite of the limitations, this study should be looked upon as the stepping stone providing important preliminary data for the Indian paediatric community. There was no intention to project mindfulness as a one-in-all solution to paediatric psychosocial problems in the COVID-19 context. It will be reasonable to look upon the mindfulness group program as a preventive additional tool only and not as a replacement of standard established therapies. This study only focus on prevention of quiescent psycho-social problems developing due to pandemic from getting manifested as diseases. The researchers suggest collaboration with mental-care specialists to deal with specific mental-healthcare needs of children. Studying multiple levels of functioning and comparison with other psychosocial interventions was outside our study purview. Further studies will be needed to substantiate the results. Group-based mindfulness interventions at the community level can be a significant addition to the strategy to maintain psychosocial health. Large-scale applications of mindfulness may have the potential to revolutionize the wellbeing of Indian paediatric population. Future directions will be research on heterogeneous/diseased population, multiple dimensions of applications, with long-term follow up, value-addition to educational curriculums, and incorporation in country-wide health programs.[25]

CONCLUSION

An online mindfulness-based intervention influences the health-related quality of life of Indian children and adolescents during the COVID-19 pandemic. The promise shown by this initial study in an Indian community needs to be substantiated by further studies.

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