Translational Medicine
ISSN: 2161-1025
OPEN ACCESS Freely available online
Research Article

The ICAN Trial-Online Yoga and Mindfulness-Based Recovery Program for Pain Perception, Fatigue and Quality of Life in Children with Chemotherapy during COVID-19: A Pilot Feasibility Study

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ABSTRACT

Background: Children undergoing chemotherapy for cancer often report fatigue, pain, and other clusters of symptoms. These symptoms are distressing and negatively influence the self-care capacities and quality of life. The pandemic has resulted in overburdening of the healthcare systems stemming from aberrations in the management of non-COVID cases leading to a surge in the need of an alternate system of therapy and its administration. Preliminary studies depict that yoga may improve cancer-related symptoms of pain and fatigue. The video-assisted administration of yoga initiates a whole new era of digitization of yoga services like other e-health modalities, a prime requisite in the pandemic era. This study aimed to evaluate the efficacy of an online assisted yoga-based intervention in improving cancer-related pain, fatigue, and quality of life in children undergoing chemotherapy during COVID-19.

Methods: In total, 40 patients who underwent at least one cycle of chemotherapy were subjected to 12 weeks yoga intervention. The 45 minutes of online yoga intervention comprised of preparatory loosening and breathing practices, restorative yoga asanas (postures), and meditation which was developed and validated during the study. In addition, fatigue, pain, and quality of life were assessed using pediatric functional assessment for chronic illness therapy, numerical pain rating scale, and pediatric quality of Life Inventory pre- and post-intervention and follow-ups.

Results: Children between the age group of 11.4 ± 2.8 years underwent yoga for 12 weeks. There is a temporal decrease in pain and fatigue scores over 12 weeks with yoga practice ($p<0.01$). In addition, an improvement in the domains of quality of life was also observed in these children ($p<0.01$).

Conclusion: Online Yoga and mindfulness-based intervention for 12 weeks can effectively improve cancer-related pain and fatigue and Quality of life in children undergoing chemotherapy during the COVID-19 pandemic.

Keywords: Yoga; Pediatric; Chemotherapy; Cancer; Pain; Fatigue; Quality of life; COVID-19

INTRODUCTION

Childhood cancers are the primary cause of death in children and adolescents worldwide. Approximately 4,00,000 children in the age range 0-19 years are diagnosed with childhood cancer each year [1]. Mostly, childhood cancers comprise brain cancers, leukemia, lymphomas, and solid tumors. The cure depends on the health care services accessible to the patient, 80% in high-income countries, whereas in low to middle-income countries is 15-20% [2]. In addition to treating the disease thoroughly, high emphasis should also be given to the perceived side-effects of these treatments and the severity of symptoms with the progression of the disease. Pain is the most common distressing symptom in these patients. It is often reported across the disease trajectory from diagnosis, treatment, or end of life or survivorship [3-5]. With the advancement in the conventional treatment modality *viz.* chemotherapy and the disease, fatigue is an unavoidable impediment to their daily life activities. Patients frequently complain of deterioration of physical as well as mental health. Fatigue has been a causative factor in several physiological and

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Received: 15-Nov-2022, Manuscript No. TMCR-22-20119; **Editor assigned:** 17-Nov-2022, Pre QC No. TMCR-22-20119 (PQ); **Reviewed:** 01-Dec-2022, QC No. TMCR-22-20119; **Revised:** 09-Dec-2022, Manuscript No. TMCR-22-20119 (R); **Published:** 16-Dec-2022, DOI: 10.4172/2167-7700.22.12.276

Citation: Kadyan J, Jha M, Joshi P, Sharma G, Sinha AP, Seth R, et al. (2022) The ICAN Trial-Online Yoga and Mindfulness-Based Recovery Program for Pain Perception, Fatigue and Quality of Life in Children with Chemotherapy during COVID-19: A Pilot Feasibility Study. Trans Med.12:276.

psychological disturbances, such as inflammation, depression, sleep disorders, and pain. [6-8]. Cancer has a debilitating effect on the physical and emotional functioning of the patients declining the Quality of life to a newer low. Fatigue, distress, time since duration, and family structure are associated with Quality of life in these patients [9].

Lifestyle interventions have been reported to significantly improve the cancer-related symptoms of pain and fatigue, resulting in an improved Quality of life [10-13]. However, limited data is available in this regard in the pediatric population. Yoga is an ancient mind-body practice characterized by the synchronized practice of physical postures (asana), breathing with awareness (Pranayama), and meditation (Dhyana) [14]. There is a plethora of evidence depicting the effectiveness of Yoga in reducing the cancer-related symptoms and chemotherapy-induced side effects in cancer survivors. Yoga significantly reduces pain, fatigue, psychological distress, anxiety, depression, sleep disorders, and balance in patients with cancer [15-18]. There is sparse evidence of the effectiveness of Yoga in childhood cancer. This study aims to bridge this gap and evaluate the effect of Yoga in reducing pain, fatigue and improving the Quality of life. The study was conducted in the COVID era, indicating its usefulness in understanding the counter measure towards the challenges faced during providing cancer care during the COVID pandemic.

In recent times, a paradigm shift has been identified due to the COVID-19 pandemic. There has been a disruption in the healthcare system, and an abundance of research has been carried out to understand its impact on the non- COVID diseases. The diagnosis and successful cancer treatment is highly time-dependent and is primarily affected by these impediments. Therefore, there is a need for an alternative approach for managing these patients with minimum contact and higher possibilities of self-administration. Video-assisted Yoga has uncovered a new domain of imparting Yoga as an efficient therapy during the pandemic to minimize cancer-related symptoms. In this study, we aimed to assess the feasibility of video-assisted yoga practice in the pediatric population to prevent a downfall in their healthcare regime during these unprecedented times.

MATERIALS AND METHODS

Study design

DR. B.R.A. Institute Rotary Cancer Hospital (Dr. B.R.A. IRCH), All India Institute of Medical Sciences, conducted a pre-experimental study examining the feasibility of Yoga in improving the pain perception, fatigue, and Quality of life in children undergoing chemotherapy. The study is a single-arm pre-post design wherein patients were recruited after screening for eligibility based on the study inclusion and exclusion criteria. The patients were recruited from the paediatric day-care center C5 ward and oncology day-care centre, Dr. B.R.A. IRCH. Patients once recruited were assessed for Pain, Fatigue, and Quality of life before and after the intervention of 12 weeks.

Study participants

Patients with cancer undergoing chemotherapy between the age group 6-18 years were recruited from the OPD's of day-care centre of the Department of Medical Oncology by the research staff. Participants after at least the first cycle of chemotherapy, willing to participate and attend yoga sessions and stay in Delhi NCR for chemotherapy, were eligible for the study. Patients with cognitive impairment or hemodynamic instability were excluded from the study. All participants filled the informed consent before enrolling in the study. The enrolment process is described in Figure 1.

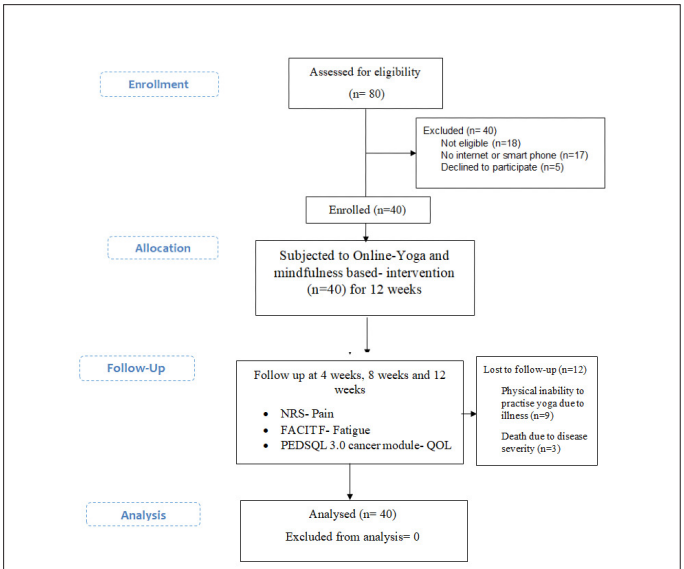

Figure 1: Consort diagram of study.

Intervention

A generic online yoga-based intervention was developed and validated for children with cancer undergoing chemotherapy. The patients underwent online supervised yoga sessions under a yoga expert, which the researcher at AIIMS facilitated. A total of 84 classes over 12 weeks were conducted for each patient. The yoga expert conducted a few physical classes at AIIMS for induction, followed by online home-based supervised sessions. The parents additionally supervised the online home-based sessions.

Development of the yoga-based intervention

A thorough review of the contemporary and traditional literature was performed. Following texts on Patanjali yoga sutras, Hatha yoga pradipika, Shiv Samhita, Gheranda samhita, Hatharatnavali, and Bhagavad Gita were referred to infer the yoga practices that can be administered in patients with cancer to mitigate the disease and chemotherapy-related symptoms. However, the precise yoga practices may not be mentioned for each symptom, so the practices are developed by approximation of the benefits of Yoga for the physical, mental and social wellbeing and its relevance to the symptom reduction in children with cancer under chemotherapy. The yoga module comprises a combination of loosening and breathing practices as the preparatory practice followed by eight asanas (physical posture) in standing, sitting, supine and prone positions, pranayama (breath manipulation) of balancing, cooling and resounding nature, dhyana (meditation) and relaxation techniques. The total duration of the module is 30 minutes. The practices which were complex, strenuous, and

contraindicated in these patients were excluded from the module. Modification based on the needs of the patients was also done for a few practices.

Validation of the yoga-based intervention

The Yoga module with a brief description of the disease and its symptoms were sent to twenty-three yoga experts, out of which nine responded with their suggestions and ratings. The experts were instructed to rate the usefulness of each practice on a scale of 1 to 3 (1=Not useful, 2=Useful but not essential, and 3=extremely essential). Based on the score rendered by the experts, a content validity ratio (CVR) was calculated using lawshe's formula. Practices scored ≥ 3 from 80 % of the experts were retained in the final yoga module. Yoga practices with CVR ≥ 0.78 were used as a cut-off to finalize the module.

Nine experts out of 23 responded to the request for content validation of the yoga module. Lawshe's content validity ratio (CVR) was calculated for all the items in the yoga practice list. (Appendix 1) The practices which scored CVR ≥ 0.78 were retained into the final module. The suggestions given by the experts were also incorporated into the module based on the author's understanding and expertise. Based on the CVR values, all the items were retained in the yoga module. (Appendix 2) The experts suggested adding spinal twisting, mantra chanting. Also, practices like cooling pranayama were suggested to be avoided in patients with oral cancers due to sensitivity. The breathing practices in lung metastasis were suggested to be avoided, and in case of bone metastasis, asana with bending affecting those areas to be avoided.

Spinal twisting was not added into the module as the suggestion was only made by one of the experts, and the practices to stretch the spinal muscles have been included in the asanas. Mantras were not added to keep the practices religiously neutral, as mantra chanting can be misunderstood as religious. Caution was taken to avoid the contraindicated practices to the patient group as suggested by the panel of experts.

Measures

The researcher recorded all the demographic and clinical data using a study-specific case report form and the patient's medical reports. A case report form is a self-developed structured tool developed by the investigators of the study (9 items for demographic details of the children and 16 items for the demographic profile of the parents. Sixteen items for the clinical details (date of diagnosis, type of tumor, hemodynamic status, history of surgery, and radiation therapy if received) were also recorded in the sheet. The patient's compliance towards the intervention was monitored using participant diary and attendance log maintained by the researcher.

The measurement of pain was carried out using a numerical pain rating scale (NPRS) [19]. It is a one-dimensional measure of pain intensity. The NPRS is a segmented numeric version of the visual analog scale (VAS) rated on a 11-point numeric scale, which ranges from '0' representing one pain extreme (e.g., "no pain") to '10' representing the extreme pain (e.g. "pain as bad as one can imagine" or "worst pain imaginable").

Fatigue in these patients was measured using Pediatric functional assessment for chronic illness therapy (Peds FACIT-F). It is an 11-item tool that grades fatigue on a scale of 0 to 4 (0=None of the time, 1=A little bit of the time, 2=Some of the time, 3= Most of the time, 4=All of the time) [20].

The Quality of life of the patients was measured using the Paediatric Quality of Life Inventory. (Peds QL) 3.0 Cancer Module is a standardized, designed to measure HRQOL dimensions specifically tailored for paediatric cancer. It is a 27-item multidimensional Peds QL 3.0 Cancer Module Acute Version comprising of 8 scales Pain and hurt (2 items), Nausea (5 items), Procedural anxiety (3 items), Treatment anxiety (3 items), Worry (3 items), Cognitive problems (5 items), Perceived physical appearance (3 items), Communication (3 items). The higher response indicates a higher quality of life [21].

Statistical analyses

Data were first coded, entered, and then summarized in the master datasheet. The patients' baseline demographic and clinical characteristics were reported as (mean ± S.D) in the case of a continuous variable and (Mean, SD) in the case of categorical variables. The data analysis was done using SPSS 21.0 version and presented in percentage, mean, standard deviation, range (minimum and maximum). Paired t-test was used to compare the mean scores of variables at baseline and 1, 2, and 3 months.

RESULTS

Baseline characteristics of participants

Children between the age group of 11.4 ± 2.8 years with both solid (n=5) and liquid tumours (n=35) underwent Yoga for 12 weeks.70 % of patients performed 65.4% of the target classes (84 classes), suggestive of good compliance. None of the children or parents reported practicing Yoga earlier and did not have a history of malignancy in the family (Tables 1 and 2)

Table 1: Comparison of baseline pain and fatigue score with pain score at 1st month, 2nd month and 3rd months.

Clinical outcome	Baseline (n=40)	1st month (n=40)	2nd month (n=28)	3rd month (n=28)
Pain (n=40)	4.3 ± 1.1	3.8 ± 1.1	3 ± 0.9	2.6 ± 0.8
Mean-Difference (95% C.I.)$	-	0.5(0.3,0.7)	0.9(0.6,1.1)	1.3(1.1,1.6)
p-value$	-	<0.01	<0.01	<0.01
Fatigue (n=42)	24.1 ± 5.5	21.4 ± 5.5	19.8 ± 5.4	16.6 ± 5.5
Mean-Difference (95% C.I.)$	-	2.9(2,3.8)	4.5(3.5,4.4)	7.7(6,9.4)
p-value$	-	<0.01	<0.01	<0.01

Note: $: Compared with baseline.

Table 2: Calculation for Content Validity Ratio (CVR scores) for practices in the yoga module.

S No.	Loosening practices	Score 1	Score 2	Score 3	Percent	Value	Retention
1	Fingers-MusthikaBandhana	0	0	9	100%	1	Retained
2	Wrist- Manibandha chakra	0	0	9	100%	1	Retained
3	Elbows-Kaphoninamana	0	0	9	100%	1	Retained
4	Shoulder- Skandhachalana	0	0	9	100%	1	Retained
5	Neck-Grivasanchalana	0	0	9	100%	1	Retained
6	Knee-Janunamana	0	0	9	100%	1	Retained
7	Ankle- Goolfnamana and chakra	0	0	9	100%	1	Retained
8	Shavasanawith deep abdominal breathing	0	0	9	100%	1	Retained
9	Sectional breathing	0	0	9	100%	1	Retained
	Asanas	0	0	9	100%	1	Retained
1	Tadasana(Palm tree pose)	0	0	9	100%	1	Retained
2	Trikonasana (Side bending)	0	0	9	100%	1	Retained
3	Pascimottanasana(Seated forward bend pose)	0	0	9	100%	1	Retained
4	Mandukasana (frog pose)	0	0	9	100%	1	Retained
5	Bhujangasana (Cobra pose)	0	0	9	100%	1	Retained
6	Salabhasana (locust pose) (Alternate leg)	0	0	9	100%	1	Retained
7	Vipareetkarni with deep abdominal breathing (With wall support if required)	0	0	9	100%	1	Retained
8	Pawanmuktasana kriya (Wind relieving pose) (with head on the ground if required)	0	0	9	100%	1	Retained
	Pranayama	0	0	9	100%	1	Retained
1	Nadisuddhi (Alternate nostril breathing)	0	0	9	100%	1	Retained
2	Cooling pranayama (sitali, shitkari and sadanta)	0	0	9	100%	1	Retained
3	Bhramari (Humming bee sound)	0	0	9	100%	1	Retained
	Deep relaxation technique	0	0	9	100%	1	Retained

Feasibility of the online yoga and mindfulness-based Intervention

Recruitment: A total of eighty children were assessed for eligibility based on the study inclusion and exclusion criteria, out of which 62 participants were eligible for the study. Five participants were not willing to participate in the study. Seventeen patients were willing but had limitations like unavailability of the internet or smart phone for online follow-up classes or inability of the patient to practice a physical activity-based intervention due to illness like yoga so they were not included in the study. A total of 40 patients participated in the study and signed the consent form. Along the study, 12 patients dropped out due to the severity of the illness or inaccessibility of the internet facility in their home town (n=9), or demise due to the illness (n=3).

Attendance and adherence: In the contact period, introductory sessions (n=8) were conducted which was followed by online home-based sessions instructed by the yoga experts and supervised by the parents at home. 67% (55/82) of the online home-based yoga sessions were attended by the study participants, except the drop out patients (n=12), suggestive of good compliance towards the intervention. Furthermore, to augment the compliance during the home-based sessions, the researchers and the yoga expert closely monitored the participants through daily telephonic counselling and updates through a closely connected group of the researcher, physicians and patients on social media platform. In addition, an attendance logbook was maintained by the researcher who was facilitating the home-based sessions. Additionally, each patient sent videos and photos as confirmation of their daily practice to ensure the compliance towards the intervention.

Safety: The patients were assessed for hemodynamic stability and fitness to perform yoga intervention based on their clinical and immunological profile by the attending consultant in the medical oncology department and the yoga physician at the Yoga center prior to the baseline assessment. Upon which they were allowed to practice Yoga to ensure patient safety. No adverse event was encountered during the study.

Efficacy of the yoga intervention

Changes in pain, fatigue, and Quality of life: The temporal change in the pain score using a numerical pain rating scale over three months showed a gradual decrease in pain with yoga-based practice. (4.3 ± 1.1 *vs.* 3.8 ± 1.1 *vs.* 3 ± 0.9 *vs.* 2.6 ± 0.8, $p<0.01$). There was a significant reduction in the scores of fatigue measured by FACIT over the period of 3 months with Yoga intervention in children undergoing chemotherapy. ($p<0.01$) The domains of Quality of life, *viz* pain and hurt, nausea, perceived anxiety, treatment anxiety, Worry, cognitive problems, perceived physical appearance, were reported to have a reduction after three months of Yoga practices in these children ($p<0.01$) (Figure 2 and Table 3).

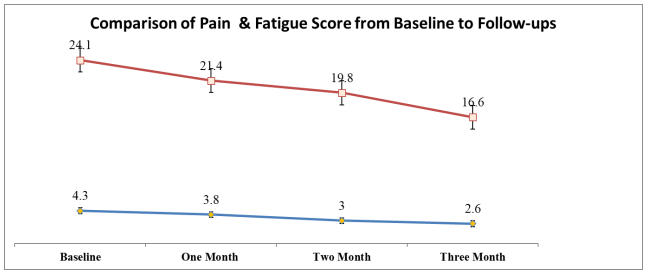

Figure 2: Comparison of Baseline to follow up values of Pain and Fatigue at 0 weeks, 4 weeks, 8 weeks and 12 weeks respectively. **Note:** (-•-): Pain score; (-□-): Fatigue score. *all the values show statistical significance, p<0.01.

Table 3: Detailed yoga module with duration and repetition of each practice.

S.NO.	Name	Rounds	Duration (minute)
	Loosening exercises	5 rounds each	6 minutes
1	Fingers-Mushtika bandhana		1 minute each
2	Wrist-Manibandha chakra		
3	Elbows-Kaphoni namana		
4	Shoulder-Skandhachalana		
5	Neck-Grivasanchalana		
6	Ankle-Gulgnamana and chakra		
	Breathing and relaxation	9 rounds each	4 minutes
1	Sectional breathing (in supine posture)		
2	Abdominal		
3	Thoracic		
4	Clavicular		
	Asana	1 round each	10 minutes
1	Standing poses		3 minutes
1.1	Tadasana (palm tree pose)		1 minute
1.2	Trikonasana (side bending)		2 minutes
2	Sitting poses		2 minutes
2.1	Pascimottasana (seated forward bend pose)		1 minute each
2.2	Mandukasana (frog pose)		
3	Prone poses		3 minutes
3.1	Bhujangasana (cobra pose)		1 minute each
3.2	Salbhasana (locust pose) (Alternate leg)		2 minutes
4	Supine poses		2 minutes
4.1	Ardhahalasana		1 minute each
4.2	Pawan muktasana kriya (Wind relieving pose)		
5	Pranayama		15 minutes
5.1	Nadisuddhi (alternate nostril breathing)		10 minutes
5.2	Cooling pranayama		2 minutes
5.2.1	Sitali		1 minute each
5.2.2	Sheetkari		
6	Bhramari (humming bee sound)		3 minutes
7	Relaxation	1 round	10 minutes
8	Deep relaxation technique		
	Duration (Total)		45 minutes

DISCUSSION

This study demonstrates the development and validation, feasibility, and efficacy of online Yoga and mindfulness-based program in improving pain, fatigue, and Quality of life in children with cancer undergoing chemotherapy during the COVID-19 pandemic. Yoga was observed to reduce the severity of pain and health-related Quality of life when administered for 12 weeks in the children with cancer undergoing chemotherapy. These patients also reported perceived improvements in various functional activities in their daily living, measured by fatigue scores. Yoga was well tolerated and accepted during the study. To the best of our knowledge, this is the first trial depicting the feasibility of video conferencing-assisted yoga administration in the paediatric cancer population during COVID-19. This study can earmark the commencement of digitization of Yoga and ensure its feasibility in childhood cancer.

A gradational shift was observed in the severity of pain and fatigue over the 12 weeks duration of Yoga, wherein the reduction in pain was significantly higher in the 12th week when compared to the other two follow-ups at the 4th week and 8th week. This is suggestive of the longitudinal effect of Yoga on the severity of pain. The stretching and breath entrainment practices during Yoga have been observed to improve muscular aches and pain and relieve psychological suffering due to the chronicity of the pain [22,23]. The scores for various domains of Quality of life in cancer patients *viz*. pain and hurt, nausea, perceived anxiety, treatment anxiety, Worry, cognitive problems, perceived physical appearance were reported to be significantly reduced over 12 weeks of yoga intervention suggestive of improved Quality of life in these children. The reduction in the physical pain, side effects of the usual treatment, sleep, psychological wellbeing, and cognitive domains may have improved overall Quality of life [8,16,24,25,]. A study conducted by Eyigor et al. reported a significant reduction in the pain scores (shoulder and arm pain) at ten weeks and 20 weeks with Hatha Yoga practice (p<0.01) in patients with breast cancer when compared to the control group. However, the quality-of-life assessment showed a significant improvement only in the domain of symptom scale at ten weeks, whereas all three domains of health, function, and symptom scale at 20 weeks which is in coherence with our study [26]. Similarly, Galantino et al. studied functional outcomes, pain, and HR-QOL in postmenopausal breast cancer survivors receiving aromatase inhibitors. He reported a reduction in the severity of pain (p<0.05), a decreasing trend towards pain interference, and improvement in HR-QOL with eight weeks of yoga intervention [27,28]. Carson et al. studied the dose/response relationship between Yoga interventions and pain in metastatic breast cancer

patients. The results connote whenever there was an increase in the length of the Yoga practice for two consecutive days, the pain relatively reduced on the next day [28].Forty head and neck cancer survivors were subjected to 8 weeks of Hatha Yoga to denote a significant reduction in pain ($p<0.05$), shoulder range of motion ($p<0.05$), and anxiety ($p=0.015$) [29].

Previous studies suggest a significant reduction in fatigue in cancer patients with Yoga-based interventions [13,24,30]. This reduction in fatigue levels may be associated with improved emotional wellbeing, mood, confidence, increased motivation with the yoga sessions, and the level of enjoyment that was subjectively reported by the children while performing Yoga [13,31]. This can be suggested that Yoga-based intervention reduces pain, fatigue and improves health-related Quality of life in children with cancer undergoing chemotherapy.

CONCLUSION

A few of the study's limitations are its small sample size; more extensive studies to validate the result of this feasibility trial need to be conducted. The longitudinal effect of yoga intervention could have been studied provided the study duration was longer (12 weeks). The study design was not a robust measure, and randomized controlled trials are to be heeded, which can be a future scope of this trial. However, this is one of the few studies that can be considered the foundation of more extensive trials. This study reports good feasibility and efficacy of online yoga intervention in children with cancer. This study also landmarks the gap between the need of the paediatric population and the conventional treatment modalities, which should be addressed clinically. Children with cancer have been debilitated with the disease burden and treatment side effects. Therefore, yoga being a feasible and efficacious therapy can be promoted as an adjunct to the conventional treatment modalities for cancer in the paediatric population to address the gaps that are deteriorating the quality of life of these patients.

ETHICAL CONSIDERATION

The Institutional ethics committee approved the study of the All India Institute of Medical Sciences (Ref. No. IECPG-61/27.02.2020) and registered with the Clinical trial registry (CTRI) (REF/2020/01/031017). The details of the project were explained to the participants and their guardians. The children and the parents signed the written consent and assent forms before enrolling in the study. They were assured of the confidentiality of their information, and patient Id was used for anonymity. They were informed that they had the right to withdraw at any point of the study if desired.

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