

Effect of *Moringa oleifera* Leaf Powder Supplementation in Children with Severe Acute Malnutrition in Gwalior District of Central India: A Randomised Controlled Trial

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ABSTRACT

Introduction: Child malnutrition is a major public health problem with a significant impact on child survival. In order to tackle this it is important to improve the nutritional quality of complementary and supplementary food while making it inexpensive and easily available. *Moringa oleifera* is a commonly grown local plant, with high nutritional and medicinal value, can be used as supplement.

Aim: To assess the effect of *Moringa oleifera* leaf powder supplementation on children with Severe Acute Malnutrition (SAM) during facility-based care and home-based care.

Materials and Methods: This randomised controlled trial was conducted in the Severe Malnutrition Treatment Unit (SMTU) of Kamla Raja Hospital, Madhya Pradesh, India. A total of 100 children in the age group of 7-59 months admitted between November 2019 to October 2020, who fulfilled the World Health Organisation (WHO) recommended criteria for identification of severe acute malnutrition were included in the study. The children were randomised to routine supplementation alone (control group) and routine supplementation with *Moringa* leaf

powder (intervention group). The anthropometric data was collected at the time of admission to the SMTU, at the time of discharge and every 15 days post discharge for two months. unpaired t-test, Chi-square test and Fischers-exact were used for statistical analysis.

Results: There was significant weight gain ($p=0.012$) in the intervention group as compared to the control group. Similarly the number of children with severe wasting were significantly less ($p=0.032$) in the intervention group at the end of two months follow-up. There was no significant difference in height, Head Circumference (HC), Chest Circumference (CC), Mid Upper Arm Circumference (MUAC), Subcutaneous Fat Assessment (SCFA), complications observed between both the groups and duration of hospital stay.

Conclusion: The use of *Moringa oleifera* leaf powder supplementation resulted in improved weight gain and reduction in severe wasting at the end of two months. It has the potential to link both facility-based and home-based care of malnourished children.

Keywords: Child, Dietary diversification, Severe wasting, Weight gain

INTRODUCTION

Malnutrition significantly impacts the survival of a child and is a major public health problem. It adversely effects the cognitive and physical development of children [1]. Although, the under five mortality has shown a significant improvement over the last few decades, but still there are many countries who are facing high burdens of malnutrition [2]. Every year more than three million children die of malnutrition, of which Low and Middle Income Countries (LMIC) bear the major burden [3]. A recent joint report on childhood malnutrition by the United Nations Children's Fund, WHO, and World bank group suggests that staggering 149 and 45.4 million children under five years of age are stunted and wasted [4].

Further, more than one-third and around half of these stunted and wasted children belong to the South Asian region [5]. The magnitude of child under nutrition in India is one of the highest in the world. According to the latest National Family Health Survey (NFHS) -5, less than 5 years of age around 35.5% are stunted, 32.1% are underweight, 19.3 % are wasted and 7.7% of children are severely wasted [6]. So that there is an urgent need to improve childhood nutrition [7].

This would predominantly include improvement of the nutritional quality (energy density, macronutrients, and micronutrients) of complementary and supplementary food. Further, given the budget constraints in the LMIC, there is a need for food based interventions that are less expensive, prepared with locally available ingredients, consistent with local or cultural food habits, and should consider safe handling [7,8].

Moringa oleifera is commonly grown local plant. Nutritional analyses show that its leaves have nutritional and medicinal values; it is rich in protein with high quantities of vitamin A and significant quantities of vitamin C, calcium, iron, potassium, magnesium, selenium, and zinc. It also contains all the essential amino acids, including two which are arginine and histamine that are especially important for children's health [9,10]. The leaves can be easily dried and ground into powder form for use as a nutritional supplement. Looking at the monetary, availability and nutritional benefit of *moringa oleifera*, it can be considered useful in the nutritional rehabilitation of children with severe acute malnutrition [11-14].

However, the clinical trials on usage of *moringa oleifera* as a nutritional supplement in children with severe acute malnutrition are very limited, with no data from India [11]. Hence, present study was done to assess the impact of *moringa oleifera* leaf powder supplementation on children with Severe Acute malnutrition (SAM) during facility-based care and home-based care.

MATERIALS AND METHODS

This randomised controlled trial was conducted in Severe Malnutrition Treatment Unit (SMTU) of Kamla Raja Hospital, Gajra Raja Medical College, and Gwalior, Madhya Pradesh, India, after getting approval from Institutional Ethics Committee (approval certificate no.-87/IEC-GRMC/2019). The study was conducted over a period of 12 months from November 2019 to October 2020. The SMTU specifically focuses on nutritional rehabilitation of SAM children after their initial stabilisation

in paediatric ward or intensive care. Informed consent was taken from the parents before enrolling the children in the study.

Inclusion criteria: All the children in the age group of 7-59 months fulfilling the WHO recommended criteria for identification of SAM - (i) Weight for height/length Z score (WFZ) <-3 Standard Deviation AND/OR; (ii) Mid Upper Arm Circumference (MUAC) <11.5 cm and/or; (iii) Bilateral symmetrical bipedal pitting oedema, were included after initial stabilisation when they were transferred to the SMTU [14]. For the feasibility of follow-up only children belong to Gwalior district were included in this study.

Exclusion criteria: The children with associated congenital/chronic problems like congenital heart disease, cystic fibrosis, malabsorption syndromes such as celiac disease, inflammatory bowel disease, and short bowel syndrome were excluded from the study.

Sample size calculation: The CONSORT guidelines for randomised controlled trials were followed [15]. After considering the prevalence of wasting among under 5 children to be 21% in accordance with National Family Health Survey-4 (NFHS-4), with 90% power, 95% confidence interval and assuming 5% decrease in wasting in the test group compared to the control group with enrollment ratio of 1:1, the sample size was calculated to be 94 participants (47 in each group) [16]. In this study, a total of 100 participants were included with 50 participants in each group.

$$k = \frac{n_2}{n_1} = 1$$

$$n_1 = \frac{\left(\sigma_1^2 + \frac{\sigma_2^2}{K}\right) (z_1 - \alpha/2 + z_1 - \beta)^2}{\Delta^2}$$

$$n_1 = \frac{(1.5^2 + 1.5^2/1)(1.96 + 1.28)^2}{1^2}$$

$$n_1 = 47$$

$$n_2 = K * n_1 = 47$$

$\Delta = |\mu_2 - \mu_1|$ = absolute difference between two means

σ_1, σ_2 = variance of mean 1 and 2

n_1 = sample size for group 1

n_2 = sample size for group 2

α = probability of type I error (usually 0.05)

β = probability of type II error (usually 0.1)

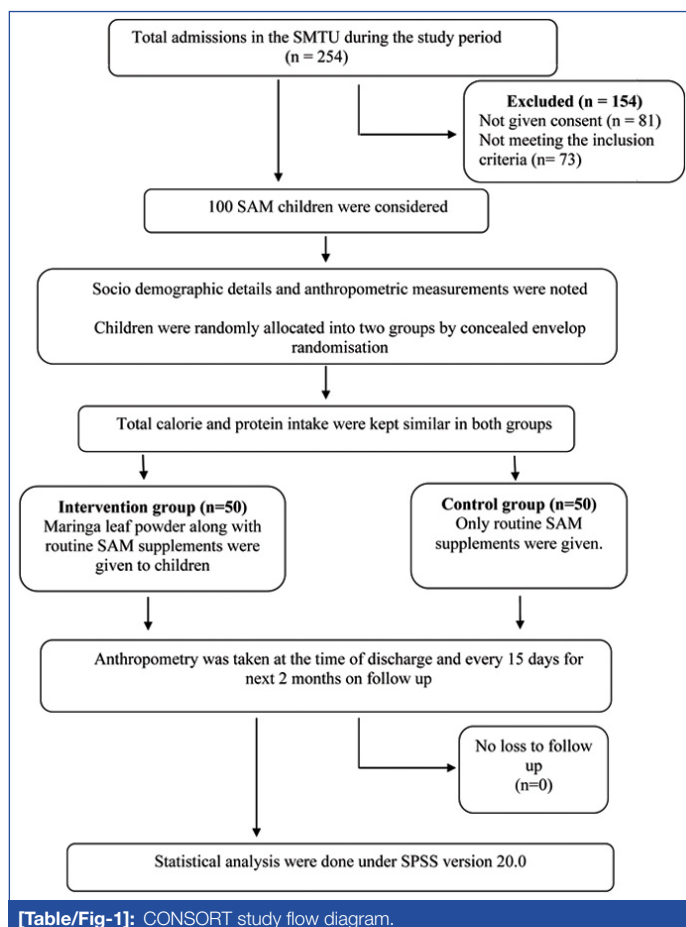
z = critical Z value for a given α or β

k = ratio of sample size for group 2 to group 1

Study Procedure

All the children with severe acute malnutrition after admission in SMTU were grouped into intervention group and control group using sealed envelope method. Each child in the Intervention group received *moringa oleifera* leaf powder in the dose of 15 gm twice a day in their diet, in addition to routine SAM supplements and catch up diet that is recommended in the rehabilitative phase of SAM management as per the facility based treatment guidelines issued by the Government of India [17]. The routine supplements included- a multivitamin combination (containing vitamin A, vitamin C, vitamin D, vitamin E and vitamin B12 in twice the recommended daily allowance), folic acid (5 mg on day one, then 1 mg/day), elemental zinc (2 mg/kg/day), copper (0.3 mg/kg/day), iron (3 mg/kg/day), potassium (3-4 meq/kg/day), magnesium sulphate (0.3 mL/kg IM on day one then followed by oral 0.4-0.6 mmol/kg/daily) and vitamin A (<6 months 50000 IU; 6-12 months or if weight <8 kg 100000 IU; >12 months 200000 IU- single dose). The catch up diet provided calories and protein in the range of 150-220 Kcal/kg/day and 2-4 gm/kg/day respectively [17]. The caregivers were trained during the hospital stay. They were explained that leaf powder could be added common food items such as salads, steamed vegetables, porridges, soups, curry, chapati or rice. Sealed packets of moringa

leaf powder were provided to them, one for each of the 15 days, at the time of discharge and on each follow-up visit. The moringa leaf powder supplementation was continued with home diet for two months post discharge [Table/Fig-1].



[Table/Fig-1]: CONSORT study flow diagram.

In the control group the child only received the recommended SAM supplements and catch up diet as per the management protocol detailed above. The overall total calories and proteins provided to both the groups were kept in recommended range. The caregivers in both the groups were given dietary advice in adherence to Facility based management guidelines of SAM children [17].

Locally and easily available *moringa oleifera* plant leaves were washed and dried in an airy place out of direct sunlight. Dried leaves were crushed with a mortar and pestle, to make leaf powder which was given to the intervention group [Table/Fig-2].

The data collected was divided into two subgroups

- (i) **Socio-demographic details:** Various socio-demographic details were collected at the time of admission to SMTU. These included- age and gender of the children, education and occupation of mother, education and occupation of father, and religion.
- (ii) **Anthropometric parameters:** Anthropometric measurements including Weight (W), Height (H), Weight for Height Z score (WFZ), Head Circumference (HC), Chest Circumference (CC), Mid Upper Arm Circumference (MUAC) and Sub-cutaneous Fat Assessment (SCFA) were collected at the time of admission to the SMTU, at the time of discharge and every 15 days post discharge for 2 months [17,18]. The SCFA was done by measuring triceps skin fold thickness with the help of happened callipers [18]. The percentage of children fulfilling the WHO criteria for severe wasting (WHZ <-3 SD) in both the groups were measured at discharge and during each follow-up visit at every 15 days for two months [14]. Various complications (indigestion, intolerance, and nausea, stomach upset and vomiting) as well as duration of SMTU stay of participants in both the groups were also compared.



[Table/Fig-2]: Prepared *Moringa oleifera* leaf powder.

STATISTICAL ANALYSIS

Data was entered in Microsoft Word and analysed using Statistical Package of the Social Sciences (SPSS) version 20.0. Frequency distribution and cross tabulation was performed to prepare tables; Microsoft office and PRISM software were used to prepare the graphs. Quantitative data were expressed as mean and standard deviation whereas categorical data were expressed as number and percentage. Mean values were compared using unpaired t-test whereas Chi-square test and fisher-exact test were used to compare percentage and distribution. The p-value of <0.05 was considered as significant.

RESULTS

Socio-demographic characteristics: In this study, it was observed that the baseline socio-demographic characteristics were comparable in both the groups [Table/Fig-3]. The majority of the participants in the intervention group and control group were hindu 44 (88%) versus 42 (84%) followed by muslim 6 (12%) versus 8 (16%). The gender-wise distribution of participants in intervention group and control groups was also similar 26 (52%) females versus 27 (54%) females.

Variables	Intervention group (n=50)	Control group (n=50)	Total (n=100)	p-value
Age (in years)				
7-12 months	29 (58%)	25 (50%)	54 (54%)	0.657
13-24 months	20 (40%)	23 (46%)	43 (43%)	
>24 months	1 (2%)	2 (4%)	3 (3%)	
Sex				
Female	26 (52%)	27 (54%)	53 (52%)	0.841
Male	24 (48%)	23 (46%)	47 (48%)	
Mother's occupation				
Farmer	2 (4%)	1 (2%)	3 (3%)	0.591
Housewife	34 (68%)	29 (58%)	63 (63%)	
Maid	5 (10%)	6 (12%)	11 (11%)	
Daily wage labourer	9 (18%)	14 (28%)	23 (23%)	

Father's occupation				
Driver	6 (12%)	5 (10%)	11 (11%)	0.998
Farmer	7 (14%)	7 (14%)	14 (14%)	
Daily wage labourer	30 (60%)	31 (62%)	61 (61%)	
Painter	4 (8%)	4 (8%)	8 (8%)	
Peon	3 (6%)	3 (6%)	6 (6%)	
Mother's education				
Illiterate	22 (44%)	20 (40%)	42 (42%)	0.685
Middle (5 th -8 th standard)	26 (52%)	30 (60%)	56 (56%)	
High school (9 th -10 th standard)	1 (2%)	0	1 (1%)	
Intermediate (11 th -12 th standard)	1 (2%)	0	1 (1%)	
Father's education				
Illiterate	12 (24%)	11 (22%)	23 (23%)	0.968
Middle (5 th -8 th standard)	25 (50%)	26 (52%)	51 (51%)	
High school (9 th -10 th standard)	11 (22%)	13 (28%)	24 (24%)	
Intermediate (11 th -12 th standard)	2 (4%)	0	2 (2%)	
Religion				
Hindu	44 (88%)	42 (84%)	86 (86%)	0.564
Muslim	6 (12%)	8 (16%)	14 (14%)	

[Table/Fig-3]: Socio-demographic characteristics of the study sample. Chi-square test for significance with yate's correction was used, p<0.05 was considered statistically significant

The rate of illiteracy was overall high. However, the education status of fathers' was observed to be better than the mothers. In the intervention group 22 (44%) of the mothers and of the fathers 12 (24%) were observed to be illiterate. Similarly, in the control group 20 (40%) of the mothers and 11 (22%) of the fathers had no formal education. Further, most of the mothers were housewives in intervention group and the control group, 34 (68%) versus 29 (58%). Also, the most common occupation amongst fathers was being daily wage labourer's in both the groups 30 (60%) and 31 (62%).

Anthropometric measurements: There was significant weight gain in the intervention group as compared to the control group at the end of two months follow-up (p-value=0.012). There was no significant difference in height, HC, CC, MUAC and SCFA at the end of two months follow-up between the intervention and control group [Table/Fig-4]. Similarly, the number of children with severe wasting were significantly less in the intervention group at the end of two months follow-up (4 in intervention group versus 30 in the control group) [Table/Fig-5].

Variables	Intervention group	Control group	p-value
Mean weight (in kg)			
Admission	6.0172	6.0460	0.905
Discharge	6.1040	6.0515	0.884
15 days follow-up	6.2160	6.0595	0.562
1 month follow-up	6.3580	6.0940	0.263
1.5 months follow-up	6.5100	6.1420	0.119
2 months follow-up	6.7640	6.1740	0.012*
Mean height (in cm)			
Admission	67.0360	67.0360	1.000
Discharge	67.0360	67.0360	1.000
15 days follow-up	67.0820	67.0400	0.971
1 month follow-up	67.1360	67.0480	0.939
1.5 months follow-up	67.1940	67.0580	0.905
2 months follow-up	67.2760	67.0680	0.988
Mean HC (in cm)			
Admission	40.9980	40.9520	0.908
Discharge	40.9980	40.9520	0.908
15 days follow-up	41.0940	40.9520	0.721

1 month follow-up	41.2140	40.9580	0.520
1.5 months follow-up	41.3260	40.9760	0.377
2 months follow-up	41.4760	41.0060	0.238
Mean CC (in cm)			
Admission	42.2780	42.2540	0.968
Discharge	42.3180	42.2940	0.967
15 days follow-up	42.3180	42.3020	0.978
1 month follow-up	42.3180	42.3420	0.967
1.5 months follow-up	42.3340	42.4220	0.880
2 months follow-up	42.3500	42.4620	0.848
Mean MUAC (in cm)			
Admission	11.5020	11.4920	0.976
Discharge	11.7280	11.5920	0.674
15 days follow-up	11.7920	11.5920	0.537
1 month follow-up	11.8880	11.5920	0.360
1.5 months follow-up	11.9760	11.5960	0.240
2 months follow-up	12.0680	11.6020	0.149
Mean SCFA (in mm)			
Admission	29.2460	29.2180	0.959
Discharge	29.4700	29.2200	0.640
15 days follow-up	29.5620	29.2180	0.529
1 month follow-up	29.7240	29.2180	0.371
1.5 months follow-up	29.8160	29.2180	0.290
2 months follow-up	29.8600	29.2180	0.258

[Table/Fig-4]: Association of various anthropometric measurements.

W: Weight; HC: Head circumference; CC: Chest circumference; MUAC: Mid upper arm circumference; SCFA: Sub-cutaneous fat assessment

Unpaired t-test was applied for statistical significance. *p-value <0.05- Statistically significant

Parameters	Group	WHZ (<-3 SD)	p-value
Admission	Intervention	50	1.000
	Control	50	
Discharge	Intervention	50	1.000
	Control	50	
15 days	Intervention	50	1.000
	Control	50	
1 month	Intervention	37	0.921
	Control	50	
1.5 months	Intervention	15	0.905
	Control	50	
2 months	Intervention	4	0.032 *
	Control	30	

[Table/Fig-5]: Frequency of severe wasting between Intervention group and control group.

WHZ: Weight for height Z score; SD: Standard deviation

Chi-square test was applied for statistical significance. *p-value <0.05- statistically significant

In this study, there was no significant difference in complications observed between both the groups [Table/Fig-6]. In both the intervention group and control group most of the children were discharged under 10 days from SMTU (44 vs 46). There was no significant difference in the duration of SMTU stay ($p=0.874$) in both the groups [Table/Fig-7].

DISCUSSION

In this study, the effectiveness and feasibility of using a locally available food source-*Moringa oleifera* leaf powder was assessed in management of malnutrition. Significant weight gain was observed at the end of two months follow-up.

In the current scenario, it is unlikely that the global SDG (Sustainable Developmental Goals) targets for 2030 will be met, with insufficient

Complications	Group				Total (n=100)		p-value
	Intervention group (n=50)		Control group (n=50)		Count	%	
	Count	%	Count	%			
Indigestion	1	2.0%	0	0	1	1.0%	0.562
Intolerance	1	2.0%	0	0	1	1.0%	
Nausea	1	2.0%	1	2.0%	2	2.0%	
Stomach upset	1	2.0%	0	0	1	1.0%	
Vomiting	1	2.0%	1	2.0%	2	2.0%	

[Table/Fig-6]: Complications observed in both the groups during the study period. Fisher exact test was applied for statistical significance. *p-value <0.05- Statistically significant

Duration of stay	Intervention group (n=50)	Control group (n=50)	Total (n=100)	p-value
<10 days	44	46	90	0.874
>=10 days	6	4	10	

[Table/Fig-7]: Duration of SMTU stay of participants in both the groups.

Fisher exact test was applied for statistical significance. *p-value <0.05- Statistically significant
SMTU: Severe malnutrition treatment unit

progress made in improving childhood malnutrition [5,19]. Moreover, the South east Asian region to which India belongs, is the predominant contributor to childhood malnutrition worldwide [5,17]. In order to reduce the burden of malnutrition, there are three main public health strategies, food supplementation, fortification of staple foods, and dietary diversification using local foods [11,20]. The efforts in tackling childhood malnutrition, have taken a dent in the ongoing COVID-19 pandemic scenario, with most of the countries struggling to provide adequate nutritional services to children while simultaneously dealing with the pandemic [5]. A survey has shown that 90% of the countries have reported a drop in nutritional services coverage [5]. Dietary diversification strategies using local, low cost, nutrient dense foods have the potential to meet all micronutrient recommendations and overcome nutrient gaps [11,20]. Therefore, there is an urgent need for more emphasis to be put on investigating local food based sustainable approaches and local resources for improving the nutritional status.

The analysis of socio-demographic details of the study population gives an insight into the problem of childhood malnutrition in the country, from a public health perspective. The major percentage of the participants belonged to the age group of 6-12 months (58%). This is a period of very high growth rate and therefore nutritional deficiencies can become more pronounced [21]. Most of the fathers were daily wage workers and mothers were housewives. This means, that there was no constant source of income in the family of the malnourished child. Poverty has been shown to be a strong determinant of malnutrition with major contributors being inadequate nutritional intake, lack of appropriate medical facilities, poor hygiene and sanitation [22,23].

The education level of the parents was observed to be poor in this study, with around half of mothers and one fourth of fathers being illiterate. An analysis done on data collected during NFHS -4 data also suggests that maternal education level were significantly associated with under nutrition in children [24]. There have also been recent studies from South Asia that have also demonstrated a relation between childhood malnutrition and education status of parents [25-27]. Poor eating habits during infancy and childhood secondary to lack of knowledge of optimal dietary habits and components of a balanced diet amongst parents are the major culprits. It has been well established that maternal education is positively associated with healthier diets in the infants and older children [28].

Moringa oleifera is an example of nutrient source that can be easily grown and used at individual or community level [11,13]. Despite lack of data of clinical trials, there is long history of usage of different parts of *moringa oleifera* by traditional healers for treatment of various acute illnesses such as, respiratory diseases, ear and dental infections, chronic morbidities like skin diseases, hypertension and

diabetes, cancer treatment, and as a rich nutritional food source for supplementation [11,29,30].

There have been animal studies showing significant weight gain and improved nutritional status by using *moringa oleifera* leaves [31,32]. However, there are very limited clinical trials testing its efficacy in malnourished children [11]. The literature review by the authors resulted in only two previously published randomised control trials in children. First, a longitudinal study was conducted in malnourished children in Burkina Faso by Zongo U et al., [33]. In this study 110 children in the age group of 6-59 months were randomly assigned to two groups. One group received a 10 gm daily supplementation of moringa leaf powder in addition to the usual diet, whereas the control group did not receive any moringa leaf powder. The average daily weight gain (8.9±4.30 g/kg) which was observed in children with moringa leaf powder supplementation was significantly higher than the control group (5.7±2.72 g/kg) (p-value=0.002).

Another, was a study from Ghana by Boating L et al., in which children in the age group of 8-12 months were randomised into three groups- one group daily received cereal- legume based flour with moringa leaf powder (5 gm), the second group received moringa leaf powder (5 gm) with usual diet and control group received cereal legume based flour without *Moringa* leaf powder [34]. The authors did not report any significant difference in the growth indicators. However, in the Ghana study the amount of *Moringa* leaf powder used for daily supplementation was very less as compared to this study (5 gm versus 30 gm in the present trial). Also, the Ghana trial did not specifically include malnourished children and the supplementation was not supervised.

In this study, significant increase in the mean weight gain in the participants of the intervention group was observed as compared to the control group at the end of two months of follow-up. Similarly, the number of children with severe wasting was found to be significantly reduced in the intervention group. However, there was no significant difference in other anthropometric parameters at the end of two months follow-up - mean height, HC, CC, MUAC, SCFA. Similar to this study, the previous trials did not report any significant increase in the height for age scores with use of *Moringa* leaf powder supplementation [33,34]. The catch up of linear growth in chronically malnourished is generally limited and therefore may not demonstrate improvement with short term nutritional supplementation [35]. The previous trial by Zongo U et al., also measured MUAC in both the groups [33]. The authors observed significant difference (p<0.001) in both groups with or without *Moringa* supplementation, with a greater difference in the group with *Moringa* supplementation. This could be explained by the fact that MUAC is a sensitive parameter to the change in food intake and there was an improvement in the diet in both the groups regardless of additional *Moringa* supplementation [36]. The authors could not find any previous data on the impact of *Moringa* leaf powder supplementation on CC, HC and SCFA in malnourished children. In this study, there was no significant difference in the *moringa oleifera* supplementation group, but long-term supplementation data is needed to further comment.

The average duration of hospital stay is considered as an indicator of effectiveness of the management of malnourished children. Previously published data has shown *moringa oleifera* supplementation to be associated with shorter hospital stay [33]. In this study, although the duration of stay was shorter in the intervention group, it was not found statistically significant. This difference may be attributed to socio-demographic differences in study population from previous studies or can be reflection of unit specific discharge policies. The authors suggest further trials to fully understand the clinical implications of *Moringa* leaf powder supplementation.

In this study, there were no significant complications or tolerability and acceptability issue with the use of *Moringa* powder. The previous study by Zongo U et al., had also reported good tolerability with

no significant increase in digestive disorders, respiratory disorders or skin allergies [33]. They had measured resistance by children to consume *moringa oleifera* supplemented porridge. The number was very small and only limited to first week of supplementation. Further, a recent study in Zambian malnourished children to assess the acceptability and safety of *moringa oleifera* powder supplementation concluded it to be a viable proposition for regular use [37].

Limitation(s)

There are certain limitations of this study. It was a single centre hospital based study. Long-term follow-up of the study participants could not be done; this would have helped in better understanding of the sustained impact of *moringa oleifera* leaf powder supplementation and also on optimal duration of supplementation.

CONCLUSION(S)

The use of *moringa oleifera* leaf powder supplementation significantly increased weight gain in severely malnourished children. It has the potential to be used in both facility-based and home-based care of malnourished children due to its low cost, easy availability and high nutritional value. There is a need for larger multicentric trials with long-term follow-up, that can provide required information for incorporation of *moringa oleifera* leaf powder supplementation in the existing guidelines on management of severe malnutrition.

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