DOI: 10.7860/JCDR/2024/66524.19230

Original Article

Paediatrics Section

Effectiveness of a Standardised Educational Package for Mothers of Children with Severe Acute Malnutrition: A Hospital-based Randomised Controlled Trial

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ABSTRACT

Introduction: Malnutrition is a major public health problem, especially in Low- and Middle-Income Countries (LMICs), contributing significantly to under-five mortality. New strategies are needed to enhance outcomes for childhood malnutrition.

Aim: To evaluate the impact of an educational package on mothers of children hospitalised with Severe Acute Malnutrition (SAM).

Materials and Methods: This was a hospital-based randomised controlled trial conducted in the Department of Paediatrics at Gajra Raja Medical College, Gwalior, Madhya Pradesh, India. Only children hospitalised between 6 months and 59 months of age with SAM were included and randomised into an Intervention group and a Control group. In the intervention group, verbal, pictorial, and demonstration techniques were used to educate the mothers. Anthropometric measurements of malnourished children and maternal knowledge scores were compared at baseline, 15 days, and two months postdischarge. Frequency and percentage were calculated for qualitative data analysis, while mean values with standard deviations were calculated for quantitative data. Independent t-tests and paired t-tests were applied, and paired t-tests were used for within-group comparisons at different time points. Data was entered into Microsoft Excel software, and analysis was performed using Statistical Package for Social Sciences (SPSS) version 22.0.

Results: The mean age of children was 1.4±0.9 years, with the majority below two years of age (86.4%). The male-to-female ratio was 1.04 (n=154 versus n=148). Most subjects belonged to lower or upper-lower socio-economic classes (75%). Mothers were commonly educated up to the primary school level (48%). Both study groups had similar socio-demographic profiles. There was a significant weight gain (p-value <0.01) and height gain (p-value <0.01) in the intervention group at the end of the follow-up period. Maternal knowledge gain in the intervention group was also significantly higher than in the control group (p-value <0.01).

Conclusion: This study supports maternal educational strategies as a low-cost intervention to address early childhood malnutrition in resource-limited settings. Further research is needed to standardise the intervention and assess long-term impact.

Keywords: Developing countries, Health education, India, Nutrition disorders, Nutritional sciences

INTRODUCTION

Malnutrition is a major public health problem, especially in LMICs, with a significant contribution to under-five mortality [1]. By eliminating malnutrition, it is estimated that child mortality could be decreased by more than half, and the burden of disease by more than 20% in developing countries [2]. A recent report by the World Health Organisation (WHO) suggests that worldwide around 150 million children under five years of age are stunted, and around 50 million children are wasted [3]. This has led to a renewed global commitment with the second Sustainable Development Goal of achieving zero hunger [4]. India has a well-established and monitored network of Nutrition Rehabilitative Centres (NRCs) along with large-scale government childhood nutrition programs. Despite these efforts, malnutrition contributes as one of the leading causes of childhood mortality in the country, and the evidence of the impact of various strategies remains extremely limited [5]. According to the National Family Health Survey 5 data (NFHS 5), among children under five years of age, around 35% are stunted, 32% are underweight, 20% are wasted, and 8% are severely wasted [6]. With such a high prevalence, there is an urgent need to upgrade and introduce newer strategies in the management of malnutrition to improve outcomes [7]. SAM is a clinical syndrome caused by multiple factors independently and by a complex interplay between them.

Economic constraints and lack of food security, although major defining factors of malnutrition, are not the only important contributing factors. Others include lack of awareness regarding the importance of breastfeeding [8], improper complementary feeding practices [9], and early or delayed introduction of complementary foods [10], peculiar food practices in the diet due to various cultural and ethnic variabilities [11], family planning practices, and birth spacing. These have been identified by various studies from South Asian countries and LMICs. Caregivers should be educated about appropriate feeding practices, including food quantity, food types, food diversity, and feeding frequency [12-14]. Additionally, they should be aware of common childhood illnesses, incorrect cultural beliefs, personal hygiene and sanitation, and family planning. Even though education of caregivers is an important part of government nutrition programs, it is generally neglected. Evidence from India discussing the overall benefits of education caregivers, bottlenecks, problems faced by healthcare workers, and monitoring the quality of counseling and knowledge of healthcare workers is also lacking [5]. Given this lack of evidence standardising and providing guidance regarding the education of caregivers in India, this study was conducted with an aim of assessing the feasibility and benefits of a novel education strategy for caregivers using a structured counseling package.

MATERIALS AND METHODS

This study was a randomised controlled trial conducted in the Severe Malnutrition Treatment Unit (SMTU) of the Department of Paediatrics, JA Group of Hospitals, and Gajra Raja Medical College, Gwalior,

Madhya Pradesh, India. This study was conducted for a duration of 24 months from October 2020 to September 2022. Informed consent was obtained from the parents. The study was approved by the Institutional Ethics Committee (IEC) (Certificate No. 82/IEC-GRMC/2019). The Consolidated Standards of Reporting Trials (CONSORT) guidelines were followed for the conduct of this study.

Inclusion criteria: All children in the age group of 6 months to 59 months who were admitted to SMTU and met the WHO criteria [15] for Severe Acute Malnutrition (SAM) were included in the study-Weight for height/length (WFH) ≤3 Z score and/or Mid Upper Arm Circumference (MUAC) <11.5 cm and/or Bilateral symmetrical bipedal pitting oedema.

Exclusion criteria: Children with any congenital anomalies or co-existing systemic impairments were excluded from the study.

Study tools: The data were collected in the following subsets:

a. **Socio-demographic variables:** Age, gender, birth order, religion, maternal education, type of SAM (oedematous or non oedematous), socio-economic class (revised Kuppuswamy) [16].

b. **Anthropometric measurements:** Weight, height, MUAC were collected. Weight was measured using a digital weighing scale (UNITECH Model-MI820021692), height was measured using a Stadiometer or infantometer (PKP Bardejov MB21), and MUAC was measured using a colour-coded tape (supplied by the United Nations International Children's Emergency Fund). The anthropometric data were recorded at the time of enrollment and then at each follow-up.

c. **Knowledge evaluation questionnaire:** The questionnaire was prepared and administered in the local vernacular language (Hindi). The total number of questions was 34, divided into five sections about breastfeeding (Section A- 5 questions), complementary feeding (Section B- 12 questions), hygiene and sanitation (Section C- 5 questions), common infections (Section D- 6 questions), and contraception (Section E- 6 questions). All the questions were of the "multiple-choice" type, each having one correct answer. The questionnaire was approved by a consensus of three local subject experts, and face validation of this questionnaire was conducted using a pilot project with 40 subjects. The questionnaire was administered at baseline to all the participating caregivers before the allocation of the children into the intervention or control group.

d. **Educational package:** The intervention group received two individual counseling sessions by the investigators. The focus was kept on following seven key messages that were developed by the investigators and subject experts: 1) Breastfeeding; 2) Complementary feeding; 3) Handwashing; 4) Food hygiene; 5) Balanced diet; 6) Diarrhoeal illness and Oral Rehydration Salts (ORS); and 7) Family planning.

Various pictorial aids were used for counseling, such as flow diagrams, charts, and flashcards. These were official publications of either the UNICEF (United Nations International Children's Emergency Fund) or WHO or Government of India. Additionally, the counseling sessions were guided by published recommendations of the Government of India and WHO [17-19]. The average duration of the session lasted around 20-30 minutes. The counseling was done during the initial days of hospitalisation and before discharge.

Sample size calculation: A pilot study was conducted on a total of 40 children-20 in each group. It was observed that the mean knowledge questionnaire score in the group counseled as per the study protocol was 16.2 (47.68%), compared to 10.7 (31.65%) in the group with routine counseling. Considering a 5% level of significance and 80% power, the sample size was calculated using the formula below to compare two proportions:

P_1=47.68 Q_1=100-47.68=52.32

P_2=31.95 Q_2=100-31.95=68.05

$$P=\frac{P_1+P_2}{2}=39.81$$

Q=100-P=60.19

$Z_{\alpha/2}$=1.96 at 5% level of significance

Power of test (1-β)=80%, $Z_{1-\beta}$=0.842

$$n_1=\frac{\{1.96\times\sqrt{2\times39.81\times60.19}+0.842\times\sqrt{(47.68\times52.32)+(31.95\times68.05)}\}^2}{(47.68-31.95)^2}$$

Hence n1=150.67≈151

n_2=151

$n=n_1+n_2$=151+151=302

The total sample size was calculated as 302, with n=151 in both the intervention and control group.

Sample collection and methodology: The children were randomly allocated using the sealed envelope method into two groups-group A (Intervention group) and group B (Control group). Socio-demographic details of all enrolled children and mothers were recorded. Baseline anthropometric measurements were taken for all the children. A Knowledge questionnaire was given to all the mothers in the study, and baseline scores were obtained. For illiterate mothers, the questionnaire was completed with the help of paramedical staff posted in SMTU.

The current counseling protocol in SMTU includes:

(a) *Daily group counseling sessions*-These sessions are conducted daily for all the caregivers of admitted patients by the SMTU staff members.

(b) *Individual counseling sessions*-These sessions are conducted twice by the SMTU staff members-once in the initial days of admission and then again before discharge. Both the group and individual counseling sessions are conducted without the use of any audiovisual aids or using any standardised approach.

In this study, the daily group counseling sessions were similarly conducted in both groups as per the existing protocol. However, there was a difference in the conduct of Individual counseling sessions. In group A (Intervention group), the Individual counseling sessions were conducted by the investigators with a standardised approach of key messages and utilising audiovisual aids and demonstration techniques. In group B (control group), the individual counseling sessions were conducted by the SMTU staff members as per the existing protocol. There was no blinding followed in this study because of the nature of the intervention.

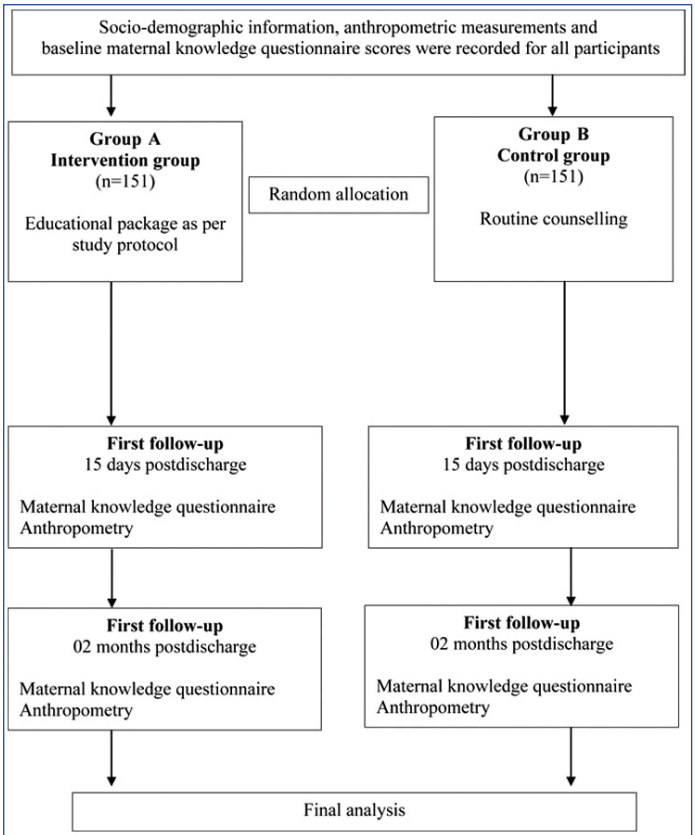
In both groups, the individual counseling session was conducted twice: once during the initial days of hospitalisation (within 48 hours) and once just before discharge. Follow-up was done after 15 days and at two months postdischarge. The dates of follow-up were assigned at the time of discharge, and a telephonic reminder was given three days prior to the assigned follow-up dates. At each follow-up, anthropometric measurements of children were recorded, and mothers' responses to the questionnaire were noted [Table/Fig-1].

STATISTICAL ANALYSIS

Data were entered into Microsoft Excel software, and the analysis was performed using SPSS version 22.0. For qualitative data, frequency and percentage were shown, while for quantitative data, the mean with standard deviation was presented. To compare two groups, the independent t-test was applied, while for within-group comparisons at different time points, the paired t-test was used. The Mann-Whitney U test and Chi-square test were employed for significance testing of categorical and ordinal variables between groups and among groups. A p-value of <0.05 was considered statistically significant.

RESULTS

The mean age of the children was 1.4±0.9 years, with most of them being below two years of age (86.4%). The ratio of males



[Table/Fig-1]: CONSORT flow diagram depicting enrolment of study participants.

to females was 1.04 (n=154 versus n=148). The majority of the study subjects were Hindus (87.7%) and belonged to the lower or upper-lower socio-economic class (75%). The mothers were commonly educated up to the primary school level (48%). Both study groups were similar in their socio-demographic profile, as detailed in [Table/Fig-2].

Variable	Group A intervention	Group B control	Total	p-value
Age group				
6 months-2 years	126	135	261 (86.4%)	0.147
More than 2-4 years	24	16	40 (13.2%)	
More than 4 years	1	0	1 (0.3%)	
Gender				
Male	74	80	154 (51%)	0.499
Female	77	71	148 (49%)	
Religion				
Hindu	131	134	265 (87.7%)	0.599
Muslim	20	17	37 (12.3%)	
Mother's education				
Graduate	16	12	28 (9.3%)	0.608
Higher secondary	11	20	31 (10.3%)	
Secondary	31	34	65 (21.5%)	
Primary	83	62	145 (48%)	
Illiterate	10	23	33 (10.9%)	
Socio-economic class				
Upper middle	2	3	5 (1.7%)	0.678
Lower middle	34	26	60 (19.9%)	
Upper lower	110	116	226 (74.8%)	
Lower	5	6	11 (3.6%)	
Birth order				
1 or 2	111	108	219 (72.5%)	0.723
3	33	33	66 (21.9%)	
4 or more	7	10	17 (5.6%)	
Type of SAM				
Oedematous	31	22	53 (17.5%)	0.173
Non-oedematous	120	129	249 (82.5%)	

[Table/Fig-2]: Comparison of baseline socio-demographic characteristics of study population among both the study groups.
Chi-square test

At baseline, the mean weight (in kg) of children in group A and group B was 6.2±1.6 kg and 6.0±1.5 kg (p-value=0.260), respectively. The mean height (in cm) in both groups was 70.8±8.5 cm and 69.4±7.8 cm (p-value=0.138), respectively. The MUAC in group A was 10.8±1.2 cm and in group B was 10.6±1.4 cm (p-value=0.180). There was a significant weight gain (p-value <0.01) and height gain (p-value <0.01) in the intervention group at the end of follow-up, but the gain in MUAC was not statistically significant (p-value=0.065), as detailed in [Table/Fig-3].

Anthropometric parameter	At baseline	First follow-up 15 days PD	Second follow-up 2 months PD
Weight (in Kg)			
Group A	6.2±1.6	6.4±1.6	6.7±1.6
Group B	6.0±1.5	6.2±1.5	6.5±1.5
	p-value 0.260	p-value 0.26	p-value <0.01
Height (in cm)			
Group A	70.8±8.5	71.1±8.3	72.2±8.0
Group B	69.4±7.8	69.8±7.7	70.8±7.3
	p-value 0.138	p-value 0.16	p-value <0.01
MUAC (in cm)			
Group A	10.8±1.2	10.8±1.2	10.9±1.2
Group B	10.6±1.4	10.6±1.2	10.7±1.2
	p-value 0.180	p-value 0.15	p-value 0.065

[Table/Fig-3]: Comparison of anthropometric measurements between the study groups at baseline and on follow-ups.
PD: Postdischarge; MUAC: Mid upper arm circumference
Independent t-test

The mean total Knowledge score of mothers at baseline in group A was 17.7±3.61 and in group B was 17.06±3.83 (p-value 0.106). Even though there was a significant gain in maternal knowledge in both groups, the gain in knowledge in group A was significantly more than in group B (p-value <0.01), as detailed in [Table/Fig-4].

Mean scores	At baseline	First follow-up	Second follow-up
Total score			
Group A	17.7±3.61	21.8±3.3	25.8±3.1
Group B	17.06±3.83	18.1±3.4	18.6±3.5
	p-value 0.106	p-value <0.01	p-value <0.01
Breastfeeding			
Group A	3.4±0.8	3.9±0.6	4.6±0.5
Group B	3.2±0.90	4.0±0.8	3.7±0.8
	p-value 0.110	p-value 0.22	p-value <0.01
Complimentary feeding			
Group A	5.6±1.5	6.7±1.4	7.6±1.4
Group B	5.3±1.2	5.5±1.2	5.6±1.2
	p-value 0.079	p-value <0.01	p-value <0.01
Hygiene and sanitation			
Group A	3.4±0.92	4.1±0.84	4.9±0.8
Group B	3.3±1.4	3.4±0.9	3.6±1.0
	p-value 0.667	p-value <0.01	p-value <0.01
Infections			
Group A	3.3±1.1	3.8±0.8	4.3±0.7
Group B	3.1±1.3	3.1±0.8	3.3±0.7
	p-value 0.136	p-value <0.01	p-value <0.01

Contraception			
Group A	2.1±1.1	3.2±1.0	3.8±1.1
Group B	2.0±1.5	2.0±0.8	2.3±0.8
	p-value 0.392	p-value <0.01	p-value <0.01

[Table/Fig-4]: Comparison of mean questionnaire scores of mothers between both study groups at baseline and on follow-ups.
Independent t-test

DISCUSSION

Most of the admissions in the SMTU were in the age group of six months to two years. This is understandable considering infancy as the period of maximal growth, and therefore, nutritional deficiencies become more pronounced during this period. Both inadequate breastfeeding and inadequate complementary feeding practices are known risk factors for malnutrition in this age group. The latest data from India are very underwhelming, with only 42% of infants breastfed within the first hour of life and only 64% of infants exclusively breastfed in the first six months [6]. Furthermore, only one-fifth of Indian children receive an adequate diet in the age group of 6-23 months [6]. In a recent meta-analysis on sex differences in undernutrition in children under five years, boys were most likely to be wasted, stunted, and underweight [20]. However, there are many social, genetic, and environmental factors leading to regional variations in the association of gender and malnutrition. The current study did not observe any gender-based differences, but this was a hospital-based study and therefore may not be a true reflection of the community.

Most of the children in this study belonged to a low socio-economic status. There have been multiple previous studies [21,22] that have observed low socio-economic status as a risk factor for malnutrition. Poverty leads to inadequate nutritional intake, poor hygiene and sanitation, vulnerability to diseases, and a lack of availability of adequate medical facilities [1]. This study highlights the impact of an educational package using verbal, pictorial, and demonstration techniques in improving maternal knowledge and the physical growth of malnourished children.

A recent community-based study was conducted among the urban poor socio-economic class of Chandigarh, India [23]. In that study, nutrition education was provided as an intervention by trained healthcare workers, resulting in a significant improvement in the timely start (72.6% versus 45.5%, p-value <0.01) and consistency (82.1% versus 41.9%, p-value <0.01) of complementary feeds. This led to a significant improvement in anthropometric measures and a significant decline in the proportion of undernourished infants in the intervention group. Another study conducted in rural Haryana showed a significant gain in length (0.32 cm) in infants in the intervention group after 18 months [13]. Interestingly, male infants showed more improvement in length (0.51 cm) compared to female infants in that study. In contrast, Nikiema L et al., concluded that the effect of nutrition counseling intervention on stunting was not significant after 18 months (OR-1.0, p=0.89) [24]. A community-based study from Bangladesh was conducted in malnourished children in the age group of 6-9 months. It involved culturally appropriate weekly nutrition education for six months [14]. The intervention group infants showed significantly more weight gain (0.86 kg versus 0.77 kg, p=0.053).

There are two important trials from Pakistan. In one cluster-randomised trial, education messages were delivered to mothers for 30 weeks, and a weight gain of 350 grams (p-value=0.001) and a 0.66 cm increase in length (p-value=0.001) were observed in infants in the intervention group [25]. In another study, nutrition counseling targeting mothers was delivered at two sites (Tando Jam and Quetta). There was a decline in the prevalence of wasting (Tando Jam-81% to 60%, Quetta-82% to 49%) and also an increase in the number of meals taken by children per day [26].

Similar results were also observed by Penny ME et al., where intervention group children gained 295 grams in weight (p-value=0.014) and 1.07 cm in length (p-value <0.0003) more than the control group children at the end of 18 months [12]. They were also eating more energy-dense and thick consistency meals (31% versus 20%, p-value=0.03).

A recent quasi-experimental study done in India [27] showed that the delivery of an education package to pregnant mothers led to a reduction in the prevalence of underweight infants at 12 months (58.5% versus 69.3%, p-value=0.047). In another hospital-based study from Karnataka [28], nutrition education was delivered every month to the caregivers of infants, resulting in about 77.5% of the mothers starting complementary feeding at six months of age.

When viewed together, the available studies [13,14,24-28] suggest that the effect of educational interventions may vary depending on the baseline characteristics of the participants, cultural acceptance of the intervention, types of foods available to the caregivers, food security, and the medium of imparting education or counseling.

Limitation(s)

There were certain limitations in this study. Firstly, long-term follow-up of study subjects was not a part of this trial, and changes in dietary habits were not assessed. Secondly, this was only a hospital-based study, so the data generated cannot be generalised to the entire community.

CONCLUSION(S)

The educational package used in this study significantly improved the growth of severely malnourished children during the study period, in addition to demonstrating better maternal knowledge. There is an urgent need to utilise such low-cost strategies in the fight against malnutrition. Furthermore, region-specific qualitative studies are needed to help in the formulation of region-specific effective counseling approaches with materials and messages that are adapted to the local setting, considering social norms and socio-cultural practices.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Jul 17, 2023
- Manual Googling: Oct 17, 2023
- iThenticate Software: Feb 03, 2024 (22%)

ETYMOLOGY: Author Origin

EMENDATIONS: 6

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. No

Date of Submission: **Jul 17, 2023**
Date of Peer Review: **Oct 12, 2023**
Date of Acceptance: **Feb 05, 2024**
Date of Publishing: **Apr 01, 2024**