Mal J Nutr 28(2): 295-303, 2022

Effect of adherence to follow-up on recovery from moderate acute malnutrition among under-fives in a supplementary feeding programme

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ABSTRACT

Introduction: Supplementary feeding programme is a strategy for managing under-fives with moderate acute malnutrition (MAM). This study aimed to determine the effect of adherence to follow-up on recovery from MAM among under-fives. **Methods:** A clinical trial to evaluate the effectiveness of daily supplementary rations of a standardised milk-based formulation (SMBF), standardised non-milk-based formulation (SNMBF), and hospital-based formulation (HBF) on recovery from MAM over a four months period was conducted among eligible children aged 6 – 59 months. Recovery from MAM among participants was determined based on their status of adherence to follow-up at week 16. It was deemed statistically significant if *p*-value was <0.05. **Results:** Of the 157 children evaluated, 41/54 (75.9%) who received the SMBF, 32/57 (56.1%) who received the SNMBF, and 22/46 (47.8%) who received the HBF had good adherence. Adherence to follow-up was significantly higher with SMBF than SNMBF and HBF (χ^2=8.923; p=0.012). In all, 95/157 (60.5%) had good adherence to follow-up with 73/95 (76.8%) recovery from MAM against 42/62 (67.7%) recovery in those with poor adherence (p=0.208). **Conclusion:** The status of adherence to scheduled follow-up was not significantly associated with recovery from MAM among under-fives enrolled in the supplementary feeding programme. Nevertheless, efforts at promoting adherence to scheduled follow-up visits should be sustained.

Key words: adherence, clinical, follow-up, malnutrition, nutrition, trial

INTRODUCTION

Malnutrition is presently a leading cause of childhood morbidity and mortality globally. Micha *et al.* (2020) gave an estimate of about 144 million stunted and 47 million wasted under-fives globally. Of the 47 million under-fives with wasting, 14.3 million have severe acute malnutrition, while 32.7 million have moderate acute malnutrition (MAM). Most malnourished children reside in Asia and sub-Saharan Africa (Micha *et al.,* 2020).

Supplementary feeding programme is one of the strategies recommended by the World Health Organization (WHO)

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doi: https://doi.org/10.31246/mjn-2021-0040

for managing childhood MAM. The programme entails provision of additional foods beside the child's regular diet that is aimed at reducing the gap between the actual dietary intake and requirement of the child. A Cochrane systematic review by Sguassero *et al.* (2012) showed that supplementary feeding optimised growth and facilitated recovery from MAM in under-fives. An overview of systematic reviews by Visser *et al.* (2018) showed that ready-to-use therapeutic foods or nutrient-dense formulations prepared from locally available food stuffs can be used over a period of time at rations to help meet the full or partial daily caloric requirements of malnourished population. The findings of Kekalih *et al.* (2019) in a clinical trial among wasted children showed that adherence to follow-up in a supplementary feeding programme impacted the frequency of clinic visits, use of foods by participants, and influenced recovery from malnutrition. Poor adherence to study protocol or dietary regimen among malnourished under-five children enrolled in a supplementary feeding programme has been reported by Pietraville *et al.* (2021) to be associated with poor clinical outcomes and failure in community management of acute malnutrition.

There is paucity of information on the relationship between the extent of adherence to follow-up schedules and recovery from MAM among under-fives enrolled in a supplementary feeding programme. Therefore, this study aimed to evaluate the effect of adherence to follow-up on recovery from MAM among children aged 6 – 59 months enrolled in a supplementary feeding programme in Nigeria.

MATERIALS AND METHODS

Study location and duration

This study was conducted in Primary Health Centres located at Mbak Etoi, Adadiah, and Okopedi Use in the Uyo Senatorial District of Akwa State, Nigeria from May 2016 to April 2017.

Sample size calculation

The sample size was calculated based on 80% certainty that the lower limit of a 95% two-sided confidence interval will be above -0.3, assuming a standard deviation of 0.55 units (Martha 1993). The sample size for each of the study arm was 48 children. To accommodate a 10% attrition, the minimum sample size was increased to 53 children per study arm.

Eligibility criteria

Children aged 6-59 months with MAM defined as weight-for-height/length z-score between -2 and -3 standard deviation (*SD*) or mid-upper arm circumference (MUAC) of 11.5 cm to 12.5 cm, in the absence of oedema or a concomitant medical or surgical illness, and with the issuance of parental consent.

Randomisation

Balloting technique was used to randomise the children to receive one of the three formulations – standardised milk-based formulation (SMBF), standardised non-milk-based formulation (SNMBF), and hospital-based formulation (HBF). Participants enrolled in PHC Adadiah received the SMBF, those enrolled in the PHC Okopedi Use received the SNMBF, while those enrolled in PHC Mbak Etoi received the HBF.

Administration of supplementary feeds

A daily supplementary ration of the SMBF, SNMBF, and HBF were given to meet 50% of the caloric requirements of children in addition to their regular family diet for four months. Table 1 shows nutrient composition of the formulations.

Table 1. Comparison of nutrient composition of different formulations

Average nutrient composition (unit)	*Cereal-based formulation (Standardised milk-based formulation)*		*Soya-cereal based formulation (Standardised non-milk based formulation)*		*Hospital-based formulation*	
	Per meal (50g=200ml)	*% RDA*	*Per meal (50g=200ml)*	*% RDA*	*Per meal (200ml)*	*% RDA*
Energy (kcal)	205	29	199	29	215	31
Fat (g)	5.0	17	4.5	15	10.7	36
Linoleic acid (g)	0.8	16	1.7	37	1.9	41
Protein (g)	7.5	68	7.5	68	7.2	65
Carbohydrate (g)	32.5	34	32.1	34	22.1	23
Dietary fibre (mg)	2.2	43	3.5	70	0.2	3
Vitamin A (IU)	650	130	750	150	555	111
Vitamin D (IU)	100	50	100	50	40	20
Vitamin E (IU)	3.4	68	3.4	68	2.0	39
Vitamin C (mg)	25	50	25	50	43.6	87
Vitamin B1 (mg)	0.3	100	0.4	133	0.4	140
Vitamin B2 (mg)	0.4	94			0.6	153
Niacin (mg)	1.5	38	2.0	50	4.8	123
Vitamin B6 (mg)	0.5	50	0.2	50	0.1	3
Folic Acid (µg)	20.0	25	40.0	50	41.0	51
Vitamin B12 (µg)	0.6	110	0.4	80	0.3	64
Calcium (mg)	300	111	195	72	129	48
Sodium (mg)	72.5	36	105.0	53	48.7	25
Iron (mg)	3.8	35	5.0	45	3.2	30
Zinc (mg)	3.0	100	3.0	100	0.4	13

Children aged 6–24 months received 100 kcal/kg/day of the formulation assigned to them, while those aged 25–59 months received 90 kcal/kg/day. The caregivers were trained by a dietitian on the preparation of the formulations, feeding of the children, and were instructed not to share the formulations with other members of the household. They were also counselled on the preparation of age-appropriate complementary foods using locally available food stuffs, infant and young child feeding practices, hand hygiene, and food hygiene. A flip chart with appropriate pictures was used to reinforce the key messages of the nutrition counselling. Mothers were encouraged to continue breastfeeding children aged 6-24 months.

Follow-up

Children were followed-up on a biweekly basis from the commencement of the study. Clinical assessment, anthropometric measurements, and nutrition counselling were performed during the follow-up visits. The supply of supplementary food for the next two weeks was given to those who kept their scheduled follow-up visits; while those who failed to keep their visits missed out on their ration of food. Adherence to follow-up visits was considered good if a child kept the entire follow-up visits (eight visits) and poor if a child defaulted on one or more follow-up visits.

Statistical analysis

Data were entered into Excel 2016

(Microsoft Corporation, USA). The software was also used for analyses. Analyses were done per protocol for children who completed the study only. The characteristics of the children were described using frequencies and percentages. Likewise, the proportion of recovery from MAM based on adherence status of the participants was presented in percentages. The test of association between the status of adherence (good adherence versus poor adherence) and recovery from MAM was assessed at week 16 among evaluable children using chi-square test. A *p*-value of <0.05 was considered as statistically significant.

Ethical approval

Approval for the conduct of the study was obtained from the Health Research Ethics Committee of the University of Uyo Teaching Hospital, Uyo, with the approval registry number UUTH/AD/S/96/VOL. XXI/341. Parental consent was obtained before enrolment of participants into the study. The primary study from which this work was derived (effectiveness and tolerability of standardised milk-

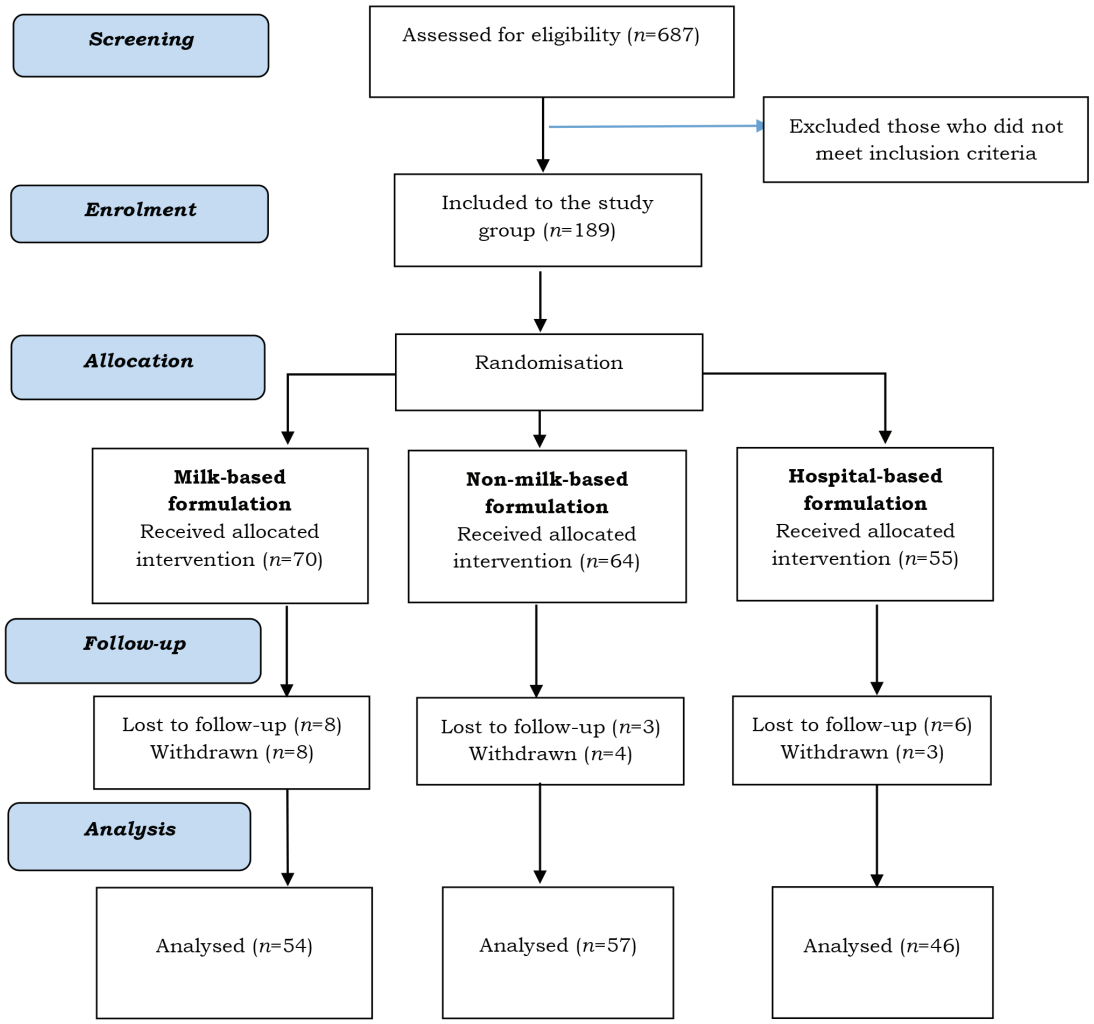

Figure 1: Flow diagram of study

Table 2: Recovery from MAM based on formulation of supplementary feed

Outcome	*SMBF n (%)*	*SNMBF n (%)*	*HBF n (%)*
Recovery from MAM	43 (79.6)	40 (70.2)	32 (69.6)
No improvement or worse	11 (20.4)	17 (29.8)	14 (30.4)
Total	54 (100)	57 (100)	46 (100)

based, standardised non-milk-based, and hospital-based formulations in the management of moderate acute malnutrition in under-five children: a randomised clinical trial) was registered with the Pan African Clinical Trial Registry with a trial registration number PACTR201704002119141.

RESULTS

Figure 1 shows the flow diagram of the study highlighting screening of participants for eligibility into the study, enrolment and randomisation of eligible participants, administration of the investigational products, follow-up of participants, and analysis of evaluable participants.

Recovery from MAM following supplementary feeding

Of the 157 evaluable children, 115/157 (73.2%) recovered from MAM. The highest proportion of recovery was noted among those that received the SMBF, 43/54 (79.6%), as seen in Table 2.

Adherence of study participants to follow-up schedules

As represented in Table 3, adherence to scheduled follow-up was good in 41/54 (75.9%) of those enrolled in the SMBF group, 32/57 (56.1%) of those enrolled in the SNMBF group, and 22/46 (47.8%) of those enrolled in the HBF group. There was a statistically significant association between the type of formulation used in the supplementary feeding programme and adherence to scheduled follow-up visits (χ^2=8.923; p=0.012). Participants in the SMBF group were more likely to adhere to scheduled follow-up visits than those in the SNMBF or HBF groups.

Overall effect of adherence to follow-up on recovery from MAM

Of the 157 evaluable children, 95 (60.5%) had good adherence, while 62 (39.5%) had poor adherence to follow-ups. Among those with good adherence, 73/95 (76.8%) recovered from MAM against 42/62 (67.7%) among those with poor adherence. The difference in proportion of recovery based on status of adherence was not statistically significant (χ^2=1.585; p=0.208) as shown in Table 4.

Effect of adherence to follow-up on recovery among participants in various groups

The effect of adherence to follow-up on recovery among participants in different study arms is displayed in Table 4. Of the 41 children with good adherence in the SMBF group, 33/41 (80.5%) recovered from MAM against 10/13 (76.9%) of those with poor adherence. There was no difference in recovery based

Table 3: Adherence status of participants to scheduled follow-up visits

Status of adherence	*SMBF n (%)*	*SNMBF n (%)*	*HBF n (%)*	*Statistical indices*
Good adherence	41 (75.9)	32 (56.1)	22 (47.8)	χ^2=8.923
Poor adherence	13 (24.1)	25 (43.9)	24 (52.2)	p=0.012
Total	54 (100)	57 (100)	46 (100)	

Table 4: Effect of adherence on recovery from MAM in all study participants and by supplementary feed grouping

Status of adherence to follow up	*Recovered n (%)*	*Not recovered n (%)*	*Total n (%)*	χ^2 *value*	*p-value*
Adherence on recovery from MAM in all study participants				1.585	0.208
Good adherence	73 (76.8)	22 (23.2)	95 (100)		
Poor adherence	42 (67.7)	20 (32.3)	62 (100)		
Adherence on recovery by supplementary feed grouping					
SMBF Group					
Good	33 (80.5)	8 (19.5)	41 (100)		0.715[a]
Poor	10 (76.9)	3 (23.1)	13 (100)		
SNMBF Group					
Good	24 (75.0)	8 (25.0)	40 (100)	0.811	0.368
Poor	16 (64)	9 (36.0)	17 (100)		
HBF Group					
Good	16 (72.7)	6 (27.3)	22 (100)	0.199	0.655
Poor	16 (66.7)	8 (33.3)	24 (100)		
Total	115 (73.2)	42 (26.8)	157 (100)		

[a]Fisher's exact test

on status of adherence in the group (p=0.715). In the SNMBF group, 24/32 (75.0%) children with good adherence recovered from MAM against 16/25 (64.0%) of those with poor adherence to follow-up. The difference in recovery based on the status of adherence in the group was not statistically significant (χ^2=0.811; p=0.368). Of the 22 children with good adherence to follow-up in the HBF group, 16 (72.7%) recovered from MAM against 16/24 (66.7%) of those with poor adherence to follow-up. The effect of status of adherence to follow-up on recovery in this group was also not statistically significant (p=0.655; χ^2=0.199).

DISCUSSION

There was 73.2% recovery from MAM among the evaluable children enrolled in the supplementary feeding programme at the end of the study. The highest recovery was noted among those who received the SMBF, while the proportion of recovery in those who received the SNMBF and HBF was similar. The recovery from MAM with the formulations evaluated in this study was less than 85% as observed by Medoua *et al.* (2016) among children treated with a lipid-based nutrient supplement (LNS), but similar to the 73% recovery among those who received a corn soy blend in the same study conducted in Cameroon. Karakochuk *et al.* (2012) in Ethiopia reported 73.0% recovery among under-fives with MAM treated with LNS. These observations highlight the influence of variation in the composition of nutritional formulations and possibly the effect of variation in nutrient concentration of formulations with similar composition on the recovery of childhood MAM.

The extent of adherence to scheduled follow-up visits was significantly higher in those who were treated with the SMBF compared to those who received either the SNMBF or the HBF. The observed differences in the adherence to follow-up based on the nature of the supplementary

food could be attributed to variations in the composition, packaging, preparation, and palatability of the formulations. The SMBF was a pre-packaged formulation contained in sachets that was relatively easy to prepare and more palatable when compared to the SNMBF or HBF. Kebede & Haidar (2014) in Ethiopia identified dislike of taste as a reason for poor adherence to supplementary feeding among HIV positive patients. On the other hand, the SNMBF was contained in tins, thereby requiring a high level of accuracy in the number and volume of scoops to be taken by the caregivers when preparing the formulation as compared to the SMBF that had a predetermined number of sachets of formulation to be used for a particular child. The HBF was the most difficult to prepare because the constituents were packed differently and needed to be introduced in an orderly sequence during preparation and heated for a specified period for optimum nutrient bioavailability. The variations in packaging and complexities in preparation, especially for the HBF, might have contributed to the differences in adherence of the participants to scheduled follow-up visits.

The overall result of this study showed that recovery from MAM was slightly better among those with good adherence to follow-up compared to those with poor adherence. This was also true among participants in different study arms even though the differences between them were not statistically significant. Recovery from MAM among those with good adherence was highest in the SMBF group, followed by the SNMBF group, and least in the HBF group. This apparent gradation in recovery appeared to be related to the extent of adherence to follow-up by participants in various study arms, as the level of adherence to follow-up was highest in those that received the SMBF and lowest in those that received the HBF.

There is no fixed cut-off value for good adherence to follow-up in clinical trials. Probstfield (1989) indicated that arbitrary values are often used based on study outcomes, condition of interest, effectiveness of the intervention, and the duration of follow-up. The inability to detect a statistically significant difference in the proportion of recovery based on adherence status among the participants in this study might be due to the fact that we used 100% adherence to follow-up to connote good adherence. In a study among children with HIV, Odeny *et al.* (2012) used a cut-off value of 90% adherence to follow-up as indicative of good adherence, while Masaya *et al.* (2017) in a study that assessed the effect of inhaled steroid for bronchial asthma used ≥80%. The lower the percentage used as the cut-off value for good adherence, the more the likelihood of appreciating the effect that status of adherence to follow-up has on outcome measures. This is particularly important in supplementary feeding programme where a reasonable length of time is needed to observe appreciable changes in outcome measures.

Poor adherence has been reported by Dunbar-Jacob *et al.* (2000) to attenuate optimum clinical benefits of treatment interventions. Poor adherence to scheduled follow-up visits had a negative impact on recovery from MAM in this study. Besides militating against recovery from MAM, poor adherence to scheduled follow-up visits among malnourished children in a supplementary feeding programme could also increase their vulnerability to other childhood co-morbidities as observed by Schaible & Kaufmann (2007).

Most cases of childhood malnutrition in developing countries like Nigeria are mainly due to dietary inadequacy arising from poverty, household food insecurity or lack of awareness in feeding practices among caregivers of young children

as noted by Bain *et al.* (2013) and Babatunde *et al.* (2011). It was therefore expected that the caregivers of children in this study would take full advantage of the free feeding programme by adhering strictly to the follow-up schedules. This was not the case as a high rate of default to scheduled follow-up visits was noted among participants in the programme.

The relatively low recovery from MAM that was associated with poor adherence to scheduled follow-ups in this study is of immense clinical importance to child survival in resource limited countries considering the health consequences of child malnutrition as reported by Black *et al.* (2008). In view of the high mortality attributable to childhood malnutrition and its adverse impacts on physical growth, cognitive and immunologic functions, it is imperative that children with MAM enrolled in supplementary feeding programmes adhere strictly to their scheduled follow-up visits.

Studies aimed at determining the factors associated with adherence to follow-up in childhood nutrition clinical trials are needed in order to develop strategies for improving adherence to scheduled follow-up visits. This will go a long way to improve recovery among under-fives with MAM enrolled in supplementary feeding programmes.

CONCLUSION

The extent of adherence to scheduled follow-up visits was not significantly associated with recovery from MAM in the participants. Nevertheless, efforts at promoting adherence to scheduled follow-up visits are still necessary in evaluating the effect of supplementary feeding programmes among under-fives with MAM.

Acknowledgement

We are thankful to the matrons of the health facilities where the study was conducted, the community leaders and the caregivers of the children for their co–operation throughout the study.

Authors' contributions

EEU, conceived the study, conducted the work, analysed the data, interpreted the results and drafted the manuscript; RAU, participated in the data collection, interpretation and preparation of the manuscript; KBE, participated in the data collection, interpretation and preparation of the manuscript; FSO, made critical inputs to the manuscript; ENU, participated in the data collection, interpretation and preparation of the manuscript; BNN, participated in the study design, data collection, analysis and preparation of the manuscript; OOM, participated in the study design, data collection, analysis and preparation of the manuscript. All authors read and approved the final version of the work.

Conflict of interest

EEU received support from Nestle Nutrition Institute Africa to conduct the study. The other authors have no competing interest to declare.

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