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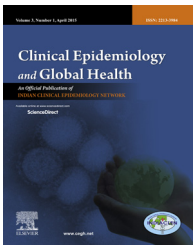

Original Article

Community-based management of severe malnutrition: SAM and SUW in the tribal area of Melghat, Maharashtra, India

Vibhawari Dani [a], Kavita Satav [b], Jayashree Pendharkar [c], Ashish Satav [d,*], Suresh Ughade [e], Ambadas Adhav [f], Bharat Thakare [g]

[a] Head of Research Division and Paediatric Consultant, Principal Investigator of Study, MAHAN trust, Nagpur, India
[b] Ophthalmic Surgeon and Co-investigator, MAHAN trust and Kasturba Health Society, Dharni, Amaravati, India
[c] Nutrition Consultant, MAHAN trust, Nagpur, India
[d] Co-investigator and Physician, President, MAHAN trust, Dharni, Amaravati, India
[e] Biostatistician, Associate Professor, P.S.M., Govt. Medical College, Nagpur, India
[f] Program Manager, MAHAN trust, Dharni, Amaravati, India
[g] Research Officer, MAHAN trust, Dharni, Amaravati, India

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ABSTRACT

Objectives: Main objectives of the study were the following:

1. To achieve a recovery rate of 75% in severe acute malnutrition (SAM) children and 35% in severe underweight (SUW) children, in tribal community based management of severe malnutrition.
2. To achieve a case fatality rate of <4% in SAM and SUW children in the above setting.
3. To reduce current prevalence rate of SAM and SUW by at least 35% after 3 years of intervention.

Design: Community-based prospective, single-group intervention study.
Setting: Primary and secondary care was given to participants from 14 villages of the tribal area of Melghat.
Participants: Severely malnourished children (SMC:734), tribal, male and female of the 6–60 months age group were enrolled and 680 children completed the study over a period of 3 years. Sample size (N = 762) was estimated considering the prevalence of severe malnutrition (SAM and SUW) in 6–60 months population as 21.5%; design effect was 3.0 and relative precision was 10%, with 95% confidence interval.
Interventions: LTF (local-therapeutic-food) with MN (micronutrients), treatment of infections and BCC (behavior change communication) were given for 90 days to SMC by VHW (village health worker).

* *Corresponding author at*: Dr. Ashish Satav, President, MAHAN, Mahatma Gandhi Tribal Hospital, Karmagram Utavali, Tahsil, Amaravati, Maharashtra 444 702, India. Tel.: +91 9423118877/07226 202291.
E-mail address: drsatav@rediffmail.com (A. Satav).
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Outcome measures: Rate of recovery, case fatality rate, and reduction in prevalence of SAM and SUW.

Results: Majority of SMC (69.1%) in the 6–24 months age group were SAM, while majority of SMC (65.3%) in the 25–60 months age group were SUW. Recovery rate of SAM is 75.9%, 77.8%, and 79.4% at the end of 8th, 10th, and 12th week, respectively; the recovery rate for SUW is 37.5%, 42.7%, and 45.4%, respectively. Case fatality rate for SAM is 0.6% and for SUW is 0.2% after 8th week. There is significant reduction in prevalence of SAM (p – 0.005) and SUW (p – 0.0001) children at the end of the study.

Conclusions: The study shows efficacy of LTF-MN and effectiveness of our community-based model in acute and chronic malnutrition. Further research is needed for deciding the exact duration of SUW therapy.

Trial registration: The study is registered under Protocol Registration and Results System (PRS) (ClinicalTrials.gov ID: NCT02671786).

1. Introduction

Globally, malnutrition remains one of the leading causes of mortality[1–4] contributing to 60% of deaths in under-five (U5) children.[1,5] Acute malnutrition is attributable to 14.6% of all child deaths having 8 times more fatality rate among malnourished children than normal children.[6–9] The prevalence of chronic malnutrition in India is among the highest in the world, and is nearly double than that of Sub-Saharan Africa, with dire consequences of mortality, morbidity, educability, and productivity.[9–11] Prevalence of malnutrition is much higher in tribal India. Severe acute malnutrition (SAM) is 6%, severe underweight (SUW) is 20%, and severe stunting is 26% in the 1–5 years age group.[12] Tribal Maharashtra has SAM at 7%, SUW at 29%, and severe stunting at 30%. Our study revealed prevalence of severe malnutrition (SAM – 7.1%, SUW – 18.7%, and severe stunting – 34.4%) in U5 children of Melghat.[8] Prevalence of moderate and severe malnutrition (−2SD WHO) in tribal Melghat is as wasting in 26%, underweight in 58.4%, and stunting in 66.1%.[8] These levels are considered very high, above the 'WHO Trigger Levels', indicating a need for public health interventions.[7]

Major contributing factors for severe malnutrition are faulty child feeding practices (like delayed initiation of breast feeding, colostrum not given, and late weaning at 9–12 months); infectious diseases like ARI, Diarrhea, and Malaria; poor hygiene and sanitation, etc.[6,11,13,14] Medical facilities in Melghat are grossly inadequate coupled with very low health-seeking behavior by the tribal population.[15,16] Hospital-based treatment limits its coverage and impact. There is no specific program to tackle this heavy burden of severe malnutrition.[17–19]

Many studies have discussed evidence-based possible interventions to address SAM.[9,20–22] Co-existence of acute and acute-on-chronic malnutrition cannot be denied in the developing world.[6–8,12] In this study, we have evaluated the efficacy of community-based management by local therapeutic food (LTF) and micronutrients (LTF-MN), home-based treatment of infectious diseases, and behavior change communication (BCC) on SAM and SUW through village health workers (VHWs) in tribal community of Melghat.

2. Objectives

1. To achieve the recovery rate of 75% in SAM children and recovery rate of at least 35% in SUW children by LTF with micronutrients (MN), BCC, and home-based treatment of infections, in usual resident population of 13,038 (from 14 villages) in the tribal area of Melghat over a period of 3 years.
2. To achieve the case fatality rate of <4% in SAM or SUW children in the above setting.
3. To reduce current prevalence rate of SAM or SUW by at least 35% after 3 years of intervention.

3. Methods

Melghat is a difficult-to-reach, hilly, forest area in Maharashtra (Central India) having a population of around 300,000 scattered over 320 villages spread over 4000 sq.km. Around 85% of the population is tribal, of which more than 90% are small farmers or agricultural laborers and are living below the poverty line.[23,16]

A community-based prospective, single-group intervention study was done in Dharni and Chikhaldara blocks of Melghat over a period of 3 years (2012–2015). Sampling frame was all children in the 6–60 months age group from 320 villages of both blocks. Dharni block was divided into five clusters (East, West, North, South, and Central) and Chikhaldara block was taken as the sixth cluster for sampling purpose. 14 villages from these six clusters were randomly selected (Annexure-1).

Assuming that the baseline prevalence of severe malnutrition (SAM and SUW) was 21.5% in the tribal children (our published data in 2012), it would be reduced at least by 30% in three years after proposed intervention (i.e. the prevalence of

severe malnutrition (SAM and SUW) would come down to 15.5% by 2015 with LTF-MN). A sample size of 654 children would be required to detect this effect size in the study population with a 5% alpha error and 80% power. Adjusting for 15% attrition among the selected study subjects during the period of observation, an effective sample size of 752 children would suffice. Sample size considered for analysis eventually constituted randomly selected 734 Severe Malnourished Children (SMC) in the 6–60 months age group from the usual resident population of these 14 villages. Microsoft Excel 2007 and Epi-info (2015 version 7.1.5.2) were used for data analysis.

Inclusion criteria were all SMC (SAM and SUW), whose parents were willing to participate in the study. Complicated SMC (SAM and SUW) were referred to a hospital; however, those who refused hospitalization were enrolled after taking high-risk consent. Parents of SMC and all U5 children were beneficiaries for intensive BCC during the study period.

The study team comprised of one VHW per village (around 1000 population), three medical supervisors, two BCC supervisors, one LTF supervisor with five tribal women, and a Project manager.

3.1. *Selection and training of VHWs*

Semi-literate, local, tribal, married, socially sensitive women were selected as VHW from each village through Gramsabha (village meetings) for better community acceptance after the test. VHWs are trained for four days each in the first two months. The refresher training of two days was done every two months till the end of enrolment.

3.2. *Baseline data collection*

Prevalence of severe malnutrition was determined before enrolment. The data regarding demographic and socioeconomic characteristics were used from a previous survey done by MAHAN in 2009–2010.

Anthropometry of all children between 6 to 60 months age was recorded monthly by VHWs. Weight record was done by standardized digital weighing machines calibrated to 5 g and height/length was recorded by standardized stadiometers/infantometers calibrated to 0.5 cm. Gradation of malnutrition was done by customized software MAHAN-soft, version 1.0, 2011. Trained medical supervisors cross-checked anthropometry of SMC in the field and prepared final list for enrollment. All SMC were screened for appetite test as per WHO guidelines.[17,24] Those who passed appetite test were enrolled for 90 days LTF-MN therapy after informed written consent was obtained.

Children were screened for medical complications (fever, diarrhea, ARI, malaria, otitis media, lethargy, edema, etc.) by VHWs and medical supervisors. The children having any serious illness or those who failed appetite test were referred to a hospital. Those who refused hospitalization were managed by VHWs after high-risk written consent was obtained.

3.3. *Appetite test*

The appetite test was conducted by a locally prepared appetite testing food, offered to the child in appropriate amount (Annexure-2) as per WHO guidelines[17,24] after making the child comfortable. 100% consumption indicates passing, >50% consumption indicates moderate appetite, and <50% consumption indicates failure in the appetite test.

3.4. *Preparation and feeding of LTF-MN*

LTF is designed as per WHO norms.[17,24] Special attention is paid to sociocultural acceptance and palatability. It is prepared from local produce by local tribal women in the form of seven palatable dishes. Three dishes are similar to the food consumed during meals (Mungdal khichri, Ground nut–Sago khichri, and Bhajni Thalipith/Upama) and remaining four are like snacks (Chivada, Ground nut–Gul Patti, Daliya Poha, and Daliya–Tilli–Groundnut Chikki). Each 100 gm packet of LTF (Annexure-3) provides 500–550 calories and around 14–17 g proteins.[17] Quality control of LTF is done by random checking for hygiene, accuracy of weight of ingredients, and daily taste register. External quality control was done by district FDA initially. Deficit micronutrients in 100 g LTF was calculated. As per WHO guidelines, micronutrient (MAHANVitMin mix) powder is developed by a pharmaceutical company.

Each participant was fed with LTF-MN, four times a day, under direct supervision of VHWs for 90 days. Appropriate amount (Annexure-4) of LTF provided 4–6 g proteins/kg/day and 175 kcal/kg/day with gradual escalation. Five grams MN was given with 100 g of LTF. Except breastfeeding, no other food was advised during the therapy. VHWs ensured hand wash with soap and nail cutting before feeding, and hygiene of the feeding center. Though shelf life of LTF was four weeks, weekly production and supply was maintained.

Complicated SMC are initially fed with locally prepared F 100 followed by LTF-MN therapy for 90 days.[17] One gram MN powder is given with 100 ml F100.

3.5. *Medications*

SAM children received oral amoxicillin 30–50 mg/kg/day initially for 7 days. SUW children, not gaining weight after two weeks, received Amoxicillin. SMC received single dose of folic acid 5 mg and two doses of Albendazole fortnightly. Measles vaccination and six-monthly Vitamin-A administration were ensured through National Programs. VHWs treated complicated SMC and infections (ARI, skin infections, UTI, otitis media, etc.) during therapy with Amoxicillin for 7 days and Norfloxacin with half strength ORS (WHO) for diarrheal diseases. Paracetamol was given for fever (Annexure-5).

3.6. *Behavior change communication (BCC)*

BCC of parents was done for hand washing, nail cutting, hygiene, and nutrition through counseling, flipcharts, audio-visual aids, demonstrations, and street plays.

3.7. *Operational definitions*

1. Recovery: Improvement of SMC (SAM or/and SUW) from severe malnutrition to moderate or normal category.
2. Relapse: Reconversion of recovered SMC to SMC.
3. Episodes of infections: Minimum interval between two episodes of fever, diarrhea, or ARI was considered as

7 consecutive days.[25–27] Fever was considered if temperature was ≥99.5 °F.[28]
4. Dropouts: Children who left the study halfway and did not return.
5. Defaulters: Irregular/absent children for >3 weeks till first 8 weeks, >4 weeks till 10 weeks, and >5 weeks till 12 weeks.
6. Re-feeding diarrhea: Passing loose stools without blood or mucous after feeding LTF due to gastrocolic reflex, not associated with dehydration or weight loss.

3.8. *Outcome indicators*

1. Prevalence of severe malnutrition;
2. Rate of recovery;
3. Case fatality rate (Annexure-6).

4. Results

Socioeconomic and demographic salient features of population of study area (Annexure-7) are the following: 91% of the U5 children are tribal, 47% mothers are illiterate, and only 2.5% mothers are educated above 11th standard. 99.6% of the targeted intervention population defecates in open fields and 93% households of 6–60 months population use firewood cooking.

Table 1 shows that out of total 734 SMC, 26.4% (194) are SAM, 94.3% (692) are SUW, and 20.7% (152) are SAM + SUW. Male:female ratio is 1.1; majority of SAM (69.1%) is seen in 6–24 months age group while majority of SUW (65.3%) is seen in 25–60 months age group. 61.8% Children in 6–24 months age group are SAM + SUW.

Birth weight data, taken from another ongoing study, "Home Based Child Care", show that 39.9% SAM children have LBW and >90% of them have intrauterine growth retardation (IUGR). 44% SUW children have LBW and >91% have IUGR. There are 134 complicated SMC. Complications included negative appetite test, fever, edema feet, diarrhea, pneumonia, and otitis media in 43.3%, 20.9%, 8.2%, 3.7%, 3%, and 3% cases, respectively.

Fig. 1 and Table 2 show recovery rate of SAM children is 75.9%, 77.8%, and 79.4% at the end of 8th, 10th, and 12th weeks, respectively; for SUW children, recovery rate is 37.5%, 42.7%, and 45.4%, respectively; for SAM + SUW children, recovery rate is 33.1%, 33.1%, and 35.8%, respectively. Dropout rate of SAM children is 5.7%, 12.9%, and 13.7% at the end of 8th, 10th, and 12th weeks, respectively; for SUW children, dropout rate is 7.4%, 8%, and 13%, respectively. Defaulter rate of SAM children is 6.7%, 0.6%, and 0%, and for SUW children, it is 5.5%, 1.2%, and 0.7% at the end of 8th, 9th to 10th, and 11th to 12th weeks, respectively.

The case fatality rate (CFR) during therapy for SAM children is 0.6% at the end of 8 weeks and for SUW children is 0.2%. There was no death in any group after 8 weeks. Only one child died during LTF-MN therapy who was categorized as SAM as well as SUW at the time of enrolment. The child died due to persistent diarrhea.

Rate of weight gain in recovered SMC in g/kg/d for SAM children is 3.2, 2.8, and 2.6 at the end of 8th, 10th, and 12th weeks, respectively; for SUW, it is 2.6, 2.3, and 1.9, respectively.

Table 1 – Characteristics of study participants for LTF-MN therapy.

	Total SAM		Total SUW		SAM + SUW		Total SMC	
	No.	%	No.	%	No.	%	No.	%
Distribution of severe malnutrition[a] (N = 734)	194	26.4	692	94.3	152	20.7	734	100
Gender								
Males	109	56.2	369	53.3	89	58.6	389	53.0
Females	85	43.8	323	46.7	63	41.4	345	47.0
6–24 months	131	69.1	240	34.7	94	61.8	277	37.7
LBW (<2.5 kg)	43	38.7	106	52.7	37	45.1	112	48.7
Full-term LBW/IUGR (N = total LBW)	40	93.0	94	88.7	34	91.9	100	89.3
Preterm LBW	3	7.0	12	11.3	3	8.1	12	10.7
Birth weight not recorded[b]	20	15.3	39	16.3	12	12.8	47	17.0
25–60 months	63	30.9	452	65.3	58	38.2	457	62.3
LBW (<2.5 kg)	22	42.3	148	39.5	21	43.8	149	39.3
Full-term LBW/IUGR (N = total LBW)	20	90.9	139	93.9	19	90.5	140	94.0
Preterm LBW	2	9.1	9	6.1	2	9.5	9	6.0
Birth weight not recorded[b]	11	17.5	77	17.0	10	17.2	78	17.1
Complicated SMC at enrolment[c]	23	11.9	96	13.9	26	27.6	134	18.3
Appetite test fail	15	65.2	55	57.3	13	50.0	58	43.3
Diarrhea	2	8.7	11	11.5	2	7.7	11	8.2
Pneumonia	2	8.7	3	3.1	1	3.8	4	3.0
Otitis media	2	8.7	4	4.2	2	7.7	4	3.0
Fever	4	17.4	25	26.0	2	7.7	28	20.9
Odema feet	2	8.7	5	5.2	2	7.7	5	3.7
Any other serious illness	1	4.3	5	5.2	10	38.5	42	31.3

[a] A child may be in more than one type of severe malnutrition.
[b] These children were delivered by TBA at home who did not record birth weight in absence of VHW.
[c] Complicated severe malnutrition is presence of edema feet, negative appetite test, or any illness.

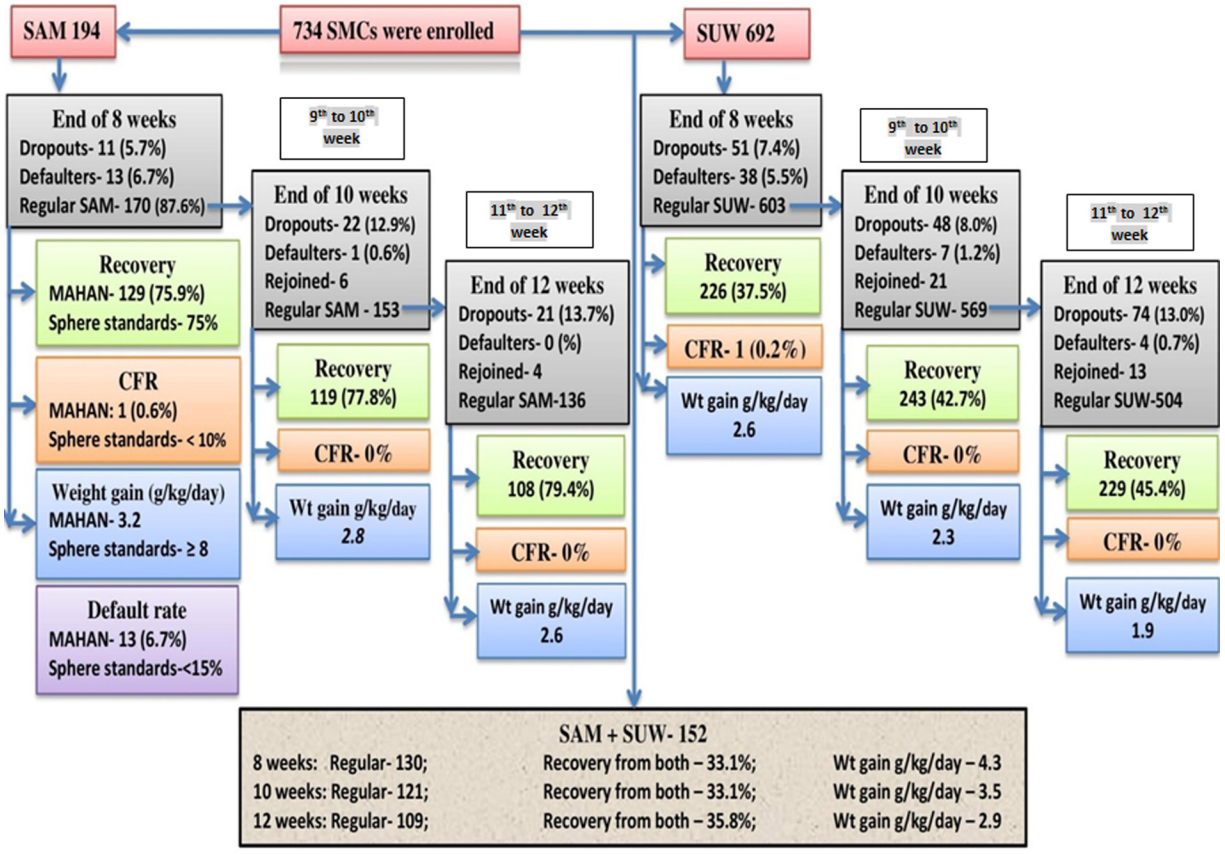

Fig. 1 – Results showing recovery rate, case fatality rate, default rate, dropouts, and weight gain (g/kg/day) of SAM, SUW, and SAM + SUW children at the end of 8th, 9th to 10th, and 11th to 12th weeks.

For SAM + SUW, weight gain is 4.3, 3.5, and 2.9 g/kg/d after the 8th, 10th, and 12th weeks, respectively. Re-feeding diarrhea is found in 10 (1.4%) children out of 734 SMC.

Relapse rate in recovered SAM children is 7.5% and 6.5%; in SUW children, it is 33.3% and 33.3%; in SAM + SUW children, it is 37.8% and 30.9% at 6 months and 12 months, respectively (Annexure-8). Out of 135 recovered SAM children, 15 were lost to follow-up at the end of 6 months; of these, 7 temporarily migrated and rejoined another cycle of LTF-MN therapy after a few months; 8 children crossed the age of 60 months and 9(7.5%) relapsed out of 120 SAM children. 4 relapsed children recovered automatically, 1 migrated, and 4 remained relapsed at the end of 12 months. 27 SAM children were lost to follow-up at the end of 12 months, of which 12 children temporarily migrated who returned to villages after a few months. 15 children crossed the age limit of 60 months. Thus, out of 108 SAMs, 7(6.5%) relapsed, of which 4 had already relapsed at the end of 6 months and 3 were newly relapsed children.

Out of 280 recovered SUW children, 46 were lost to follow-up at the end of 6 months; of these, 12 temporarily migrated

Table 2 – Recovery rate and case fatality rate in SAM, SUW, and SAM + SUW children.

	Total enrolled SMCs (N = 734)									
	SAM (194)				SUW (692)			SAM + SUW (152)		
	End of 8 weeks		End of 10 weeks	End of 12 weeks	End of 8 weeks	End of 10 weeks	End of 12 weeks	End of 8 weeks	End of 10 weeks	End of 12 weeks
	MAHAN	Sphere standard								
Regular	170		153	136	603	569	504	130	121	109
Recovery	129		119	108	223	243	229	43	40	39
Recovery %	75.9	75	77.8	79.4	37.5	42.7	45.4	33.1	33.1	35.5
Case fatality rate (CFR)	1		0	0	1	0	0	–	–	–
CFR %	0.6	<10	0	0	0.2	0	0	–	–	–

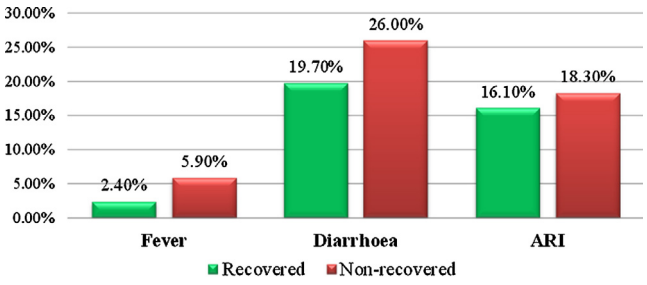

Fig. 2 – Episodes of fever, diarrhea, and ARI during therapy in SMC.

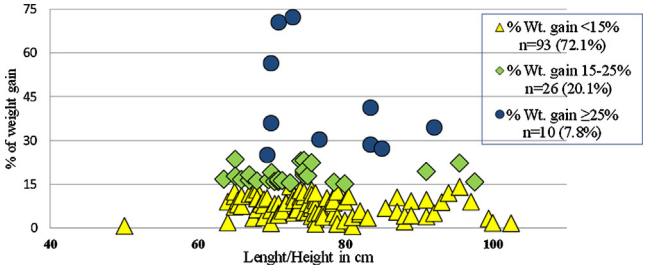

Fig. 3 – Percentage of weight gain in recovered SAM children at the end of 8 weeks (N = 129).

and rejoined another cycle of therapy, 34 children crossed the age of 60 months, and 78(33.3%) relapsed out of 234 SUW children. 31 relapsed children recovered automatically, 2 migrated, 10 crossed the age of 60 months, and 35 remained relapsed at the end of 12 months. 67 SUW children were lost to follow-up at the end of 12 months, of which 15 temporarily migrated who returned to villages. 52 crossed the age limit of 60months. Thus, out of 213 SUWs, 71(33.3%) relapsed, of which 35 had already relapsed at the end of 6 months and 36 were newly relapsed children.

Fig. 2 shows episodes of fever, diarrhea, and ARI in recovered and nonrecovered SMC. Nonrecovered children had more episodes of infections.

Fig. 3 shows the percentage weight gain in 129 recovered SAM children after eight weeks. Up to 15% weight gain is seen in 93(72.1%) children, 15–25% weight gain is seen in 26 (20.1%) children, and >25% weight gain is seen in 10 (7.8%) children.

Fig. 4 shows that the prevalence of SAM in 2012 was 6.4, and in 2015 it is 3.6. Prevalence of SUW in 2012 was 19.54, and 13.13 in 2015, indicating statistically significant reduction in prevalence of SAM (p-value 0.00497) and highly significant reduction in SUW (p-value 0.000125). Prevalence of SAM increased to 6.5, and SUW increased to 17.4 after withholding the interventions for one year (2016). This shows the efficacy of our LTF-MN therapy model. This increase was due to addition of new cases and relapsed children of severe malnutrition.

5. Discussion

U5 children in tribal India are chronically undernourished and have high mortality. Geographic location, prevailing sociocultural practices, low health-seeking behavior, and limited health infrastructure have aggravated the problem. Most interventions address the treatment of acute malnutrition (SAM) and indicate preventive strategies for acute-on-chronic malnutrition (SUW).[9,22,29,30] Facility-based treatment of acute malnutrition has very limited coverage and more cost.[31] Guidelines for therapy of chronic malnutrition are unavailable. In this study, we have assessed efficacy of LTF-MN therapy in acute (SAM) and acute-on-chronic (SUW) malnutrition.

In our study, vast majority of SAM (69.1%) is seen in 6–24 months, while vast majority of SUW (65.3%) is seen in the 25–60 months age group. This implies that faulty weaning with inappropriate and inadequate nutrition causes acute malnutrition in early age, with continuation of inadequate nutrition in the later age group; common occurrence of improperly treated infections lead to acute-on-chronic malnutrition.

LTF is prepared from local produce in a socioculturally accepted way by local women in the form of various palatable dishes. It builds confidence in the local community that severely malnourished children (SMC) can be treated with their own food. All LTF recipes are processed by roasting or puffing to remove inhibitory factors and breaking peptide bonds of amino acids, making it easily digestible. Since LTF is not water based, the risk of bacterial growth is limited, and consequently it is safe to use without refrigeration at

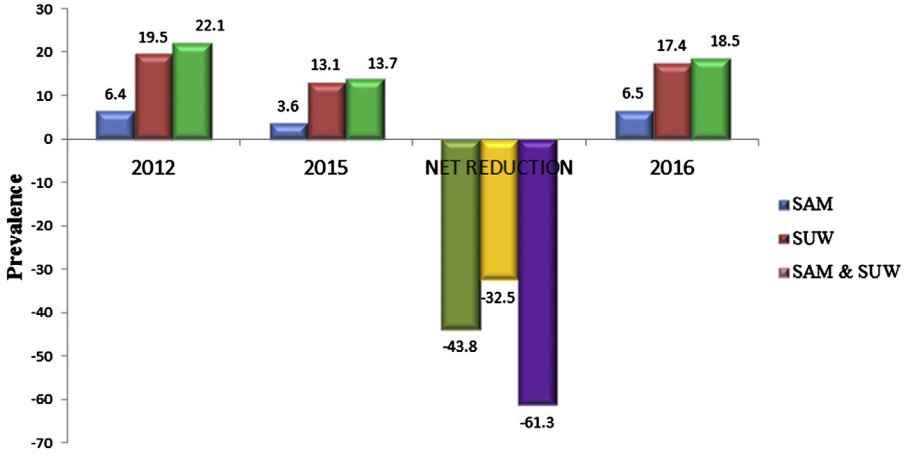

Fig. 4 – Prevalence of SAM and SUW before (2012), after (2015), and one year after (2016) completion of the study.

household level. Preservatives or food colors are not added and no allergic reactions are noticed. LTF is cost-effective and the child can be treated in much cheaper cost than other available industrial RUTF prepared dishes.[17,32] Micronutrients supplementation corrected the deficiencies associated with severe malnutrition, which helped in nutritional recovery.[33,34]

LTF-MN is fed under direct supervision of VHWs ensuring its consumption by malnourished children only and not by other family members. Hygiene of feeding center reduced the risk of infections. Early identification, with appropriate and timely treatment of infections during therapy by VHWs under supervision of medical supervisors, helped in quick recovery, reducing risk of mortality significantly. BCC helps in creating awareness of parents regarding hygiene, preparation of nutritious recipes from local produce in a culturally acceptable way. After therapy, children fed with nutritious food at home prevent recurrence of malnutrition and relapse helping in sustaining normal growth of the child.

6. Limitations of the study

1) Weekly anthropometry was not feasible ethically in control area; hence, RCT could not be done.
2) All SMC were not screened for TB at the time of enrolment.
3) VHWs made mistakes in length/height measurement and hence length/height was confirmed by supervisors.

Our study has shown that trained semi-literate VHWs under proper supervision can manage severe malnutrition at community level. Our SAM recovery rate (75.9%) at the end of 8 weeks is more than international sphere standards (75%). At present, there are no initiative/guidelines for treatment of SUWs. Our results show that SUWs are treatable and have progressively increasing recovery rate with increase in duration of therapy. However, duration of therapy needs to be determined with further research for better recovery rate and lower relapse rate. Dropout rate, CFR, and Defaulter rates of our study are also much less than acceptable limits of WHO and international sphere standards.

There is significant reduction in prevalence of SAM and SUW before and after the study period of 3years in our study area. This shows efficacy of LTF-MN and effectiveness of our model.

This model is affordable, safe, measurable, cost-effective, educative, socioculturally acceptable, is approachable by community, feasible with locally available resources, and sustainable; hence, it is replicable.

The community-based intervention study was done by MAHAN (Meditation-Aids-Heath-Addiction-Nutrition) through village health workers (VHWs). The study was approved by Institutional Ethics Committee of MAHAN and is registered under Protocol Registration and Results System (PRS) (ClinicalTrials.gov ID: NCT02671786).

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Conflicts of interest

The authors have none to declare.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.cegh.2016.11.003.

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