

CompPAS trial in South Sudan and Kenya: Headline findings and experiences

By Bethany Marron, Pamela Onyo, Eunice N Musyoki, Susan Were Adongo and Jeanette Bailey



Bethany Marron is a nutrition advisor and former CompPAS Research Coordinator at the International Rescue Committee (IRC), where she provides global technical support to nutrition programmes and leads work on the integration of nutrition into integrated community case management.



Pamela Onyo is a nutritionist and former Action Against Hunger (AAH) Research Coordinator for the CompPAS trial in Aweil East, South Sudan.



Eunice N Musyoki is a nutritionist and former IRC Research Manager for the CompPAS trial in Nairobi, Kenya.



Susan Were Adongo is a nutritionist and former IRC Nutrition Research Officer for the CompPAS trial in Nairobi, Kenya.



Jeanette Bailey is the Senior Advisor for Nutrition Research and Thought Leadership at the IRC, principal investigator for the CompPAS trial and a PhD candidate at the London School of Hygiene and Tropical Medicine.

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Location: *South Sudan and Kenya*

What we know: Acute malnutrition is a continuum condition, yet severe acute malnutrition (SAM) and moderate acute malnutrition (MAM) are treated separately, which creates logistical, human resource and cost inefficiencies.

What this article adds: The Combined Protocol for Acute Malnutrition Study (CompPAS) aims to test a simplified, combined approach to treat uncomplicated SAM and MAM with one protocol through the community-based management of acute malnutrition (CMAM) delivery model. Stage 1 research generated a simplified dosage protocol based on mid-upper arm circumference (MUAC) only. Stage 2 (cluster-randomised non-inferiority trial) tested the effectiveness of the combined protocol compared to national protocols in Kenya and South Sudan; results are pending publication. Operational insights from trial implementation include significant supply chain challenges (particularly in procuring ready-to-use supplementary food); benefits for health facility staff in efficiently delivering treatment; and appreciation by caregivers. While MUAC-only programming remains a concern, one third of weight-for-height indices were inaccurately calculated by facility staff. Operational pilots of the combined, simplified protocol are planned in Chad and Mali to investigate outstanding questions about programme cost and coverage, supply chain and considerations for implementing at scale.

Overview

Acute malnutrition is a continuum condition, yet severe acute malnutrition (SAM) and moderate acute malnutrition (MAM) are treated separately with different protocols, at times from independent geographical locations, and using different therapeutic products managed by separate United Nations agencies. Although children with MAM are three times more likely to die than well-nourished children, many nutrition programmes manage to provide treatment for the most severe form of malnutrition only (Black *et al*, 2008). The current division of malnutrition and its treatment has, in practice, created logistical, human resource and cost inefficiencies that threaten the continuity of care. Children require transition between protocols and treatment products. The scarcity of resources limits the availability of treatment for moderately malnourished children who are at risk of death and deterioration but may be deprioritised.

The Combined Protocol for Acute Malnutrition Study (CompPAS) aims to test a simplified, combined approach to treat uncomplicated SAM and MAM with one protocol through the community-based management of acute malnutrition (CMAM) delivery model. The aim is to improve global coverage, quality, continuity of care and cost-effectiveness of treatment. A previous article, summarised below, and pending peer-reviewed publication of CompPAS trial results, hypothesise that a single ther-

apeutic food product, provided at doses tested to optimise growth and using mid-upper arm circumference (MUAC) as the sole entry criterion, is a non-inferior, cost-effective approach compared to current national protocols to recover children with acute malnutrition.

Evidence that a simplified, integrated SAM/MAM protocol is comparable to the current approach to treat acute malnutrition could empower health systems to treat more children earlier in their episode of malnutrition, improve the continuity of care between SAM and MAM by eliminating the need for separate products and resources, simplify current procedures for health workers and caregivers, and demonstrate a programme model which can be more easily and efficiently scaled in access-constrained settings.

This article shares a summary of Stage 1 results, an overview of the Stage 2 CompPAS field trial in Kenya and South Sudan, and operational insights from implementing the field study.

Stage 1 CompPAS

Stage 1 of CompPAS, published in *Field Exchange* in 2016 (Bailey, Chase *et al*, 2016), retrospectively analysed treatment data from 8,233 acutely malnourished children between the ages of 6 and 59 months across five countries in order to observe their response to treatment and make recommendations for an optimised dose of ready-to-use therapeutic food (RUTF) correlated

with MUAC category. The study found that growth trends in MUAC and weight change mirrored each other and slowed as children progressed toward recovery, indicating MUAC status is an appropriate proxy for growth. Stage one assessed energy requirements to recovery from acute malnutrition and found that 1,000 kcal/day covers energy needs for children with a MUAC <12.5cm. An expert committee developed a simplified MUAC-based dosing chart to treat all children age 6-59 months with MUAC <12.5cm and/or oedema (+/+++). The resulting combined protocol admits and treats children with MUAC <11.5cm and/or oedema using two sachets of RUTF/day (1,000 kcal) and children with MUAC 11.5cm- <12.5cm using one sachet of RUTF/day (500 kcal).

Stage 2 CompAS

Stage 2 of CompAS tested the effectiveness of the combined protocol compared to the current national treatment protocol (standard protocol) for SAM and MAM in Kenya and South Sudan. It also evaluated cost-effectiveness. The study was a cluster-randomised non-inferiority trial conducted in 12 health facilities in Nairobi County, Kenya and 12 health facilities in Aweil East, South Sudan. Children age 6-59 months presenting at any of the 24 health facility clusters with a MUAC <12.5cm and/or oedema (+/+++) and no medical complications were eligible for enrolment. Randomisation of health facilities was stratified by country. Children admitted to combined-protocol health facilities received RUTF according to their MUAC and/or oedema status; children admitted to standard-protocol health facilities received RUTF in the outpatient therapeutic programme (OTP) to treat SAM or ready-to-use supplementary food (RUSF) in the supplementary feeding programme (SFP) to treat MAM. From May 8 2017 to August 31 2018, a total of 2,071 children were treated in

12 combined-protocol clinics and 2,039 in 12 standard protocol clinics.

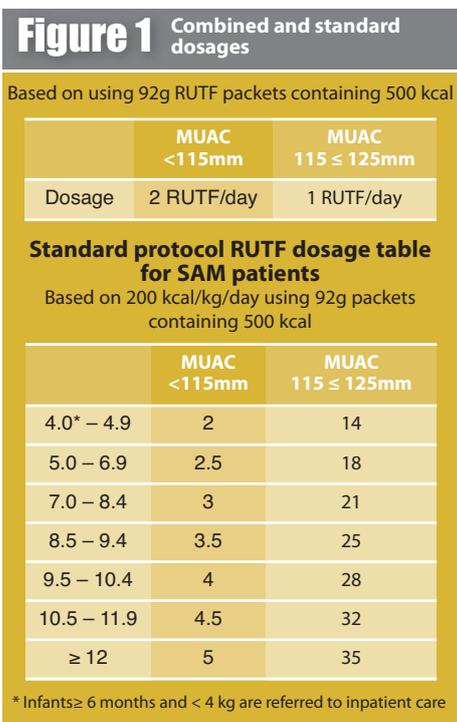
Children were treated until cured or otherwise discharged from the treatment programme according to the criteria in Table 2.

The primary outcome for analysis was recovery (cured). Secondary outcomes included non-response (16 total weeks in any treatment without achieving recovery), default, referral out of the treatment programme, and death. Length of stay, average daily weight gain (g/kg/day), and average daily MUAC gain (mm/day) for children who achieved recovery were also compared. A full description of the methods for this trial was published in BMC Trials on 24 April 2018 (Bailey, Lelijveld *et al*, 2018). The detailed final analysis is currently under review for peer-reviewed publication.

Experiences from CompAS implementation

In addition to the pending field trial results, the study offers valuable insight on implementing CMAM in Kenya and South Sudan. International Rescue Committee (IRC) and Action Against Hunger (AAH) applied the 'gold standard' for treatment (RUTF and RUSF) in all standard protocol health facilities; equipped all health facilities with additional staff, supervision and training; and ensured uninterrupted supply of RUTF and/or RUSF during the implementation period. However, the study faced several operational challenges. High defaulting and frequent missed visits persisted across both study arms. The rainy season in South Sudan, a national nurse's strike and two national elections in Kenya disrupted access to health facilities and increased opportunity costs for caregivers. In Nairobi in particular, urban employment often took priority over attending follow-up visits. These and additional contextual factors will be discussed in the final peer-reviewed publication.

This article focuses on observations specific to implementing the new simplified, combined protocol which are most operationally relevant to strengthening the continuum of acute malnutrition treatment. The combined protocol was implemented by health workers with support from the Ministry of Health (MoH) and IRC in



six health facilities in Nairobi County, and in six health facilities in Aweil East with support from AAH for the study period. During the implementation, IRC and AAH programme and research teams gained key insight on how the combined protocol was operationalised from set-up to close-out. This included challenges and/or barriers to uptake and adherence by health workers and caregivers, and general impressions and preferences by all stakeholders of the protocol at the health facilities during implementation. Key lessons learned were as follows.

Supply chain

From the outset of the trial, study operations in Kenya and South Sudan were directly impacted by supply chain obstacles inherent in the current system of separate SAM and MAM treatment programmes. Global shortages of RUSF in late 2016 through early 2017 delayed the start of the trial by several months. Despite utilising a global tender process, IRC was unable to source a buffer stock of RUSF to support standard-protocol research sites from any supplier or partner. Of the organisations approached for help, few had supply

Table 1 Combined (Intervention) and standard (Control) treatment protocols

Combined Protocol (Intervention)	Standard Protocol (Control)
MUAC < 115mm and/or oedema (+/+++): • Weekly treatment • Routine medical treatment as recommended for OTP patients • 2 sachets RUTF (1,000 kcal) / day	SAM (MUAC <115mm and/or WHZ <-3 and/or oedema +/+++): • Weekly treatment • Routine medical treatment as recommended for OTP patients • RUTF 200kcal / kg / day (according to chart)
Transition: 2 consecutive weekly measurements ≥115mm AND no oedema	Transition: 2 consecutive weekly ≥115mm and/or WHZ >-3 and no oedema
MUAC 115 ≤ 125mm: • Biweekly treatment • 1 sachet RUTF (500 kcal) / day	MAM (MUAC 115<125mm and/or WHZ <-2 to >-3): • Biweekly treatment • RUSF 500kcal/ day (1 sachet)

Table 2 Combined (Intervention) and standard (Control) discharge criteria

	Combined Protocol (intervention)	Standard Protocol (control)	
		OTP	SFP
Cured	MUAC ≥125mm for 2 consecutive measurements and no oedema	MUAC >115mm AND/OR WHZ >-3 z-score AND no oedema for two consecutive visits	Child maintains WHZ >-2 z-score AND/OR MUAC ≥125mm for a period of two consecutive weights/measurements
Non-response	Has not achieved discharge criteria within 16 weeks		
Default	Absent for 3 consecutive visits		
Referred	Any child who develops medical complications and/or is not responding to treatment will be referred for a medical evaluation and/or to the stabilisation centre		
Death	Child died while receiving treatment		



Caregiver interview, Nairobi, Kenya, 2018

official or on-the-job training and are expected to implement CMAM in addition to their regular responsibilities (if they are not nutritionists).

Although weight and height were taken and recorded for inclusion in the study database, the combined protocol is a MUAC-only programme. As such, health workers acknowledged the time-saving potential of eliminating weight-for-height z-score (WHZ) as an admission and discharge criteria. While MUAC-only programming remains an issue of concern in the global community due to its inability to identify the same population of malnourished children as WHZ, the implication of using WHZ as an indicator is an interesting finding from this study. Preliminary analysis using statistical software to recalculate WHZ scores indicates that more than a third of all reported WHZ scores were calculated incorrectly by health worker staff at admission. Administration of the standard protocol has implications for training, availability and accuracy of anthropometric equipment and job aids such as salter scales, height boards and WHZ charts, and staff availability to take weight and height in a hectic, under-staffed health facility environment. The simplified, combined protocol may eliminate these issues without compromising treatment outcomes.

or they had very limited stock which could not be diverted, even as a stopgap. While severe drought in the Horn of Africa undoubtedly exacerbated normal supply and demand for RUSF in the region, it is also worth noting that IRC procured RUTF during the same time period without issue (due to easier access of RUTF via UNICEF and better global availability). The randomised control trial (RCT) protocol to run both standard and combined treatment protocols notwithstanding, treatment for acute malnutrition using the combined protocol could have begun several months earlier.

AAH operations in South Sudan also faced delays due to procurement procedures. Unlike IRC, AAH was able to partner with World Food Programme (WFP) in-country to obtain an initial buffer stock of RUSF. However, by the study mid-term, depleting stock necessitated AAH to engage in a complicated pre-approval and tax-exemption process to procure additional RUSF, as well as RUTE. The administrative task of procuring RUTF and RUSF magnified the increased burden that operating separate SAM and MAM treatment programmes and protocols impose on procurement and supply-chain operations.

RUTF and RUSF were never procured at the same time in Kenya or South Sudan, which meant that other programme logistics like transporting supply from a central warehouse in Juba or pre-positioning RUTF or RUSF could not always be streamlined. Rather, duplicate time and costs were incurred to ensure standard-protocol sites received the two products necessary to provide treatment. While it should be noted that IRC and AAH had heavy involvement in procuring, positioning and managing RUTF and RUSF during the study, it is reasonable to believe that ministries of health and/or national partners contracted to manage the supply chain

of RUTF and RUSF would face similar challenges to source and transport multiple treatment products, versus focusing effort on RUTE.

During implementation at the combined-protocol sites in Kenya and South Sudan, other logistical benefits of programming RUTF as the single treatment product were quickly realised by IRC, AAH and MoH health worker staff. Storage and tracking of supply were easier to manage, both because RUTF did not require separate counting from RUSF and because non-health staff could be relied on to support storage, tracking and movement of supply without any supervision to differentiate products. Staff who had pre-study CMAM experience programming with corn-soya blend to treat MAM were especially convinced by the ease of transporting and storing shelf-stable cartons of RUTF to treat MAM.

Implications for health staff time and capacity

The combined protocol was well received by MoH health workers in Kenya and NGO staff in Aweil East in the 12 clinics where it was implemented. The protocol streamlines the infrastructure required to administer treatment by simplifying anthropometric measurement requirements, condensing patient tracking and paperwork, eliminating referral between SAM and MAM treatment programmes, and setting a fixed 2:1 RUTF dosing chart. Health workers found the combined-protocol procedures easier to understand and implement with limited staff assistance and/or lower personal or support staff experience. While the preferred staff structure for CMAM programmes typically includes a nurse or clinician, a nutritionist and community health workers (CHWs), the reality in Kenya, South Sudan and many programmes around the world is that CMAM is run without this team. More often, a few staff receive limited

Due to the short-term nature of the CompAS RCT, health worker staff at combined-protocol sites had also to adhere to MoH requirements on documenting SAM and MAM treatment. However, health clinic staff acknowledged that the simplification and unification of treatment protocols would reduce current time and effort spent on filling out separate patient cards and registers for SAM and MAM children, particularly as they improve or deteriorate between criteria. Also, staff agreed that treatment by a single protocol and product would alleviate the cumbersome process of aggregating individual SAM and MAM patient data for entry into the national DHIS monitoring system.

The simplicity of the combined protocol also empowered CHWs who are relied on to provide significant assistance during CMAM programming in Kenya and South Sudan and, in some instances, improved their communication with caregivers during follow-up visits and community MUAC screening campaigns. The elimination of complex anthropometry and introduction of a 2:1 RUTF dosage chart based on MUAC meant that CHWs could easily and effectively support health facility staff during treatment at the health facility as well as accurately communicate the entire protocol directly to caregivers when visiting their homes. Based on a child's MUAC, CHWs knew if a child was eligible for treatment, the treatment product and quantity of sachets he or she would receive, and the frequency of follow-up visits. Also, as a MUAC-only programme, CHWs were able to assess for acute malnutrition in the community in the exact same way the facility-based staff would assess, diagnose and treat which reduced confusion for caregivers.

Health worker and caregiver experiences

Health workers in the combined-protocol sites reported feeling confident in their ability to diagnose, provide and explain the simpler combined-protocol treatment and felt high satisfaction with the protocol's principle of providing treatment for all acutely malnourished children through to recovery. Particularly among health workers with prior CMAM experience, the vision of combining and simplifying treatment seemed to align with a pre-existing willingness to modify the standard protocol to maximise resources. During pre-study scoping activities, it was observed that few health facilities were able to fully implement the standard protocol due to limited or no supply of RUTF and/or RUSF and lack of anthropometric equipment or trained staff. Given this, several health workers were already applying various methods to triage cases, such as applying their own MUAC cut-offs for admission and discharge, reducing and/or mixing treatment dosage, and holding vulnerable children in OTP SAM treatment instead of discharging to an SFP MAM programme. Particularly where there was limited or no MAM treatment available, health workers retained children in OTP SAM treatment past standard protocol graduation criteria. In addition to their expressed preference for the combined protocol, health workers' instinct in Kenya and South Sudan to adapt the standard protocol even before the ComPAS RCT began suggests that effort to officially simplify and combine treatment would be accepted in similar resource-constrained contexts.

Overall, caregivers had good awareness of the combined-protocol nutrition programme and satisfaction with the combined-protocol treatment. Coverage surveys implemented in Nairobi and Aweil East indicated comparable coverage across the study arms. However, it is difficult to differentiate whether their satisfaction indicates preference for the new protocol or their general appreciation of consistent availability of treatment due to the programmatic support provided by IRC and AAH. Similar to the standard protocol, the combined protocol stipulates that children admitted with a MUAC <11.5cm attend weekly follow-up visits to allow closer monitoring of progress, but can graduate to bi-weekly follow-up once their MUAC reaches ≥ 11.5 mm. Notably, caregivers in Kenya and South Sudan preferred less frequent follow-up visits and valued the biweekly transition in alignment with the standard protocol.

Conclusions

A simplified, combined approach to treat SAM and MAM has great potential to ensure that resources are optimised, more children are reached with treatment, continuity of care between SAM and MAM treatment is improved, and health systems are able to treat MAM children before they deteriorate into SAM. While operationalisation at the health-facility level would require a shift from current protocol, benefits like those observed in Kenya and South Sudan may be immediately realised:

- A combined, simplified protocol eliminates the need for multiple treatment products,

easing procurement, logistics and stock management procedures.

- A combined treatment programme reduces the administrative burden of implementing and documenting two programmes, both from the individual patient perspective and from aggregating health data for reporting.
- A MUAC-based treatment protocol requires less time and equipment to implement and may enable more health workers to be trained to assist the administration of treatment.
- Health workers prefer a simplified, combined protocol because it is easier to implement and enables them to treat children through recovery.

Ultimately, we envision one programme which can admit any child with a MUAC <125mm and treat through recovery using a lower simplified dosage. This would include direct admissions of MAM cases into the simplified, combined programme. While our hypothesis is that a simplified combined approach will achieve time and cost efficiencies in the larger CMAM system which lead to greater availability of treatment it is important to note that this was not tested in the CompAS trial. Given this and the high level of oversight and support provided by IRC and AAH for this RCT, future research should assess programme performance and health worker and caregiver preferences over time and under routine MoH management. Furthermore, in order for health systems to consider adopting this approach, it will also be important to rigorously evaluate the CompAS hypothesis that a combined, simplified approach achieves time and cost efficiencies in the larger CMAM system that lead to greater availability of treatment and ensure that care of the most vulnerable SAM cases is not compromised. IRC and partners (UNICEF and WFP, funded by ECHO) will conduct operational pilots of the combined, simplified protocol in Chad and Mali with the aim of addressing remaining questions about programme cost and coverage, supply chain, and ways to integrate with other nutrition activities when implementing at scale.

Published results of the Stage 2 CompAS trial will be shared on www.enonline.net/fex as soon as available.

For more information please contact Bethany Marron at bethany.marron@rescue.org



Appetite test at health facility, Nairobi, Kenya, 2018

Natasha Lelijveld

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