Marzia Lazzerini
Humphrey Wanzira
Peter Lochoro
Giovanni Putoto

Improving the quality of care for children with acute malnutrition in Uganda

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About this report

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Marzia Lazzerini
Institute for Maternal and Child Health (IRCCS) Burlo Garofolo

Humphrey Wanzira
IRCCS Burlo Garofolo

Peter Lochoro
Doctors with Africa (CUAMM), Kampala, Uganda

Giovanni Putoto
CUAMM, Kampala, Uganda

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Summary

Arua is one of the districts in Uganda's West Nile region to be hosting a large number of refugees. Most recent estimates indicate that the prevalence of moderate and severe acute malnutrition in children in this region (10.4%) is significantly higher than the national estimates (5.6%).

Official data from 2016 indicate that the average cure rate of malnourished children treated at health centres in the district is around 50 per cent, far below international Sphere standards of 75 per cent, thus suggesting deficiencies in the quality of care. To date, no robust study has explored the effectiveness of supportive supervision in improving health outcomes of children with malnutrition.

This study tests whether supportive supervision can improve outcomes of malnourished children at the outpatient level, together with improving overall quality of care, quality of data and access to care. The study also aims to evaluate the cost-effectiveness of supportive supervision.

This study used a cluster randomised controlled trial with the health centre as the unit of randomisation. The intervention was delivered at health system level (to health centre staff), with the primary outcome (cure rate of malnourished children) measured at population level, amongst children treated in the health centres involved in the study.

Six health centres in Arua with the higher volume of work were randomised to receive either intervention (enhanced supportive supervision) or control (standard of care). Children with malnutrition presenting at health centre level were enrolled, with follow-up for each child at fixed intervals.

The supportive supervision intervention consisted of a high-frequency, peer-to-peer supervision, using the national nutrition guidelines as reference and encouraging networking and community engagement. It occurred in two phases – the first delivering supportive supervision to health centre staff only, and the second extending supportive supervision to community health workers.

The primary outcome was the rate of cured children. Secondary outcomes measured at the individual level included other health outcomes (e.g. non-responders, defaulters, transfer and death), quality of case management (measured by predefined process indicators) and quality of data (measured by pre-defined indicators).

Overall quality of services (assessed using the national nutrition service delivery assessment tool that, based on predefined criteria, evaluates 10 key areas in 4 categories: poor, fair, good or excellent) and access to care (measured by the number of children accessing care) were measured at health centre level.

Categorical variables were presented as absolute numbers and proportions (95% confidence interval [CI]) and compared using the Fisher exact test or Yates corrected chi-square, as appropriate. Continuous variables were compared using the t-test and mean difference. A multivariate logistic regression was conducted to estimate the crude and adjusted odds ratio (95% CI) for the outcome cured or not cured, after correcting for possible imbalance in baseline characteristics. A p-value of less than 5 per cent was considered statistically significant.

A cost-effectiveness analysis compared costs and outcomes of providing supportive supervision versus no intervention, using a provider perspective. Outcome data were obtained from the study, and cost data were obtained from the implementing agency's accounting records. The cost of providing supportive supervision to one health centre (with and without supportive supervision to community health workers) for one year, and the incremental cost-effectiveness ratios per children cured, were calculated.

Overall, 765 children were screened and 737 children were enrolled. All enrolled children were included in the final analysis. Children in the intervention group had a higher frequency of risk factors for negative outcomes.

In the health centres receiving supportive supervision, the cure rate was significantly higher than in the control facilities (83.8% [95% CI: 71.0–96.6] versus 44.9% [95% CI: 38.2–51.6]; mean difference 38.9% [results ratio = 1.91 (95% CI: 1.56–2.34), p = 0.010]). The defaulting rate was significantly lower in the intervention health centres than in the control facilities (1.4% [95% CI: 1.1–1.8%] versus 47.2% [95% CI: 37.3–57.1%]; mean difference 45.8% [results ratio = 0.03 (95% CI: 0.0–0.06), p = 0.001]).

Overall, less than 5 per cent of children had any of the other health outcomes (non-responder, outpatient therapeutic care transfer, in-patient therapeutic care transfer or death), and there were no statistically significant differences amongst allocation groups. After controlling for all baseline characteristics, being in the intervention group was significantly associated with increased odds of being cured (adjusted odds ratio = 7.6 [5.3–10.9], p = 0.001).

The quality of case management did not significantly differ between the two groups for most indicators. Diagnosis, treatment with ready-to-use therapeutic foods, HIV evaluation, counselling and assignment of the exit outcomes were correctly performed in most cases in both groups. On the other side, complementary treatment was correctly assigned only in 58.8 per cent (95% CI: 43.2–74.3) of control facilities, compared with 94 per cent (95% CI: 83.7–100) of intervention facilities (RR = 1.52 [1.40–1.67], p = 0.001).

At baseline, all facilities except one scored either poor or fair in any of the 10 nutrition assessment areas of the national tool, without significant difference between the intervention and control groups. At the end of the study period, both groups had increased the number of areas scoring either good or excellent, with a significant difference between the intervention and control arms (24 / 30 [80%] versus 14 / 30 [46.6%], risk ratio = 1.7 [95% CI: 1.1–2.6], p = 0.015).

After the extension of supportive supervision to the community health workers, there was a significant 38.6 per cent increase (118 children) in the total number of children enrolled in the intervention facilities, compared with the control facilities (p = 0.001).

The cost of providing supportive supervision to one health centre for one year was 1,340 euros with supportive supervision to community health workers (95% CI: 1,139–1,541) and 1,648 euros (95% CI: 1,401–1,895) without supportive supervision to community health workers. The estimated incremental cost-effectiveness ratios were 23.9 euros and 18.3 euros per child cured.

This randomised evaluation shows that supportive supervision as a low-cost intervention is able to significantly improve health outcomes, quality of nutrition care, quality of data and access to care for malnourished children at outpatient level. Given these positive findings, the supportive supervision approach, as proposed in this study, could be scaled up in other districts in Uganda and in other similar settings. Future studies should explore effectiveness and cost-effectiveness of supportive supervision in different settings.

What we already knew about the topic:

- Under-nutrition is a major cause of morbidity and mortality in children under 5 years, especially in low- and middle-income countries. Quality of care delivered to malnourished children has been reported as substandard in several low- and middle-income countries; and
- Supportive supervision has been suggested as a promising intervention to improve the quality of paediatric care, but there is very limited evidence of its impact on health indicators and in children with malnutrition.

What this study adds to what we know about the topic:

- This study shows that supportive supervision is an effective intervention to improve the overall cure rate and quality of care; quality of case management; and access to care of malnourished children, at outpatient level, in a setting with very low resources; and
- These findings contribute to the growing body of evidence from other studies, in similar settings, which suggest supportive supervision as a possible effective intervention to improve the quality of paediatric care and the health status of children.

Contents

List of figures and tables

Abbreviations and acronyms

CHW	Community health worker
CI	Confidence interval
CUAMM	Doctors with Africa
ICER	Incremental cost-effectiveness ratio
IMAM	Integrated management of acute malnutrition
ITC	In-patient therapeutic care
MAM	Moderate acute malnutrition
NSDA	Nutrition service delivery assessment
OTC	Outpatient therapeutic care
RCT	Randomised controlled trial
SAM	Severe acute malnutrition
WHO	World Health Organization
WHOCCMCH	World Health Organization Collaborating Centre for Maternal and Child Health

1. Introduction

1.1 Burden of acute malnutrition in children under 5 years

In low-income countries, especially in Sub-Saharan Africa, under-nutrition and HIV are two of the main causes of morbidity and mortality in children under 5 years (Black et al. 2013; Liu et al. 2015). The two conditions are tightly connected, with children with HIV being at higher risk of under-nutrition and children with under-nutrition being at higher risk of disease progression and mortality when affected by HIV (Black et al. 2013; Rose et al. 2014).

Uganda is no exception, and the Ministry of Health considers both malnutrition and HIV in children as conditions of great public health importance. According to national estimates, malnutrition in childhood is a serious concern: 11.5% of children are born with low birth weight (UNICEF n.d.), 4% of children aged under 5 years suffer from moderate acute malnutrition (MAM) and 1% are diagnosed with severe acute malnutrition (SAM), according to the Uganda Bureau of Statistics (2016).

The Ministry of Health developed national guidelines for integrated management of acute malnutrition (IMAM) in 2006 and updated them in 2011 (Ministry of Health 2016). The IMAM guidelines include the treatment of MAM and SAM, community therapeutic care and aspects of treatment of malnourished HIV/AIDS children and adults.

The point of management of acute malnutrition depends on the classification at the time of diagnosis. Children diagnosed with complicated SAM are admitted to in-patient therapeutic care (ITC). Those diagnosed with SAM without complications and MAM but HIV-positive or exposed are referred to outpatient therapeutic care (OTC). Children with MAM who are HIV-negative are referred to supplementary feeding centres.

There are specific national criteria to classify children in nutritional categories, which include weight-for-height, according to World Health Organization (WHO) growth standards (WHO Multicentre Growth Reference Study Group 2006) and mid-upper arm circumference (Uganda Ministry of Health 2016). Care is provided by the public sector, and access to care is supposed to be free of charge. Beneficiaries of this programme include large segments of the population, possibly the poorest.

1.2 Burden of malnutrition in the West Nile region

The burden of malnutrition is known to be higher in areas experiencing a humanitarian crisis, such as areas of conflict and those receiving refugees. The influx of a large number of individuals into a region with inadequate resources, such as food, quickly leads to food insecurity – and ultimately malnutrition – especially amongst children under 5 years and amongst the refugees (Taylor 2013).

Most of these malnourished children end up at the nearest health facility for treatment, thereby increasing the number of children with malnutrition in the area. This makes health facilities in areas of conflict or with refugees a priority target for interventions aimed at treating malnutrition in children.

Uganda's West Nile region, on the border of the Democratic Republic of Congo and South Sudan, is in a state of humanitarian crisis, hosting refugees fleeing from civil wars in the neighbouring countries (McKinsey and Ringuette 2014). Recent estimates report that there are approximately 175,000 refugees in Arua District (World Vision Uganda 2017), compared with a total overall population of about 780,000.

The West Nile region also has the highest prevalence of MAM and SAM in Uganda (Bureau of Statistics 2016): the prevalence of MAM and SAM in children under 5 years in this area is estimated at 10.4% and 5.6% respectively – significantly higher than the national estimate of 3.6% and 1.3%.

1.3 Quality of care and supportive supervision

The importance of quality of care in service delivery and its potential impact on child and maternal survival is increasingly being recognised in a number of scientific publications (Chopra et al. 2012; Souza et al. 2013; van den Broek and Graham 2009) and policy documents (WHO 2013; WHO Europe 2013).

Recognised underlying causes for poor quality of care include lack of supervision; lack of training, equipment and supplies; lack of organisation; poor staff motivation and satisfaction; and poor satisfaction from users, with high rates defaulting from the programme. Other general causes include poverty, high rates of diseases such as HIV and tuberculosis, and structural deficiencies in the health system (Hoque et al. 2014; Taylor et al. 2014; Testa et al. 2008).

The most common approach for improving the case management of common children's diseases has included the adoption and dissemination of evidence-based guidelines, usually combined with training of staff. However, formal studies and technical assessments have both shown that training alone does not ensure adherence to guidelines and acceptable health outcomes (Ayieko et al. 2011; Gillespie et al. 2015; Huicho et al. 2005).

Supportive supervision has been suggested as a promising intervention for ensuring higher adherence to guidelines in different contexts (Rohde 2006; McAuliffe et al. 2013; National Department of Health [NDoH] 2009). As a technique to improve the quality of healthcare, supportive supervision has been used in different contexts, such as in Bangladesh, India and South Africa, and partly in Uganda (Doctors with Africa [CUAMM] 2013; Hoque et al. 2014; Rohde 2006; NDoH 2009).

1.4 Study justification

We conducted a cluster randomised controlled trial (RCT) to evaluate the impact of high-intensity supportive supervision, specific for nutritional services (enhanced nutritional supportive supervision), as compared with the standard of care. The study was justified by the following observations:

- Ensuring adequate supportive supervision may be one of the effective interventions to improve the quality of care provided by health staff, and therefore the health outcomes of children suffering from malnutrition;
- High-quality evidence, such as that provided by RCTs, on the efficacy of supportive supervision is still extremely scarce (Dettrick et al. 2013; Nair et al.

2014). Similarly, in Uganda, although there is some supportive supervision practised in the country in nutritional services, there is no robust evidence (in the form of a proper study) of its effectiveness. Therefore, this study contributes to the current knowledge gap on whether enhanced nutritional supportive supervision provided by local teams of professionals to health workers in nutritional services can be an effective intervention to improve the quality of care of children with malnutrition;

- Findings of the present study may be relevant locally and internationally. This impact evaluation may contribute to improving the health and well-being of children in low- and middle-income countries. If the intervention proves to be effective, it could be scaled up or translated into other contexts and benefit a larger population; and
- The WHO Collaborating Centre for Maternal and Child Health (WHOCCMCH) and Doctors with Africa (CUAMM) both have experience with supportive supervision. CUAMM Uganda has experience in facilitating supportive supervision in the Karamoja region (CUAMM 2013). The collaborating centre collaborated with WHO and local partners as a primary investigator in a large, cluster RCT in 20 hospitals in Kyrgyzstan, where supportive supervision visits at regular intervals provided by a team of national professionals significantly improved key outcomes of case management and overall quality of care (Lazzerini et al. 2017). These lessons from the field, which used strict research methods, showed that supportive supervision may also improve staff satisfaction and knowledge, and may improve access to care from the population.

Supportive supervision is most effective when health centre staff are well trained in the management of acute malnutrition, if essential equipment and supplies are in place, and if community involvement is present. For this reason, although the main intervention was supportive supervision, we combined it with other complementary interventions aimed at improving training, availability maintenance of essential supplies (e.g. ready-to-use therapeutic foods) and community involvement.

1.5 Study questions

This study's original research questions are presented in Table 1.

Table 1: Original research questions

Original research question:	*Does enhanced nutritional supportive supervision, provided by a team of local professionals, in a regular way with a peer-to-peer model to staff at health centre (including community health workers) in charge of managing malnourished children …*
Primary question	… significantly improve the cured rate (attaining a weight-for-height greater than or equal to –2 standard deviation from the mean based on the WHO 2006 standards or mid-upper arm circumference of greater than or equal to 12.5 centimetres)?
Secondary questions	… significantly reduce: 1. Defaulting rate (absent for two consecutive follow-up visits)? 2. Transfer rate (to ITC if condition has deteriorated and requires in-patient care or not responding to treatment or to OTC as requested by a caregiver)? 3. Death rate (patient died whilst still in the programme)? 4. Non-responders' rate (not reaching discharge criteria after three months or four months for the HIV and tuberculosis patients)? 5. Rate of children progressing to severe acute malnutrition (SAM) after being admitted as moderate acute malnutrition (MAM)? … significantly improve: 1. Quality of health services assessed using the national nutritional service delivery assessment (NSDA) tool? 2. Quality of case management (correct diagnosis, treatment, HIV evaluation, counselling of caregivers and exit health outcomes criteria such as cured, non-responders, defaulters, transfers to ITC and OTC, and died)? 3. Overall access to care (which may reflect patient satisfaction)? Is enhanced supportive supervision a cost-effective intervention compared with standard of care? Are stakeholders satisfied and motivated?

2. Intervention, theory of change and research hypotheses

2.1 Intervention

The intervention was 'enhanced nutritional supportive supervision', which means high-intensity supportive supervision dedicated to the nutritional services. The enhanced nutritional supportive supervision model used in this study combined monitoring, support and complementary activities as shown in Box 1. Beginning in April 2017, supportive supervision was extended to include the village health team workers attached to the intervention facilities, with the objective of improving community screening, case referral and active involvement in tracing defaulters.

All supportive supervision activities used the national IMAM guidelines as the reference standard and used dedicated tools (checklists). This enabled supervisors to provide guidance on the technical aspects of services in a standardised way (i.e. covering a standardised list of key issues).

Box 1: Characteristics of supportive supervision and specific activities

Phase 1: Supportive supervision to health centre staff

A. Characteristics

- Frequency: biweekly in the first three months, then monthly;
- Duration: approximately 2 hours in each health centre at each visit;
- Provider: local staff (nutritionist, District Health Office team) trained in IMAM guidelines and in methods of enhanced nutritional supportive supervision;
- Receivers: staff working at health centre level with children with malnutrition (Phase 1) and community health workers (Phase 2);
- Reference guidelines: current national IMAM guidelines; and
- Attitude and philosophy: participatory peer-to-peer model with open communication between the supervisor and staff members, aimed at listening to staff perspectives, clarifying doubts in relation to how to implement the national guidelines and developing solutions together with a proactive, participatory, 'problem-solving' attitude. The objective was not only to improve staff knowledge and skills, but also to improve staff's confidence and motivation in doing their job. Follow-up on agreed-upon solutions was based on the 'Plan–do–study–act' quality improvement cycle (Taylor et al. 2014).

B. Activities

- Monitoring activities: checking essential equipment and supplies; checking case management against the national guidelines; checking data quality (completeness, accuracy and consistency); and checking health centre staff knowledge and skills;
- Supporting activities: based on the specific deficiencies identified, providing technical support, e.g. on-site refresher training on the national protocols and on data reporting; discussing local problems and conceptualised solutions in a participatory approach with local staff; facilitating good team dynamics; and clarifying issues on case management; and
- Complementary activities: facilitation of networking amongst the staff of different health centres, with the objective of building ownership of the process; and tools for tracing defaulters, e.g. telephone credit and location maps (tracing defaulters is recommended in the national guidelines, but no specific tool is provided to health centre staff). The study protocol also included the delivery of essential key equipment, if needed, but since all key equipment was already available, only regular checks of accuracy of the weighing scales for calibration were performed.

Phase 2: Supportive supervision extended to community health workers

C. Characteristics

- Frequency: every week, a selection of villages associated with the intervention health centres was visited and every worker was involved in supportive supervision at least twice during the project duration. Other characteristics were similar to Phase 1.

D. Activities

- On-site training on the key concepts of the IMAM guidelines;
- Enhanced supervision during work; and
- Provision of a small financial incentive (recommended in the Ugandan guidelines, but not formalised in practice).

2.2 Monitoring the implementation of the intervention

The following procedures were instituted to ensure that the supportive supervision intervention was implemented according to the protocol:

1. Supervised the training of all personnel involved in supportive supervision to ensure that the study procedures, the methods of supportive supervision and the national IMAM were clear. The training included a mix of theoretical and practical sessions by two experienced study researchers and a nutritionist, led by the principal investigator, a paediatrician and an epidemiologist with extensive experience in research and in studies on supportive supervision;
2. A monthly schedule for supportive supervision visits to facilities was developed by the project manager and study coordinator, in collaboration with the study principal investigator, who monitored its implementation;
3. A checklist was developed by the principal investigator and project manager to standardise the supportive supervision visits (list of predefined activities);
4. A robust data quality assurance system was put in place; and
5. Interim analyses were conducted to monitor trends in outcomes over time.

2.3 Study hypothesis and objectives

If regular enhanced nutritional supportive supervision is delivered to staff at health centre level managing malnourished children, together with complementary interventions, **then** the knowledge of staff and practical case management should improve, **and** as a consequence, health outcomes of children accessing the health centre with malnutrition, patient satisfaction and access to care will also improve.

Health centres managing acute malnutrition in Arua District were randomised to either receive the intervention (enhanced nutritional supportive supervision) or continue with the standard of care.

Primary objective:

- Compare the rate of cured children in the two study arms.

Secondary objectives:

- In the two study arms:
  - Compare the rate of defaulters, rate of transfer, rate of deaths, rate of non-responders and rate of children progressing to SAM;
  - Ensure the quality of data;
  - Compare quality of health services using the NSDA tool;
  - Compare quality of case management;
  - Compare overall access to care;
  - Estimate the cost per unit increase of the cure rate in the intervention compared with the control; and
  - Assess stakeholder motivation and satisfaction.

2.4 Theory of change

The process of change includes the use of the following inputs: financial resources from 3ie and WHOCCMCH; human resources from WHOCCMCH, CUAMM and the School of Public Health at Makerere University; technical support from WHOCCMCH; and the research team's time. Such inputs were used for supportive supervision visits delivered regularly to staff at the health centre level, including community health workers (CHWs), plus complementary activities (Box 1).

Evidence uptake was realised through meetings with stakeholders and development of knowledge products (e.g. videos, posters, working papers, policy briefs, media coverage and publications).

Expected outputs include the following: staff have better knowledge, are more satisfied and motivated, leading to improved quality of care; users are more satisfied with the care delivered; the community perceives better quality of care; data quality improves; staff and health authorities have ownership of the intervention and are committed to improving the quality of care; and stakeholders are informed about the study design and study progress and are committed to improving quality of care.

All of the above should result in improving health outcomes of malnourished children treated at health centre level and possibly in increased access to health centres. In the future, this impact evaluation could contribute to improving the overall health and well-being of children in Uganda and in other low- and middle-income countries.

Almost all the above assumptions were met (Table 2), except for those related to the final stakeholders' meeting that was planned for July 2018.

Table 2: Status of theory of change assumptions

Stage	Assumptions	Status
Inputs	• Financial resources (3ie, WHOCCMCH) • Human resources (WHOCCMCH, CUAMM, School of Public Health at Makerere University) • Technical support (WHOCCMCH) • Time (research team)	• All met
Activities	• Supervision visits and other intervention components regularly delivered	• All met
	• Evidence uptake realised through meetings with stakeholders and development of knowledge products (e.g. videos, posters, working papers, policy briefs, media coverage and publications)	• Met (video, local meetings) • Final stakeholder satisfaction to be assessed after at the final stakeholder meeting (July 2018)
Outputs	• Staff have better knowledge and satisfaction • Users and community are more satisfied with the care delivered • Improvement of data quality • Improved quality of service provision • Staff and health authorities have ownership of the intervention and are committed to improving quality of care • Stakeholders are informed about the study design and study progress and are committed to improving quality of care	• Not assessed • Not to be assessed in our protocol • Met • Met • Met • Met
Outcome	• Significantly improved cure rates amongst intervention facilities as compared with the control facilities • Improved access to care at facility level.	• All met

2.5 Actors

Actors involved in the process include the research team (WHOCCMCH), other independent researchers (through CUAMM), the staff at health centre level (nurses, doctors and managers), the users of health centre (mainly mothers with their malnourished children), the whole community in the intervention area, and other stakeholders directly or indirectly involved (e.g. local, regional and national health authorities; UNICEF; and other NGOs and entities providing support to the health sector in different ways, such as supporting drug provision).

3. Context

3.1 Rationale for selection of Arua District

In February 2016, we carried out a baseline assessment, which resulted in the following findings:

- Of the eight districts in this region, Arua District recorded the highest burden of malnutrition (Uganda Bureau of Statistics 2016);
- When reviewing Health Management Information System official data, outcomes for children with malnutrition treated as outpatients at health centre level did not meet international standards (75% of cure rate, according to Sphere standards); the mean recovery rate was around 50 per cent (Wanzira et al. 2018);
- Supportive supervision of these health facilities' nutritional services was limited, with some facilities reporting that they had received none; and
- In the current Ugandan IMAM guidelines, supportive supervision is recommended on a quarterly basis. However, methods are not further detailed, and the guidelines do not include any specific tool to carry out supportive supervision activities (Uganda Ministry of Health 2016). In practice, supportive supervision is not conducted if there are not dedicated funds and supporting partners. Specifically, during our study, only a few activities were conducted. Importantly, no activity was conducted in the intervention group.

4. Evaluation: design, methods and implementation

4.1 Study design

This was a cluster RCT study, with the health centre as the unit of randomisation. Health facilities were selected based on their volume of work. The six health centres with the highest-reported number of children accessing nutrition services (according to official 2016 Health Management Information System data) were included in the study. After stratification by characteristics such as health centre level, setting (urban versus rural) and number of staff assigned to the nutritional unit, the study team randomly allocated health centres by extraction ('urn randomization'; Cochrane 2017) to either supportive supervision or standard care (no intervention). Health centre staff and CHWs were aware of the allocation group, whilst patients were blinded.

4.1.1 Intervention

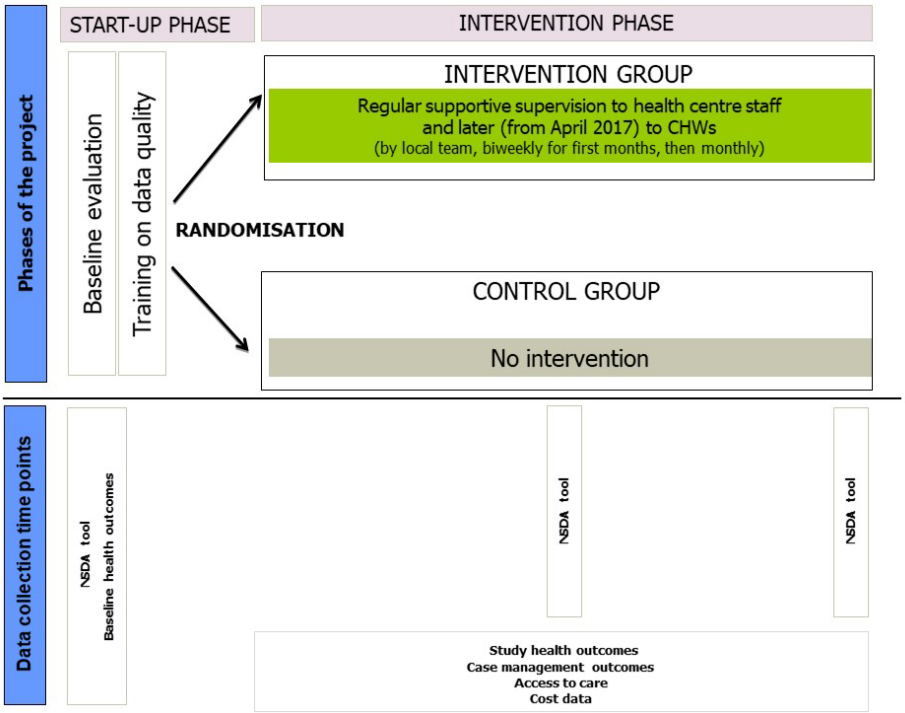
Details of the intervention are explained in Section 2.

4.1.2 Standard of care

No intervention was delivered in the control group, which was therefore considered as standard care. During the study period, there were no other activities in the health centres involved in the study (e.g. training or additional supportive supervision) from any provider that could affect the quality of care.

The randomisation process and key activities in the study are depicted in Figure 1.

Figure 1: Randomisation arms and study key activities



4.2 Study population

For the primary outcome, the study sample consisted of children with malnutrition treated at health centres in Arua District. All children with SAM or MAM presenting in the study health centres were evaluated for inclusion.

Inclusion criteria were based on the national IMAM guidelines, as follows:

- Children 6 months to 5 years;
- Diagnosis of SAM or MAM according to national criteria (Uganda Ministry of Health 2016):
  - SAM – weight-for-height less than –3 standard deviation from the mean based on the WHO 2006 standards (WHO Multicentre Growth Reference Group 2006).
  - MAM – weight-for-height less than –2 and greater than –3 standard deviation from the mean based on the WHO 2006 growth reference standards (WHO Multicentre Growth Reference 2006); and
- Documented HIV status – HIV status definition and testing for HIV-exposed children (the state in which an HIV-negative infant of an HIV-positive mother is still being breastfed and, therefore, still exposed to HIV) following the national testing guidelines, as per the algorithm.

Exclusion criteria:

- Not matching the above criteria for SAM and MAM;
- Refusal to participate or consent; and
- Unable to adhere to study follow-up procedures

4.3 Sample size calculation

The sample size was calculated by taking into account a fixed number of clusters (six health centres), the intra-cluster correlation coefficient, the control event rate, the expected effects, and the level of significance and power of the study (Hemming et al. 2011). The figure of six clusters was arrived at after a thorough consideration of the number of clusters that could give a scientifically sound result with the available funding.

An estimated sample size of 716 children was calculated, based on the assumption that in the intervention health centres, the mean cure rate would have been 85%, compared with 45% in the control health centres, with an intra-cluster correlation coefficient of 0.2, a power of 80% and an alpha of 5%.

4.4 Study variables

The study outcomes are reported in Box 2. The rate of cured amongst the enrolled children (SAM and MAM) was the primary outcome. Each child was followed up with prospectively to assess their primary outcome. All children who defaulted were followed up with to ascertain their living status.

Box 2: Study outcomes

Primary outcome

- Rate of cured children

Secondary outcomes

- *Other health outcomes*
  - Rate of transferred to ITC
  - Rate of transferred to OTC
  - Rate of defaulted
  - Rate of not cured
  - Rate of dead
- *Quality of health services:* Assessed using the NSDA tool, the official national instrument for assessing performance of nutritional service.
- *Quality of case management:* Assessed having the national guidelines as source of reference standards (Uganda Ministry of Health 2016) and using six predefined process indicators: (1) correct diagnosis; (2) correct treatment; (3) correct complementary treatment; (4) correct evaluation of HIV; (5) correct patient counselling; and (6) correct exit outcome assignment.
- *Access to care:* Measured by the crude number of children accessing the nutritional service at the health centre. We explored equity in access to care using a list of predefined patient characteristics associated with wealth.
- *Cost-effectiveness of supportive supervision:*
  - Provider-perspective cost of providing supportive supervision to one health centre; and
  - Incremental cost-effectiveness ratio per child cured.

4.5 Data collection and data entry

During the intervention, data on each of the study outcomes was collected prospectively. Specifically, data on health outcomes, quality of case management and quality of data were collected prospectively for each child enrolled in the study by six trained staff (each assigned to one health centre). The data collectors were stationed at the facilities every day of the entire study duration, with the aim of capturing patient data on a daily basis.

Dedicated data collection tools were pilot tested before use, and standard operating procedures were developed to standardise the data extraction process, directly supervised by a nutritionist. Additionally, all children who defaulted were followed up with to ascertain their living status.

The quality of nutritional services was measured at three points (before the study, at midterm and at the end of the study) using the NSDA tool, the official national instrument for assessing performance of nutritional services (NSDA tool 2015).

The tool assesses 10 key capacity areas of nutrition service relevant at the outpatient level: (1) general information on service implementation; (2) adequate human resources; (3) provision of nutritional services; (4) community linkages; (5) quality improvement activities; (6) materials and supplies; (7) nutrition unit requirements; (8) store management; (9) logistics management for commodities; and (10) monitoring and evaluation.

For each section in the tool, using strict criteria specified in the tool, a final judgment on the quality of the services is made and a final score is assigned in the form of one of four predefined categories: poor, fair, good and excellent. The study team involved in the NSDA assessment included a senior paediatrician, a nutritionist and a public health expert, all experienced in the national nutritional guidelines (Uganda Ministry of Health 2016) and in the use of the NSDA tool.

Access to care was measured by the crude number of children with SAM or MAM accessing the nutritional service at the health centre. To evaluate the additional effectiveness of supportive supervision to CHWs, access to care in the first phase of the study (September 2016–March 2017) – when supportive supervision was delivered only to health centre staff – was compared with access in the second phase (April–December 2017), where supportive supervision was extended to CHWs.

We assumed the total population in the coverage area did not change. Coverage was not estimated, due to the lack of a reliable estimate of the reference population for each health centre. Data on cost were collected from the accounting records of the implementing agency. Stakeholder satisfaction and motivation were assessed at the final stakeholder meeting in July 2018 by dedicated predefined pilot-tested tools.

4.6 Data management and quality control

Strict quality assurance procedures were put in place to ensure accountability of data. Roles and responsibilities were clearly distributed amongst the research team to ensure all activities had a responsible team capable of carrying them out efficiently.

Data were collected using predefined pilot-tested tools. Guidance materials with clear and comprehensive operational instructions on how to collect data (e.g. case definition, inclusion criteria and exclusion criteria) were developed and made available in a user-friendly format. Data collection staff were trained and their knowledge pretested and monitored at fixed intervals throughout the data collection process. Reliability of data collection was tested at subsequent time points.

Data were routinely checked before data entry for completeness and internal consistency. The database for data collection included internal validation rules and queries. Data were collected at fixed intervals and entered in the databases in real time by dedicated staff trained in data entry.

The databases were monitored at fixed intervals for completeness and internal consistency, and any problems (e.g. missing data) were discussed in real time. All efforts were made to achieve data completeness and accuracy within the given deadlines. A random check of data entered was performed in a subsample of the data collection forms. Interim data analysis was performed at fixed intervals and checked by an independent analyst.

4.7 Data analysis

Data was analysed using Stata 14. Categorical variables were presented as absolute numbers and proportions (95% confidence interval [CI]) and compared using the Fisher exact test or Yates corrected chi-square, as appropriate. Continuous variables were compared using the t-test and mean difference.

To assess the effect of possible imbalances in patient characteristics, crude and adjusted odds ratio and 95 per cent CI were estimated by forward fitting logistic regression models. We opted for a logit model, as it is the more frequently used in medicine. The outcome was *cured/not cured*, and the covariates were baseline characteristics – age group, sex, vaccination status, nutritional status and the randomisation arm. Upon request of the funders, we also performed a probit model, using the same variables and calculating marginal effects.

All statistical tests were two-sided. A p-value of less than 0.05 was considered statistically significant. Results were interpreted looking at both the level of statistical significance and the plausibility and consistency of results across different outcomes.

4.8 Cost analysis

With the cost-effectiveness analysis, we aimed to answer the following questions:

1. What is the cost, from a provider perspective, of providing supportive supervision to one health centre (with and without supportive supervision to CHWs) for one year?
2. What are the incremental cost-effectiveness ratios (ICERs) per child cured?

4.8.1 Model parameters

Measurement of effect

The cure rate, as directly derived from the cluster RCT, was the key outcome for this cost-effectiveness analysis. The effect comparison was the difference in cure rate before

supportive supervision, as compared with cure rates during supportive supervision, amongst the three intervention health centres. Details of the assumptions used for calculations of average number of children and estimated number of cured children are summarised in Table 3.

Table 3: Base parameters for the cost-effectiveness analysis and assumptions

Parameter	Estimate	Range	Source
Average number of children treated per health centre per year, Phase 1	110	106–112	RCT results
Average number of children treated per health centre per year, Phase 2	177	169–187	RCT results
Baseline cure rate, %	32.9	14.1–51.6	RCT results
Estimated number of cured children at baseline in Phase 1	54.3	23.3–85.1	RCT results
Estimated number of cured children at baseline in Phase 2	30.9	13.3–48.5	RCT results
During supportive supervision cure rate, %	83.8	71.0–96.6	RCT results
Estimated number of cured children during supportive supervision in Phase 1	78.8	66.7–90.8	RCT results
Estimated number of cured children during supportive supervision in Phase 2	111.0	93.7–127.5	RCT results
Difference in number of cured children in Phase 1 (supportive supervision to health centres only minus baseline)	47.9	42.3–53.5	RCT results
Difference in number of cured children in Phase 2 (supportive supervision extended to CHWs minus baseline)	67	59.4–75.1	RCT results
Start-up costs			
Training of two supervisors	120.0	102.0–138.0	Implementing agency accounts
Training of a coordinator (district nutritionist)	60.0	51.0–69.0	
Training of the health facility staff	136.0	115.6–156.4	
Subtotal costs	316.0	268.6–363.4	
Running costs			
Supportive supervision to the health centre	391.7	333.0–450.5	Implementing agency accounts
Fuel for transportation	60.0	51.0–69.0	
Communication and patient follow-up	206.0	175.1–236.9	
Equipment maintenance	3.7	3.2–4.3	
Printouts	2.8	2.4–3.2	
Networking activities	359.7	305.7–413.7	
Subtotal costs	1024.0	870.4–1177.6	
Supportive supervision to CHWs	308.16	261.9–354.4	Implementing agency accounts
Discount rate per year[1]	3.0%	0–6.0%	Drummond et al. 2005

Assumptions

- Final analysis results indicated that the cure rate significantly rose from 32.9% (95% CI: 14.1–51.6%) before supportive supervision to 83.8% (95% CI: 71.0–96.6%) during supportive supervision, p-value = 0.001;
- The average number of children treated in one health centre per year was calculated as follows: mean number of children enrolled in the experimental group (considering the two

phases separately) in each health centre x time fraction in months out of a year, thus resulting in a) before supportive supervision to CHWs in (165 / 3) x (12 / 6) = 110 children (95% CI: 106–112); b) with supportive supervision to CHWs = (265 / 3) x (12 / 6) = 177 children (95% CI: 169–187);
- The estimated number of cured children was calculated as (average number of children) x (cure rate);
- This analysis included only additional costs of delivering the intervention from a provider perspective;
- The costs of training included the daily allowance (per the local government official daily allowances) and, when appropriate, meals (from local service providers in Arua);
- Cost estimates included a daily allowance to the district nutritionist and CHW members as per the local government guidelines, and fuel for transportation;
- Other healthcare delivery-related costs (e.g. medication, staff remuneration) were not included. Cost of activities that were only study-related (impact evaluation) were not included in this analysis. The following costs were therefore not included: ethical applications, research personnel remuneration, office expenses, verification of data collection tools, data collection and entry, dissemination workshops, and media coverage;
- Costs of developing the supportive supervision tools were not included, as we assumed these were developed at an early stage, at Ministry of Health level, and included in the national guidelines;
- The key outcome evaluated is the primary outcome of the study, i.e. cure rate;
- Following the study aims, costs are calculated per health centre with a time horizon of one year, based on the data provided from the study;
- We assumed that, as in the RCT study, a total of four supportive supervision visits to the health centre's staff were delivered biweekly for the first two months, then monthly for a total of 14 total visits in a year;
- Personnel involved in the supportive supervision visits included two supervisors; costs were calculated based on the Ugandan daily allowance rate; and
- The cost of coordinating the supportive supervisors is not included in the primary analysis, as this is already a duty of the district nutritionist; however, training of the district nutritionist is included under start-up costs.

Note: [1] Discount rate not applied due to the short time duration of the study.

4.8.2 Measurements of costs

Perspective: This was a provider perspective cost-effectiveness analysis, focusing on only the additional cost of delivering supportive supervision; therefore, zero costs for this activity were considered at baseline, as supportive supervision had not been started. Two supportive supervision approaches were evaluated: (1) supportive supervision at health centre level only; (2) supportive supervision at health centre level, including an extension to CHWs attached to the respective health centres.

All estimates on costs were obtained from the project financial accounts and are presented in euros in accordance with these reports (Table 1). Costs were divided into (1) start-up costs, and (2) cost of delivering the intervention under steady-state conditions. Start-up costs included training two supervisors, a coordinator (district nutritionist) and the health facility staff (five for each health centre), based on the Ugandan daily allowance rate.

The intervention running costs included supportive supervision activities, fuel for transportation to the sites during supportive supervision, communication (phone calls, airtime), equipment maintenance (which consisted only of replacing the batteries in the

electronic weighing scales) and networking activities (workshops with the health facility staff to discuss strategies for the improvement of care and to share lessons learned).

Other healthcare delivery-related costs (e.g. medication, health centre staff or remuneration) were not included because they were not specific to the intervention. The costs of developing the tools for supportive supervision were not included, as we assume these were developed at an early stage, at Ministry of Health level, and included in the national guidelines. Costs of coordinating the supportive supervisors were also not included, as this is already a duty of the district nutritionist; however, training of the district nutritionist was included under start-up costs.

Time horizon and discount: All estimates on costs were directly obtained from the project financial account, reporting the actual costs at the time when each expenditure was made during the one-year study period; no other adjustment for inflation was therefore needed. As suggested by Drummond and colleagues (2005), we opted not to discount costs given the overall short time horizon and the short time frame between the intervention and the effect.

Incremental cost-effectiveness analysis: The ICERs for Phase 1 and Phase 2 to determine the additional cost for every child cured under the two supportive supervision approaches were calculated using the formula

$$\frac{C_1 - C_0}{E_1 - E_0} = \frac{C_1}{E_1}$$

In this formula, C_1 is the cost of supportive supervision and E_1 is the number of cured children for the two supportive supervision approaches.

1. Phase 1 ICER, where C_1 is the cost of supportive supervision delivered to only the health centre staff and E_1 is the number of children cured during this phase; and
2. Phase 2 ICER, where C_1 is the cost after extending supportive supervision to CHWs and E_1 is the number of children cured during this phase.

Additionally, C_0 and E_0 are the costs and effects estimated at baseline before delivery of supportive supervision in these facilities. Because only additional supportive supervision costs were considered and supportive supervision had not yet been started in these health centres, C_0 was taken as zero for both phases.

4.9 Possible sources of bias and strategies to reduce them

Externalities and spillovers were not expected, since children from the same family were expected to access the same health centre and receive the same type of treatment. Contamination in regard to the delivery of the intervention was minimised by using the health centre as a unit of randomisation, not the health workers. The intervention was delivered at health centre level; i.e. all staff in each health centre received the same intervention. Health workers did not routinely rotate amongst health centres. Contamination amongst receivers (e.g. mothers migrating from one health centre to another) was prevented by checking patients' residence.

Children and their families were blinded to the characteristics of the intervention and to the allocation group; blinding of receivers of the intervention (health staff) was not possible due to the characteristics of the intervention. Additionally, given the characteristics of the key outcomes measured (the rate of cured children being an objective outcome), lack of blinding should only affect the study with minor risks of bias.

Hawthorne effects were mitigated by the fact that the study was conducted as a pragmatic study (i.e. study in real-life settings). The intervention was delivered by a local team of professionals, using relatively limited resources, and not in a highly sophisticated or unnatural study setting. This pragmatic design was chosen because the study aimed to explore the impact of solutions that could then be sustained in routine settings. However, we observed some study effect, possibly related to the presence of data collectors in each facility (see section 5).

John Henry effects cannot be ruled out; after discussion with local professionals, it is possible that staff in the control health centre actively worked harder to overcome the 'disadvantage' of being in the control group.

4.10 External validity

Overall, based on the characteristics of the study, it is reasonable to suggest that findings of the study are valid and transferable to similar settings:

- General setting: Arua District is characterised by a high prevalence of refugees, low economic resources, high prevalence of SAM and MAM, low women's education and empowerment, high poverty, fair coverage with health services for treating malnourished children, substandard quality of care, medium level of security, and urban or peri-urban context;
- Population: it is reasonable to think that this sample is not significantly different than the broader populations of children with malnutrition in other refugee settings in Uganda, and is similar to the population of children with malnutrition in other Sub-Saharan countries with similar characteristics;
- Intervention: the intervention was delivered in a real-life setting by local professionals. A similar intervention could be implemented in other similar settings;
- Control: control was standard care (no intervention);
- Outcomes: health outcomes are the standard health outcomes used for the evaluation of nutritional programmes. Case definitions were based on the national IMAM guidelines; and
- Timelines: when transferred to other settings, the intervention will need adequate time for piloting (development of guidance material, building local capacities, learning lessons from the local context) and thereafter implemented.

4.11 Ethical considerations

4.11.1 Institution review boards

The study was submitted to competent ethical authorities, including the Uganda National Council of Science and Technology (clearance received 6 June 2016), the Ethical Committee of the School of Public Health at Makerere University (clearance received 27 April 2016) and the Ethical Committee of the IRCCS Burlo Garofolo (clearance received 1 April 2016).

In implementing the study, all relevant regulations for ethical consideration in human research were followed, including the Nuremberg Code (Sebring et al. 2013), the Helsinki Declaration latest version 2013 (Persson and Henriksson 2013), and all relevant procedures of Good Clinical Practice and International Conference of Harmonization (European Medicines Agency 2014, n.d.). As requested for transparency in research reporting, the protocol of the study was registered at ClinicalTrials.gov (NCT02001116).

4.11.2 Informed consent

Approval from local leaders was sought before beginning activities in Arua District. Before starting the study, the team conducted awareness activities to secure commitment and encourage participation from local stakeholders. Health authorities were informed of the authorisation received to carry forward the study. At the cluster level, staff were informed of the objectives and methods of the study, and their written consent was obtained. At the individual level, children and their parents or guardians were informed and enrolled if providing written consent to participate and for the information derived to be published.

Written consent to participate in the research study was documented on the appropriate form approved by the ethical committees. All consent forms were available in English and the local languages, describing the purpose of the study, the procedures to be followed, and the risks and benefits of participation.

All informed consent discussion was conducted in the appropriate language (usually English or Lugbara). A translator was used, if necessary. During the consent discussions, each section of the consent form was read exactly as written, either by study personnel or by the translator, and then further explained to the participant or parent or guardian, if necessary. All participants and parents or guardians were informed that participation in the study was completely voluntary and that they could withdraw from the study at any time.

If the person asked to provide consent was unable to read or write, their fingerprint was substituted for a signature, and a signature from a witness to the informed consent procedures was obtained.

4.11.3 Confidentiality

To ensure confidentiality, study personnel treated all information gathered as private, and records were kept securely in locked filing cabinets and offices. For all data collected as part of the study, each participant was assigned a unique identification number. No personally identifying information (e.g. names) was used in any reports arising from this research. All project staff were trained on procedures for maintaining confidentiality.

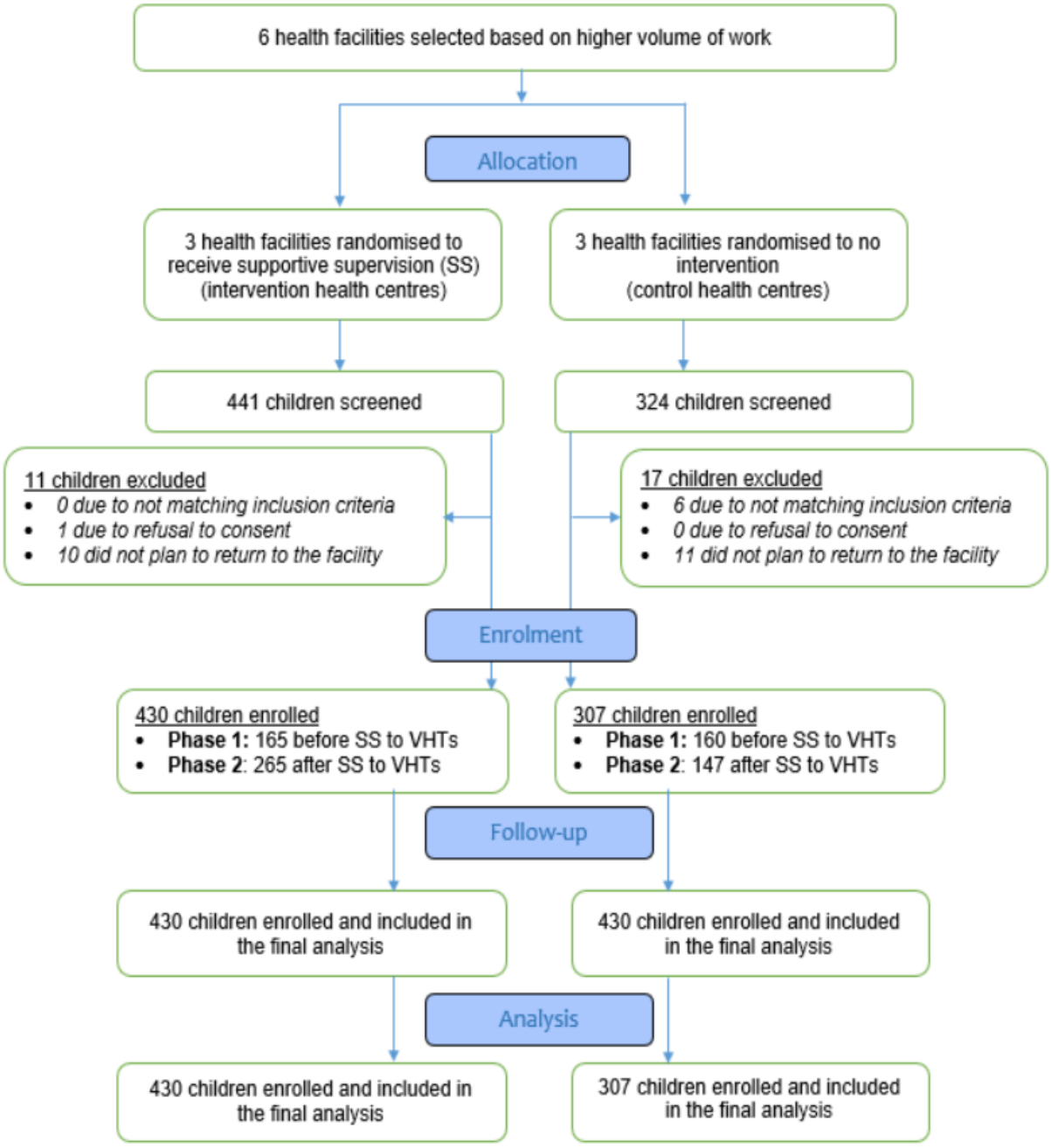
5. Impact analysis and results of the key evaluation questions

5.1 Characteristics of enrolled children

Baseline characteristics of health centres did not show significant differences. Child enrolment flow is shown in Figure 2. Overall, 765 children were screened and 737 were enrolled. All enrolled children were included in the final analysis. As expected, there was an increase in the number of children accessing care in Phase 2 in the intervention arm, compared with control.

The characteristics of the enrolled children are reported in Table 4. Children in the intervention arm had a higher prevalence of risk factors for negative outcomes: more children in the intervention group had SAM (p = 0.005), were twins (p = 0.001), were HIV-positive (p = 0.001), had a mother no longer breastfeeding (p = 0.014), or died or were abandoned children (p = 0.023). The distribution of the other variables (e.g. age, sex and vaccination status) was not statistically different between the two arms.

Figure 2: CONSORT flow diagram



Note: VHT means village health team

Table 4: Children's characteristics at enrolment

Variable	Randomisation arm		
	Intervention N = 430	Control N = 307	Chi p-value
Age categories (months)			
6–12	203 (47.2)	122 (39.7)	
12–24	139 (32.3)	118 (38.4)	
Above 24	88 (20.5)	67 (21.8)	0.114
Sex			
Male	209 (48.6)	133 (43.3)	
Female	221 (51.4)	174 (56.7)	0.156
Vaccination status			
Up to date	369 (85.8)	249 (81.1)	
Not up to date	59 (13.7)	58 (18.9)	
Never vaccinated	2 (0.5)	0	0.085
Child status			
Single	373 (86.7)	290 (94.5)	
Twin	**57 (13.3)**	17 (5.5)	**0.001**
Feeding practice			
Exclusive breastfeeding	7 (1.6)	0	
Replacement feeding	0	0	
Mixed feeding	5 (1.2)	4 (1.3)	
Complementary feeding	241 (56.1)	201 (65.5)	
No longer breastfeeding	**177 (41.2)**	102 (33.2)	**0.014**
Mother status			
Pregnant	18 (4.2)	18 (5.9)	
Lactating	256 (59.5)	204 (66.5)	
Died or abandoned	**55 (12.8)**	18 (5.9)	
Non-lactating	97 (22.6)	64 (20.9)	
Unknown	4 (0.9)	3 (1.0)	**0.023**
Nutritional status			
MAM	122 (28.4)	117 (38.1)	
Uncomplicated SAM	**308 (71.6)**	190 (61.9)	**0.005**
HIV status			
Positive	**17 (4.0)**	1 (0.3)	
Negative	413 (96.0)	302 (98.4)	
Unknown	0	0	
Exposed	0	4 (1.3)	**0.001**

5.2 Health outcomes

Table 5 presents the health outcomes during the intervention phase of the study. In the health centres receiving supportive supervision, the cure rate was significantly higher than in the control facilities (83.8% [95% CI: 71.0–96.6] versus 44.9% [95% CI: 38.2–51.6]; mean difference 38.9% [results ratio = 1.91 (95% CI: 1.56–2.34), p = 0.010]).

On the other side, the defaulting rate was significantly lower in the intervention health centres compared with control facilities (1.4% [95% CI: 1.1–1.8%] versus 47.2% [95% CI: 37.3–57.1 %] in the control; mean difference –45.8% [results ratio = 0.03 (95% CI: 0.0 to –0.06), p = 0.001]). All defaulting children were ascertained to be alive when they were followed up with.

Overall, less than 5 per cent of children had any of the other outcomes (non-responder, OTC transfer, ITC transfer, dead), and there were no statistically significant differences amongst allocation groups for these outcomes.

Table 6 shows that even after controlling for imbalances in baseline characteristics between intervention and control arms, the odds of being cured in the intervention arm were approximately 7.6 times those of the control arm (adjusted odds ratio = 7.6 [5.3–10.9], p = 0.001).

There was a trend of increasing odds of being cured with a child's increasing age (AOR = 1.6 [1.0–2.3], p = 0.036 for age group 12–24 months and AOR = 1.7 [1.0–2.8], p = 0.032 for age group 24 months and above), whilst children diagnosed with uncomplicated SAM had lower odds of being cured (AOR = 0.5 [0.3–0.7], p = 0.001). Other variables (e.g. sex and vaccination status) did not have a statistically significant effect on the odds of being cured.

The results of the probit model are consistent with the results of the logit model. When corrected for baseline characteristics, being in the intervention arm increased the probability of being cured by 42 per cent (95% CI: 0.35–0.48, p = 0.001). Having SAM rather than MAM decreased the probability of being cured by 12 per cent (95% CI: –0.18 to –0.06, p = 0.001).

5.3 Quality of case management

Table 7 presents process outcomes on case management (as the mean proportion and 95% CI). Six process outcomes measured quality of case management as a proportion of correct management against a reference standard (national guidelines). Quality of case management did not significantly differ between the two groups for most indicators. Diagnosis, ready-to-use therapeutic foods treatment, HIV evaluation, counselling and assignment of the exit outcomes were correctly performed in most cases in both groups.

On the other side, complementary treatment was correctly assigned only in 58.8 per cent (95% CI: 43.2–74.3) of control facilities, compared with 94.0 per cent (95% CI: 83.7–100%) of intervention facilities (results ratio = 1.52 [1.40–1.67], p = 0.001).

5.4 Data quality

Ensuring high-quality data was essential for the study. Table 8 presents data quality, as measured by three predefined indicators: data completeness, consistency and accuracy. During the intervention phase, the proportion of cases with data of good quality was greater than 99 per cent in both groups, for all indicators.

Table 5: Health outcomes

Health outcomes	Randomisation arm								Difference in mean %	P-value
	Intervention health centres (HCs)				Control HCs					
	HC 1 n (%)	HC 2 n (%)	HC 3 n (%)	**Mean % (95% CI)**	HC 4 n (%)	HC 5 n (%)	HC 6 n (%)	**Mean % (95% CI)**		
	182	114	134		140	82	84			
Cured	153 (84.1)	110 (96.5)	95 (70.9)	**83.8 (71.0–96.6)**	52 (37.6)	40 (48.8)	41 (48.8)	**44.9 (38.2–51.6)**	**38.9**	**0.010**
Non-respondent	13 (7.1)	2 (1.8)	9 (6.7)	**5.2 (2.2–8.2)**	4 (2.9)	5 (6.1)	5 (6.0)	**5.0 (3.1–6.8)**	0.2	0.926
Defaulters	2 (1.1)	2 (1.8)	2 (1.5)	**1.4 (1.1–1.8)**	82 (58.6)	33 (40.2)	36 (42.9)	**47.2 (37.3–57.1)**	**–45.8**	**0.001**
OTC Transfer	5 (2.8)	0	4 (3.0)	**1.9 (0.3–3.6)**	0	0	1 (1.2)	**0.4 (–0.3–1.1)**	1.5	0.231
ITC Transfer	9 (5.0)	0	24 (17.9)	**7.6 (–1.6–16.9)**	2 (1.4)	3 (3.7)	1 (1.2)	**2.1 (0.7–3.5)**	5.5	0.364
Dead	0	0	0	**0**	0	1 (1.2)	0	**0.4 (–0.3–1.1)**	**–**0.4	0.378

Table 6: Multivariate logistics regression results

Characteristics	Patient cure status				
	Cured N = 492	Not cured N = 245	Crude OR (95% CI)	Adjusted OR (95% CI)	P-value
	n (%)	n (%)			
Study arm					
Control	134 (43.7)	173 (56.4)	1	1	
Intervention	358 (83.3)	72 (16.7)	6.4 (4.6–9.0)	7.6 (5.3–10.9)	**0.001**
Age categories (months)					
6 to 12	209 (64.3)	116 (35.7)	1	1	
12 to 24	174 (67.7)	83 (32.3)	1.2 (0.8–1.6)	1.6 (1.0–2.3)	**0.036**
Above 24	109 (70.3)	46 (29.7)	1.3 (0.9–2.0)	1.7 (1.0–2.8)	**0.032**
Sex					
Male	236 (69.0)	106 (31.0)	1	1	
Female	256 (64.8)	139 (35.2)	0.8 (0.61–1.1)	0.9 (0.6–1.2)	0.438
Vaccination status					
Up to date	419 (67.8)	199 (32.2)	1	1	
Not up to date	72 (61.5)	45 (38.5)	0.8 (0.5–1.1)	1.1 (0.7–1.8)	0.730
Never vaccinated	1 (50.0)	1 (50.0)	0.5 (0.0–7.6)	0.1 (0.0–2.3)	0.163
Nutritional status					
MAM	171 (71.6)	68 (28.5)	1	1	
Uncomplicated SAM	321 (64.5)	177 (35.5)	0.7 (0.5-1.0)	0.5 (0.3-0.7)	**0.001**

Table 7: Quality of case management

Process outcomes	Randomisation arm									
	Intervention health centres (HCs)				Control HCs					
	HC 1 n (%)	HC 2 n (%)	HC 3 n (%)	**Mean % (95% CI)**	HC 4 n (%)	HC 5 n (%)	HC 6 n (%)	**Mean % (95% CI)**	**Difference in mean %**	**P-value**
	182	114	134		140	82	84			
Correct diagnosis	182 (100)	114 (100)	134 (100)	**100 (100)**	140 (100)	75 (91.5)	84 (100)	**97.2 (92.3–100)**	2.8	0.378
Correct treatment	182 (100)	114 (100)	134 (1,000)	**100 (100)**	140 (100)	82 (100)	84 (100)	**100 (100)**	0	-
Correct complementary treatment	182 (100)	114 (100)	110 (82.1)	**94.0 (83.7–100)**	105 (75.0)	47 (57.3)	37 (44.0)	**58.8 (43.2–74.3)**	35.3	0.031
Correct HIV evaluation	182 (100)	114 (100)	134 (100)	**100 (100)**	140 (100)	82 (100)	84 (100)	**100 (100)**	0	-
Patient counselling	182 (100)	114 (100)	134 (100)	**100 (100)**	140 (100)	82 (100)	84 (100)	**100 (100)**	0	-
Correct exit outcome	182 (100)	114 (100)	134 (100)	**100 (100)**	140 (100)	82 (100)	84 (100)	**100 (100)**	0	-

Table 8: Data quality

Data quality	Randomisation arm								Difference in mean %	P-value
	Intervention health centres (HCs)				Control HCs					
	HC 1 n (%)	HC 2 n (%)	HC 3 n (%)	**Mean % (SD)**	HC 4 n (%)	HC 5 n (%)	HC 6 n (%)	**Mean % (SD)**		
	182	114	134		140	82	84			
Completeness	182 (100)	114 (100)	134 (100)	**100 (0)**	140 (100)	82 (100)	84 (100)	**100 (0)**	0	-
Consistency	182 (100)	114 (100)	133 (99.3)	**99.8 (99.4–100)**	140 (100)	80 (97.6)	84 (100)	**99.2 (97.8–100)**	0.6	0.515
Accuracy	182 (100)	114 (100)	134 (100)	**100 (0)**	140 (100)	82 (100)	84 (100)	**100 (0)**	0	-

5.5 Quality of nutritional services

Quality of nutritional services was measured at three time points – at baseline before the start of the intervention, at midterm and at the end of the intervention phase – using the national NSDA tool. The tool provides, through predefined checklists, a summary score of the quality of 10 key capacity areas (Section 1.8 in the NSDA tool) using four predefined categories (poor, fair, good, excellent).

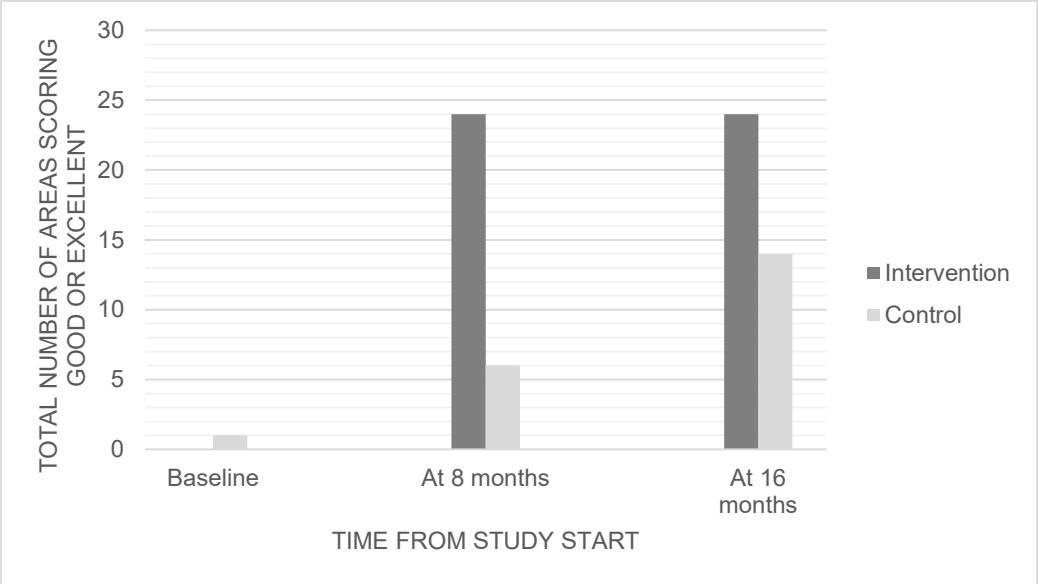
Table 9 summarises quantitative results. Figure 3 presents details of the summary of scores at three time points.

As Table 9 reports, at baseline, all facilities except one scored either poor or fair under all 10 assessment areas of the NSDA tool, and there was no statistical significance between the intervention and control for good or excellent scores (p = 0.313). At the end of the intervention phase, both groups had increased the number of areas scoring either good or excellent, with a significant difference between intervention and control arm (24/30 [80%] versus 14/30 [46.6%], risk ratio = 1.7 [95% CI: 1.1–2.6], p = 0.007).

Table 9: Quality of nutritional services

	Intervention group (N = 30) n (%)	Control group (N = 30) n (%)	P-value
Before the intervention			
Total area assessed as good or excellent	0	1 (3.3)	p = 0.313
Total area assessed as poor or fair	30 (100)	29 (96.7)	
End of the intervention (12 months)			
Total area assessed as good or excellent	24 (80)	14 (46.6)	p = 0.007
Total area assessed as poor or fair	6 (20)	16 (53.3)	

Figure 3: Total number of areas with either good or excellent NSDA score, by group, over time



5.6 Access to care

One of the study objectives was to increase access to care. To accurately evaluate the effectiveness of the intervention, the study period was split in two phases. In Phase 1 (up to March 2017), supportive supervision was delivered only to health centre staff, and in Phase 2 (from April 2017), supportive supervision was extended to CHWs.

As Table 10 reports, before the extension of supportive supervision to the CHWs, the number of children enrolled in each group was not significantly different (Phase 1: 165 children in the intervention group versus 160 children in the control arm).

After the extension of supportive supervision to the CHWs, there was a significant (38.6%) increase in children accessing nutritional care in the intervention arm, compared with the control (Phase 2: 265 children in the intervention group versus 147 in the control arm, risk ratio = 1.26 [95% CI 1.11–1.44], p = 0.001). This explains the difference in the total number of children enrolled (430 in the intervention group versus 307 in the control).

To the best of our knowledge, there were no major changes in the population surrounding the intervention health centres, compared with control, that could justify an increase in access to the intervention health centres after April 2018.

Table 10: Effect of supportive supervision on village health teams

Study phases	**Randomisation arm**			
	Intervention N = 430	Control N = 307	Difference N = 123	P-value
Before supportive supervision to CHWs, n (%)	165 (38.4)	160 (52.1)	5 (4.1)	
After supportive supervision to CHWs, n (%)	265 (61.6)	147 (47.9)	118 (95.9)	0.001

5.7 Cost-effectiveness analysis

The total cost of delivering supportive supervision in Phase 1 to a single health centre over one year was estimated at 1,340.0 euros (range: 1,139–1,541), with running costs contributing up to 75 per cent of this cost (Table 11).

The three largest expenditures in the running costs were supportive supervision visits (391.7 euros), networking activities (359.7 euros), and communications and patient follow-up (206.0 euros).

When supportive supervision was extended to CHWs, this additional activity, which was estimated to cost 308.2 euros, raised the cost of delivering supportive supervision in Phase 2 in a single health centre over one year to 1,648.2 euros (range 1,401–1,895).

Table 11: Costs of delivering supportive supervision in Phase 1 and Phase 2

Intervention phases	Cost (euros)	Percentage cost contribution	15% variation in cost
Phase 1: supportive supervision to health centre staff only			
Start-up costs	316.0	23.6	268.6–363.4
Running costs	1,024.0	76.4	870.4–1,177.6
Total costs	**1,340.0**		**1,139–1,541**
Phase 2: supportive supervision to health centre staff + extended to CHWs			
Start-up costs	316.0	19.2	268.6–363.4
Running costs	1,024.0	62.1	870.4–1,177.6
Supportive supervision to CHWs	308.2	18.7	261.9–354.4
Total costs	**1,648.2**		**1,401–1,895**

Table 12 presents the base ICER estimates. The incremental effect of supportive supervision on the number of cured children in Phase 1 was 56 children, and the incremental cost was 1,340.0 euros. This resulted in an ICER of 23.9 euros, the additional cost required for every additional child cured compared with the baseline.

When supportive supervision was extended to CHWs in Phase 2, 90 children were estimated to have been cured, and the incremental cost was 1,648.2 euros. This resulted in an ICER of 18.3 euros, the additional cost required for every additional child cured in phase 2 compared with the baseline.

Table 12: Base incremental cost-effectiveness ratio results

Phases	Effectiveness			Cost		
	Cure rate	**Effect** *(Number of cured children)*	**IE**	**Total cost**	**IC**	**ICER**
Phase 1 comparison						
Supportive supervision to health centre staff only	83.8%	92	56	1,340.0 0	1,340.0	23.9
Baseline	32.9%	36				
Phase 2 comparison						
Supportive supervision to health centre staff + extension to CHWs	83.8%	148	90	1,648.2 0	1,648.2	18.3
Baseline	32.9%	58				

Note: IE = incremental effectiveness; IC = incremental cost

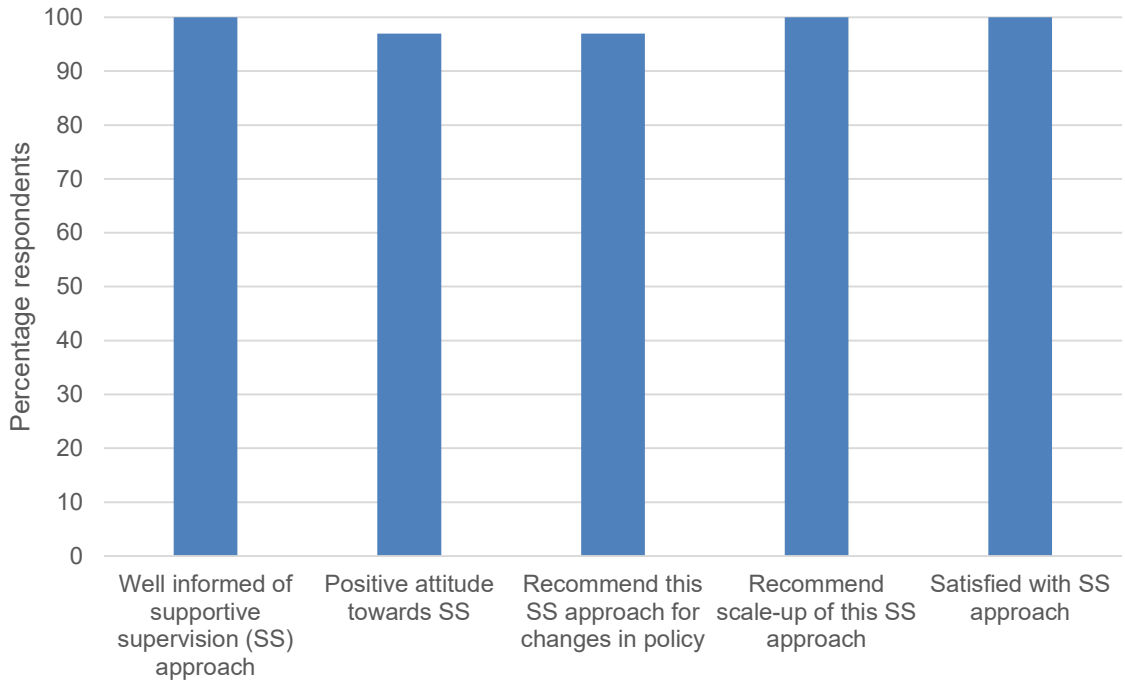
5.8 Stakeholder satisfaction and motivation

Three stakeholder dissemination workshops were held: one in Trisete with the project partners; one in Arua District (the study setting), involving the local team, staff of the health centre involved in the study, and local health authorities and partners; and a large national restitution workshop in Kampala involving national stakeholders. The aims of the

workshops were to present the final results of the study to all key district and national stakeholders. During these meetings, there were also detailed discussions of possible strategies to facilitate evidence uptake and sharing of study communication products (e.g. the policy brief).

We also conducted a stakeholder satisfaction and motivation assessment, whose results are presented in Figure 4. Of the 37 stakeholders interviewed, most were either very satisfied (51.4%) or satisfied (48.7%) with the study and the supportive supervision approach. One stakeholder suggested that this approach could be piloted in a programme setting to strengthen the evidence before scale-up.

Figure 4: Parameters for stakeholder satisfaction of the supportive supervision approach



6. Discussion

This cluster RCT has shown that enhanced nutritional supportive supervision as delivered in this study (i.e. high-intensity) was a low-cost intervention, able to significantly improve cure rates amongst malnourished children admitted at outpatient level. This result was observed despite the fact that the children in the intervention group had more risk factors. The intervention also resulted in a significant decrease in the defaulter rate and a significant improvement in the quality of case management, quality of data, general nutritional service delivery and access to care.

Other studies in low- and middle-income countries have suggested that supportive supervision can be an effective strategy to improve the quality of case management and health outcomes of mother and children at hospital or outpatient level (Hoque et al. 2014; Lazzerini et al. 2017; McAuliffe et al. 2013). However, this is the first study that specifically tests supportive supervision to improve the health outcomes of malnourished children.

The study was conducted in a humanitarian setting with very low resources and where baseline quality of care was highly substandard. In settings like this, identifying effective interventions capable of improving health outcomes, especially for malnourished children who have a very high risk of death, is crucial. As such, the study findings are extremely relevant. This study adds to previous knowledge that supportive supervision could be a highly effective strategy for improving the health of malnourished children in a setting with very low resources.

Notably, despite the fact that the control group did not receive supportive supervision, we observed a relative improvement in several outcomes in this group (cure rates, quality of case management, quality of data and general nutritional service delivery), notwithstanding that the intervention facilities performed better. This could be explained as a study effect (i.e. it is plausible that the presence, at facility level, of well-trained nutrition data collectors positively affected the overall performance of the health facility staff).

Heterogeneity in quality of care at baseline was observed in our sample, despite no significant differences in the mean cure rate amongst groups. Heterogeneity in quality of care – even amongst nearby facilities in the same setting – is a common finding (NDoH 2009; Rohde 2006) and should not be perceived as unusual. Most importantly, this study showed that supportive supervision can reduce heterogeneity in health outcomes.

Obviously, supportive supervision alone cannot solve all gaps in quality of care. The fact that, according to the health service assessment, some areas still performed as ‘poor or fair’ (e.g. human resources) irrespective of the intervention is not surprising. Some improvements (e.g. having adequate human resources) require economic resources and actions from district and central government authorities – activities that go beyond supportive supervision and beyond the mandate of the supervisors.

The finding that supportive supervision also increased access to care is extremely important, since delays in accessing care could imply the deaths of vulnerable children suffering from malnourishment. Collaborative supportive supervision encouraged CHWs to improve how they conducted their activities (e.g. community screening and case referral). Specific interventions implemented for CHWs included training on basic nutrition concepts, enhanced supervision and provision of a small financial incentive (which is recommended in the Ugandan guidelines, as well as in other guidelines, but often not formalised in practice).

Other studies have suggested that these activities may have some effectiveness in improving CHWs’ performance (Kok et al. 2015). Our study combined a small financial incentive with supportive supervision; this model proved to be effective, and even more cost-effective than providing supportive supervision only at health centre level. Future studies may test whether providing CHWs with an economic incentive plus supportive supervision is more effective than providing only an economic incentive.

We acknowledge some limitations of this study. First, accountability of baseline data on health outcomes, essentially represented by historical data in the Health Management Information System and in the nutritional registers, may be suboptimal. However, these are the official data, and no other data is available. Study findings show a clear

improvement in outcomes according to the before-and-after comparison, but also when comparing the intervention with the control group, thus suggesting that the intervention is effective.

Imbalance amongst treatment groups with regards to patient characteristics did not favour a positive effect of the intervention, resulting in a possible underestimation, and not in an overestimation, of the treatment effect.

Although the study sample may be regarded as relatively small, the included health centres contributed more than 45 per cent of cases of malnourished children in Arua District (Wanzira et al. 2018).

It is possible that part of the effect observed in the study was due to other components besides the intervention, e.g. the presence of data collectors. However, the study could not be conducted without data collectors. Data collectors were present in both study groups and, again, the observed difference in effect between groups suggests that supportive supervision was effective.

This study was conducted with well-trained, highly motivated local staff, and the supervision was conducted at high frequency (two- to four-week intervals). These characteristics may be difficult to replicate in a 'real' setting, where absenteeism, high staff turnover, lack of coordination (Kiwanuka et al. 2008) and lack of resources are frequent problems. However, the study still offers lessons suggesting that quality of care can be achieved when the above-described factors are present.

Strengths of the study include the cluster RCT design and the data quality assurance procedures. Quality of data exceeded 99 per cent on all indicators (data completeness, accuracy and consistency) in both groups. Although the study was not blinded, the use of objective outcome measures should have limited the potential for assessment bias.

Results of the study may be generalisable to other similar settings. Importantly, characteristics of the intervention may have affected results: in this study, supportive supervision was provided by a local team of trained and highly motivated staff and conducted in a participatory, peer-to-peer environment at two- to four-week intervals. Future studies exploring the effectiveness of supportive supervision in other settings should take into account both contextual factors and intervention characteristics.

7. Specific findings for policy and practice

Study findings offer an important lesson for researchers and policymakers, suggesting that supportive supervision may be an effective and reasonably low-cost intervention to improve the health outcomes of malnourished children at the outpatient level in a setting with very low resources. This approach also may improve access to health facilities, quality of case management and quality of data. Future studies should explore the effectiveness of supportive supervision in other settings and confirm these results.

In policy terms, the supportive supervision approach, as proposed in this study, could be scaled up in similar districts of Uganda and in other similar settings. Current Ugandan guidelines, despite recommending supportive supervision, do not detail specific activities or tools to be used in this regard. This study provides a specific model of supportive

supervision, with defined activities and tools, and thus could be used to improve national guidelines. The use of locally available staff – who are already under district employment – as supportive supervision providers, and the use of local guidelines as a reference standard, should facilitate the sustainability of the intervention.

8. Stakeholder engagement and evidence use

8.1 Valuing collaboration

The collaboration between WHOCCMCH and CUAMM dates back more than 20 years through a number of projects in Burkina Faso, Ethiopia, Mozambique, Tanzania, Togo and other countries. CUAMM is working in collaboration with UNICEF, the Ministry of Health and local health authorities in other quality improvement projects in Uganda. In 2014, CUAMM explicitly requested that WHOCCMCH collaborate in evaluating quality of care for children with malnutrition in CUAMM's ongoing projects.

The opportunity to conduct an impact evaluation on supportive supervision in the West Nile region was discussed with CUAMM and found immediate agreement. The evaluation questions and methods were developed in collaboration with CUAMM and other local stakeholders. They reflect the current main areas of interest for CUAMM (malnutrition, HIV, maternal and child health, and quality of care) and other stakeholders (e.g. UNICEF, the Ministry of Health, local health authorities and local communities).

The research team is part of the national team of stakeholders in charge of malnutrition.

8.2 Implications for programming and policies

There is strong interest in the results of this impact evaluation amongst local policymakers and implementing agencies, considering (a) the high prevalence of malnutrition in children in the West Nile region and (b) the fact that the beneficiaries of the quality improvement intervention represent large segments of the population, likely the poorest.

All of the relevant stakeholders – e.g. the Office of the Prime Minister, the Ministry of Health, the Ministry of Education, local government representatives, UNICEF and the academic community – have indicated satisfaction with the intervention, and almost all would recommend it for informing programme and policy changes and scaling. Most importantly, all key stakeholders have signed a support letter. This positive attitude is especially important at a time when the Ministry of Health is reviewing and updating the national IMAM guidelines, for which such evidence can be considered to fill gaps related to effective supportive supervision.

As is the case in many low- and middle-income countries, the inadequacy of funds allocated to supervision activities by the Ministry of Health was discussed as a limitation to scale-up. Stakeholders suggested that in such instances, the study findings provide evidence and a platform for funding advocacy beyond what has been the norm (e.g. provision of supplies, materials and human resources).

Stakeholders made a number of recommendations to foster scale-up:

- Targeted dissemination meetings and engagement with policymakers;
- Development of a policy brief summarising the study findings and recommendations for wider dissemination;
- Development of a supportive supervision package (including tools and checklist) that could be piloted in a smaller region (possibly one overseen by the implementing partner, CUAMM) to strengthen this study's evidence; and
- Scientific publications.

The study team and CUAMM are already in the process of carrying these recommendations forward.

Online appendixes

Note to the reader: These appendixes are only available online and have been published as received from the authors. They have not been copy-edited or formatted by 3ie, and can be accessed through the links provided below:

Online appendix A: Map of West Nile region, Uganda
https://www.3ieimpact.org/sites/default/files/2019-07/TW6.1031-Online-appendix-A-Map-of-West-Nile-region-Uganda.pdf

Online appendix B: HIV national algorithm
https://www.3ieimpact.org/sites/default/files/2019-07/TW6.1031-Online-appendix-B-HIV-national-algorithm.pdf

Online appendix C: Case definitions
https://www.3ieimpact.org/sites/default/files/2019-07/TW6.1031-Online-appendix-C-Case-definitions.pdf

Online appendix D: Data collection: who collected data, when and from where
https://www.3ieimpact.org/sites/default/files/2019-07/TW6.1031-Online-appendix-D-Data-collection-who-collected-data%2C-when-and-from-where.pdf

Online appendix E: Template for collecting health outcomes
https://www.3ieimpact.org/sites/default/files/2019-07/TW6.1031-Online-appendix-E-Template-for-collecting-health-outcomes.pdf

Online appendix F: Data quality control indicators
https://www.3ieimpact.org/sites/default/files/2019-07/TW6.1031-Online-appendix-F-Data-quality-control-indicators.pdf

Online appendix G: Key characteristics of the health facilities
https://www.3ieimpact.org/sites/default/files/2019-07/TW6.1031-Online-appendix-G-Key-characteristics-of-the-health-facilities.pdf

Online appendix H: Baseline health indicators
https://www.3ieimpact.org/sites/default/files/2019-07/TW6.1031-Online-appendix-H-Baseline-health-indicators.pdf

Online appendix I: Informed consent #1
https://www.3ieimpact.org/sites/default/files/2019-07/TW6.1031-Online-appendix-I-Informed-consent-%231.pdf

Online appendix J: Informed consent #2
https://www.3ieimpact.org/sites/default/files/2019-07/TW6.1031-Online-appendix-J-Informed%20consent%20%232.pdf

Online appendix K: Table of results of PROBIT with marginal effects
https://www.3ieimpact.org/sites/default/files/2019-07/TW6.1031-Online-appendix-K-Table-of-results-of-PROBIT-with-marginal-effects.pdf

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