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

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Note to readers

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Plain-language summary

INTRODUCTION

Background Arua is one of the districts in the West Nile region of Uganda hosting a large number of refugees. Most recent estimates indicate that the prevalence of moderate and severe acute malnutrition in children in this region is significantly higher than the national estimates (10.4% and 5.6% respectively). Official data from 2016 indicated that the average cure rate of malnourished children treated at health centres (HC) level in the district was around 50%, far below the international SPHERE standards of 75%, thus suggesting deficiencies in the quality of care. So far, no robust study explored the effectiveness of Supportive Supervision (SS) in improving health outcomes of children with malnutrition.

Objectives This study aimed at testing if SS can improve outcomes of malnourished children at outpatient level, together with improving overall quality of care, quality of data, and access to care. The study also aimed at evaluating cost-effectiveness of SS.

METHODS

Study design This was a cluster randomised controlled trial (RCT) with HC as unit of randomisation. The intervention was delivered at health system level (ie, to the staff of the HCs), while the primary outcome (ie, cure rate of malnourished children) was measured at population level, among children treated in the HCs involved in the study.

Population and setting The six HC in Arua with the higher volume of work were randomised to receive either intervention (enhanced SS) or control (standard of care). Children with malnutrition presenting at HC level were enrolled and each child was followed up individually at fixed intervals.

Intervention The intervention, SS, consisted of a peer-to-peer high frequency supervision, using the national nutrition guidelines as reference, encouraging networking and community engagement. This was in two phases, the first included delivering SS to HC staff only and in the second phase, SS was extended to community health workers (CHWs).

Outcomes The primary outcome was the rate of cured children. Secondary outcomes measured at the individual level, included: other health outcomes (ie, non responders, defaulters, transfer, death); quality of case management (measured by pre-defined process indicators); quality of data (measured by predefined indicators). Overall quality of services (assessed using the national NSDA tool that, based on pre-defined criteria, evaluates 10 key areas into four categories of poor, fair, good or excellent) and access to care (measured by the number of children accessing care) were measured at HC level.

Data analysis Categorical variables were presented as absolute numbers and proportions (95% 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 (MD). A multivariate logistic regression was conducted to estimate the crude and adjusted OR (95% CI) for the outcome cured or not cured taking after correction for possible

imbalance in baseline characteristics. A p value < 0.05 was considered statistically significant. A cost effectiveness analysis (CEA) was conducted comparing costs and outcomes of providing SS versus no intervention, using a provider perspective. Data on the outcomes were obtained from the RCT, and data for the cost were obtained from the accounting records of the implementing agency. Cost of providing SS to one health centre (with and without SS to CHWs) for one year, and the incremental cost-effectiveness ratios (ICERs) per children cured were calculated.

RESULTS

Population 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.

Health outcomes In the HCs receiving SS, the cure rate was significantly higher than in the control facilities [83.8% (95%CI 71.0-96.6) vs 44.9%(95%CI 38.2-51.6)], mean difference 38.9% [RR = 1.91 (95% CI 1.56 to 2.34), p=0.010]. The defaulting rate was significantly lower in the intervention HCs compared to control facilities [1.4% (95%CI 1.1% to 1.8%) vs 47.2% (95%CI 37.3% to 57.1 %)] mean difference - 45.8% [RR = 0.03 (95%CI 0.0 to-0.06), p=0.001]. Overall less than five percent of children had any of the other health outcome (non-responder, OTC transfer, ITC transfer, dead), and there were no statistical significances differences among allocation groups. After controlling for all baseline characteristics, being in the intervention group was significantly associated with an increased odd of being cured (AOR = 7.6(5.3-10.9), p = 0.001).

Quality of case management Quality of case management did not significantly differ between the two groups for most indicators. Diagnosis, RUTF 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% (95%CI 43.2 to 74.3) of control facilities, compared to 94.0% (95%CI 83.7% to 100%) of intervention facilities (RR= 1.52 [1.40-1.67], p=0.001).

Quality of nutrition service delivery At baseline, all facilities except one scored, in any of the 10 assessment areas of the NSDA tool, either poor or fair, without significant difference between the intervention and control groups. At the end of the study period both groups had increased the number of area scoring either good or excellent, with a significant difference between intervention and control arm [24/30 (80%) vs 14/30 (46.6%), RR = 1.7 (95%CI 1.1 to 2.6), p = 0.015].

Access to care After the extension of SS to the CHWs there was a significant 38.6% increment (118 children) in the total number of children enrolled in the intervention facilities compared to the control facilities (p=0.001).

Cost effectiveness Cost of providing SS to one HC for one year was 1340 euro (95%CI 1139 to 1541) and 1648 euro (95%CI 1401 to 1895) respectively, with and without SS to CHWs. The estimated ICERs were 23.9 and 18.3 euro per child cured.

CONCLUSION

This cluster RCT shown that SS was a low-cost intervention 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 SS approach as proposed in this study may be scaled up in other districts in Uganda, as well in other similar settings. Future studies should explore effectiveness and cost-effectiveness of SS in different settings.

What was already known 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.
- Supportive Supervision (SS) has been suggested as a promising intervention to improve 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/contributes about the topic

- This study shows that SS was 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.
- These findings contribute to the growing body of evidence from other studies in similar settings that suggest SS as a possible effective intervention to improve quality of paediatric care and the health status of children.

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Abbreviations and acronyms

3ie	International Initiative for Impact Evaluation
AIDS	Acquired Immune Deficiency Syndrome
ART	Anti Retro-viral Therapy
CI	Confidence intervals
CUAMM	Doctors with Africa
HC	Health Center
HIV	Human Immune-deficiency Virus
HMIS	Health Management and Information System
ICC	Intra Cluster Correlation Coefficient
ICER	Incremental Cost Effectiveness Ratio
IMAM	Integrated Management of Acute Malnutrition
IMCI	Integrated, Management of Childhood Illness
INR	Integrated Nutrition Register
ITC	In-Patient Therapeutic Care
LMIC	Low and Middle Income Countries
MAM	Moderate Acute Malnutrition
MoH	Ministry of Health
MUAC	Mid-Upper Arm Circumference
NGO	Non Government Organization
NSDA	Nutrition Service Delivery Assessment
OPD	Out Patients Department
OTC	Out-Patient Therapeutic Care
QI	Quality Improvement
QoC	Quality of Care
RCT	Randomized Controlled Trial
RUTF	Ready-to-Use Therapeutic Foods
SAM	Severe Acute Malnutrition
SD	Standard Deviation
SEEP	Stakeholder Engagement and Evidence uptake Plan
SF	Supplementary Feeding
SS	SS
TB	Tuberculosis
UN	United Nations
UNICEF	United Nations International Children's Emergency Fund
USAID	United States Agency for International Development
CHW	Village Health Team
WHO CC	WHO Collaborating Center
WHO	World Health organization

1. Introduction

1.1 Burden of acute malnutrition in children under 5 years

In low-income countries, especially in Sub-Saharan Africa, under-nutrition, together with 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 (MOH) 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% children under 5 years suffer from moderate acute malnutrition (MAM) while 1% are diagnosed with severe acute malnutrition (Uganda Bureau of Statistics, 2016, n.d.).

The national guidelines, the Integrated Management of Acute Malnutrition (IMAM), were developed by the MoH in 2006 and updated in 2011 (Uganda Ministry of Health, 2016, n.d.). The IMAM guidelines include the treatment of moderate acute malnutrition (MAM) and severe acute malnutrition (SAM), those for the community therapeutic care and aspects of treatment of malnourished HIV/AIDS children and adults. The point of management of acute malnutrition is dependent on the classification at the time of diagnosis: children diagnosed with complicated SAM are admitted to the in-patient therapeutic care (ITC); those diagnosed with SAM without complications and MAM but HIV positive or exposed are referred to the out-patients therapeutic care (OTC); children with MAM and HIV negative are referred to the Supplementary Feeding (SF) centers. There are specific national criteria to classify children in nutritional categories, which include basically: weight-for-height according to WHO Growth Standards (WHO Multicenter Growth Reference Study Group, 2006) and mid-upper arm circumference (MUAC) (Uganda Ministry of Health, 2016, n.d.). Care is provided by the public sector, and access to care is supposed to be free of charge. Beneficiaries of this program 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 conflicts and those receiving refuges. The influx of a large number of individuals into a region with inadequate resources like food quickly leads to food insecurity, and ultimately malnutrition especially among children under 5 years and among the refugees(Sabastian Taylor, 2013, n.d.). 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 area of conflict/refugees a priority target for interventions aiming at treating malnutrition in children.

The West Nile region, on the border with The Democratic Republic of Congo and Southern Sudan is currently in a humanitarian crisis state, hosting refugees fleeing from civil wars in the neighboring countries (UNHCR, 2014, n.d.). Recent estimates reports that that the number of refugees in Arua district is approximately 175,000 people (World Vision Uganda, 2017), compared to a total overall population of about 780,000. This region has also the highest prevalence of MAM and SAM in the country (Uganda Bureau of Statistics, 2016, n.d.): the prevalence of MAM and SAM in children under

5 years in this area is estimated to be 10.4% and 5.6% respectively, which is significantly higher than the national estimate (3.6% and 1.3%).

1.3 Quality of Care and Supportive Supervision

The importance of quality of care in services delivered and its potential impact on child and maternal survival is increasingly being recognized 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, n.d.; WHO Europe, 2013, n.d.).

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

The most common approach used so far 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, both formal studies and technical assessments have shown that training alone does not ensure adherence to guidelines and acceptable health outcomes (Ayieko P et al., 2011; Gillespie S et al., 2015; Huicho L et al., 2005).

Supportive supervision (SS) has been suggested as a promising intervention for ensuring higher adherence to guidelines in different contexts (Management Science for Health, 2006, n.d.; McAuliffe E et al., 2013; National Department of Health, 2009, n.d.). SS is a technique used to improve the quality of health care, and as such it has been used in different contexts, such as South Africa, India, Bangladesh, and partly in Uganda (Doctors with Africa, 2013, n.d.; Hoque DM et al., 2014; Management Science for Health, 2006, n.d.; National Department of Health, 2009, n.d.).

1.4 Study justification

We conducted a cluster randomized controlled trial (RCT) to evaluate the impact of SS, intended as high intensity SS and specific for nutritional services ("***enhanced nutritional Supportive Supervision"***) as compared to the standard of care. The study was justified by the following observations:

1. Ensuring adequate SS 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.
2. High quality evidence, such as that provided by randomised controlled trials (RCTs), on the efficacy of SS is still extremely scarce (Dettrick Z et al., 2013; Nair M et al., 2014). Similarly, in Uganda, although there is some SS practised in the country in nutritional services, there is no robust evidence (in form of a proper study) of its effectiveness. Therefore, study contributes to the current knowledge gap on whether ***enhanced nutritional SS*** 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.
3. Findings of the present study may be relevant both locally, and internationally. This impact evaluation may contribute to improving the health and wellbeing of children in low and middle income countries (LMIC). Iif the intervention proves to be effective, it may be scaled up or translated into other contexts, and benefit a larger population).

4. Both the WHO Collaborating Center for Maternal and Child health and CUAMM, Doctors with Africa, had previous experience in supporting activities of SS. CUAMM Uganda has experience in facilitating SS in the Karamoja region (Doctors with Africa, 2013, n.d.). The WHO CC has collaborated with WHO and local partners, as primary investigator in a large Cluster RCT in twenty hospitals in Kyrgyzstan where SS 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 utilised strict research methods, showed that SS may improve also staff satisfaction and knowledge, and may improve access to care from the population.

SS is most effective when HC staff is well trained in the management of acute malnutrition, if essential equipment and supplies are in place, and if community involvement is present. For these reasons, although the main intervention was SS, we combined it with other complementary interventions aiming at improving training, availability maintenance of essential supplies (such as RUTF) and community involvement.

1.5 Study questions

This study's original research questions were as follows.

Does enhanced nutritional SS, provided by a team of local professional, in a regular way with a peer-to-peer model to staff at HC (including CHW) in charge of managing malnourished children:

1.4.1 Primary question

- Significantly improve the cured rate (attaining a weight-for-height ≥ -2 standard deviation (SD) from the mean based on the WHO 2006 standards or mid upper circumference (MUAC) of ≥ 12.5 cm)?

1.4.2 Secondary questions

- Significantly reduce
  - 1) defaulting rate (absent for 2 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 while still in the program)?
  - 4) Non-responders rate (not reaching discharge criteria after three months or four months for the HIV/TB patients)?
  - 5) Rate of children progressing to Severe Acute Malnutrition (SAM) after being admitted as Moderate Acute Malnutrition (MAM)?
- Significantly improve
  - Quality of health services assessed using the national nutritional service delivery assessment (NSDA) tool
  - Quality of case management (correct diagnosis, treatment, HIV evaluation, counselling of care givers and exit health outcomes criteria such as cured, non-responders, defaulters, transfers to ITC and OTC and died)
  - Overall access to care (which may reflect patients' satisfaction)?
- Is enhanced SS a cost-effective intervention compared to standard of care?
- Are stakeholder satisfied and motivated

2. Intervention, theory of change and research hypotheses

2.1 Intervention

The intervention was "**enhanced nutritional Supportive Supervision**", which was SS with "high intensity" and "dedicated to the nutritional services".

The specific characteristics of the enhanced nutrition SS in this project are and activities are outlined below in Box 1.The enhanced nutritional SS model used in this study combined monitoring, supporting, and complementary activities as shown in Box 1. From April 2017, SS was also extended to include the village health team workers (CHWs) attached to the intervention facilities with the objective of improving community screening, case-referral, and active involvement in tracing of defaulters.

All activities during the SS used the national IMAM guidelines as reference standard and dedicated tools (checklists). This enabled the supervisors to provide guidance on the technical aspects of services in a standardized way (ie covering a standardized list of key issues).

Box 1: Characteristic of SS and specific activities

Phase 1: SS to HC staff

A. Characteristics

- Frequency: biweekly in the first 3 months, then monthly.
- Duration: approximately 2 hours in each HC at each visit.
- Provider: local staff (nutritionist, District Health Office Team) trained in IMAM guidelines and in methods of "enhanced nutritional SS".
- Receivers: staff working at HC level with children with malnutrition (phase 1); CHW (phase 2).
- Reference guidelines: Current National IMAM guidelines.
- Attitude and philosophy: Participatory peer-to-peer model with and open communication between the supervisor and staff members, aiming at listening to the staff perspectives, clarifying doubts in relation on how implement the national guidelines, and developing solutions together, with a proactive, participatory "problem solving" attitude. The objective was not only improving staff knowledge and skills, but also improving confidence and motivation of staff in doing their job. Follow up on solutions agreed was based on the Plan – Do- Study- Act QI Cycle (Taylor MJ et al., 2014).

B. Activities

Monitoring activities:

- Checking essential equipment and supplies
- Checking case management as per the national guidelines
- Checking data quality (data completeness, accurate and consistency)
- Checking HC staff knowledge and skills

Supporting activities:

- Based on the specific deficiencies identified, providing technical support, such as 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
- Clarifying issues on case management

Complementary activities

- facilitation of networking among staff of different HCs, with the objective building ownership in the process
- Tools for tracing of defaulters such as telephone credit and location maps (although tracing of defaulter is recommended in the national guidelines, no specific tool is provided to HC staff).
- The study protocol also included the delivery of essential key equipment if needed, but since all key equipment were already available, only regular check of accuracy of the weighing scales for calibration was performed

Phase 2. SS extended to CHW

C. Characteristics

- Frequency: every week, a selection of villages associated with the intervention HCs was visited, and every CHW was involved in SS at least twice during the duration of the project. Other characteristics were similar as for Phase 1.

D. Activities

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

2.2 Monitoring the implementation of the intervention

The following procedures were instituted in order to ensure that the implementation of intervention (SS) was conducted according to the protocol:

1. Supervision on the training of all personnel involved in SS, to ensure that the study procedures, the methods of SS, and the national IMAM. were clear. The training included both the theoretical and practical sessions by two experienced study researchers and nutritionist lead by the Principal Investigator, a paediatrician and epidemiologist with extensive experience not only in research but also in studies on SS.
2. A monthly schedule for visiting the facilities for SSs was developed by the project manager and study coordinator in collaboration with the study PI, who monitored its implementation.
3. A checklist was developed by the PI and project manager to standardise the SS visits (list of pre-defined activities).
4. A robust data quality assurance system (see section 4.8) was in place
5. Interim analyses were conducted to monitor trends in outcomes over time.

2.3 Study hypothesis

If regular enhanced nutritional SS is delivered to staff at HC 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 with malnutrition, patients' satisfaction and access to care will also improve (i.e. number of children accessing the HC).

2.4 Study objectives

HC managing acute malnutrition in Arua district were randomized to either receive the intervention ("enhanced nutritional SS"), or to 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 rate of defaulters, rate of transfer, rate of deaths, rate of non-responders, 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 to the control
- Assess stakeholder motivation and satisfaction

2.5 Theory of change

The process of change includes;

1. The use of the following inputs: Financial resources (3iE, WHO CC); Human resources (WHO CC, CUAMM, School of Public health, Makerere University); Technical support (WHO CC); Time (research team).
2. Such inputs were used for the following activities: SS visits delivered regularly to staff at HC level, including CHW plus complementary activities (Box 1).
3. Evidence uptake was realized through: 1) meetings with stakeholders, 2) development of knowledge products such as: videos, posters, working papers, policy briefs, media coverage and publications.
4. Expected outputs include; staff have better knowledge, are more satisfied and motivated leading to improved QoC; users are more satisfied with the care delivered; the community perceives better QoC; improvement of data quality; staff and health authorities have ownership of the intervention and are committed to improving QoC; stakeholders are informed about the study design and study progress and are committed to improving QoC.
5. Outcomes: all the above should result in improving health outcomes of malnourished children treated at HC level, and possibly, in increased access to HC.
6. In the future, this impact evaluation may contribute to improve the overall health and wellbeing of children in Uganda, as well in other LMIC.

Almost all these assumptions made have been met (**Table 1**) except for those related to the final stakeholders meeting that has been planned for July 2018.

Table 1: Status of theory of change assumptions

Stage	Assumptions made	Status
Inputs	• Financial resources (3iE, WHO CC) • Human resources (WHO CC, CUAMM, School of Public health, Makerere University) • Technical support (WHO CC) • Time (research team)	• All met
Activities	• Supervision visits and other intervention components regularly delivered	• All met
	• Evidence uptake was realized through: 1) meetings with stakeholders, 2) development of knowledge products such as: 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)
Out puts	• Improved 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 QoC • Stakeholders are informed about the study design and study progress and are committed to improving QoC.	• Not assessed • Not to be assessed in our protocol • Met • Met • Met • Met
Outcome	• Significantly improved cure rates among intervention facilities as compared to the control facilities • Improved access to care at facility level	• All met

2.6 Actors

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

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, n.d.).
- When reviewing HMIS official data, outcomes of children with malnutrition treated as outpatients at health centre level did not reach the international standards (75% of cure rate according to SPHERE standards): the mean recovery rate was around 50% (Wanzira et all, submitted for Publication).
- SS of these health facilities nutritional services was limited, with some facilities reporting that they had received none.
- In the current Ugandan IMAM guidelines SS is recommended on a quarterly basis; however methods are not further detailed, and the guidelines do not include any specific tool to carry out SS activities (Uganda Ministry of Health, 2016, n.d.). In practice, SS is not conducted if there are not dedicated funds and supporting partners. Specifically, during our study only few activities were conducted. Importantly, in the intervention group no activity was conducted.

4. Evaluation: Design, methods and implementation

4.1 Study Design

This was a Cluster Randomized Trial (RCT) study, with HC as the unit of randomization.

4.2 Randomisation process

Health facilities were selected based on their volume of work: the six HCs with the highest reported number of children accessing the nutrition services - according to the official 2016 HMIS data - were included in the study. After stratification by characteristics - such as HC level, setting (urban vs rural), number of staff assigned to the nutritional unit- the study team randomly allocated HCs by extraction (“urn randomization (Cochrane, 2017, n.d.) to either SS or standard care (no intervention). HC staff and CHW were aware of the allocation group, while patients were blinded.

4.3 Randomisation arms

4.3.1 Intervention

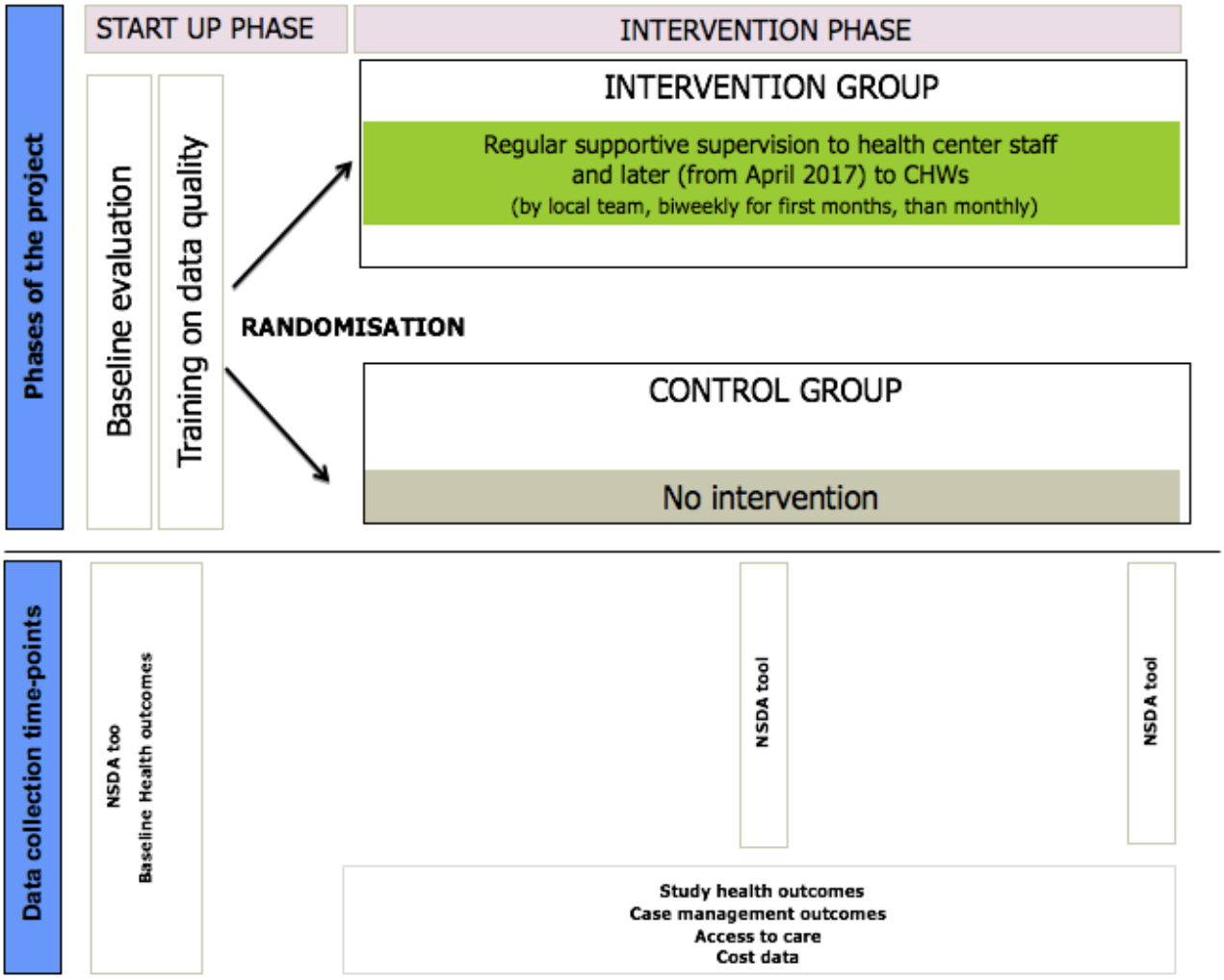
Details of the intervention have been explained under section 2.0 “Intervention, theory of change and research hypotheses”.

4.3.2 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 HCs involved in the study (such as training, or additional SS) from any provider, that could affect the quality of care.

The randomization process and the key activities in the study are depicted in figure 1 below.

Figure 1: Randomisation arms and study key activities



4.4 Study population

For the primary outcome, the study sample consisted of children with malnutrition treated at in HC in Arua district. All children with SAM or MAM presenting in the study HCs were evaluated for inclusion. Criteria for inclusion were based on the national IMAM guidelines, as reported below.

Inclusion criteria:

1. Children 6 months-5 years
2. Diagnosis of SAM or MAM according to National criteria (Uganda Ministry of Health, 2016, n.d.)
   SAM: weight-for-height <- 3 standard deviation (SD) from the mean based on the WHO 2006 standards (WHO, 2006).

MAM: weight-for-height <- 2 and > -3 standard deviation (SD) from the mean based on the WHO 2006 growth reference standards (WHO, 2006).

3. 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 breastfeed, and therefore still exposed to HIV) following the national testing guidelines as per the algorithm.

Exclusion criteria:

1. Not matching the above criteria for SAM and MAM
2. Refusal to participate/ consent
3. Unable to adhere to study follow up procedures

4.5 Sample size calculation

The sample size was calculated by taking into account a fixed number of clusters (6 HC), the intra-cluster correlation coefficient (ICC), the control event rate, the expected effects, and the level of significance and power of the study (Hemming K et al., 2011). Six clusters were 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 assumptions that in the intervention HCs the mean cure rate would have been 85% compared to 45% in the control HCs, with an ICC of 0.2, a power of 80%, an alfa of 5%.

4.6 Study variables

The study outcomes are reported in the Box 2.

The rate of cured among the enrolled children (SAM and MAM) was the primary outcome.
Each child was followed up prospectively to assess his/her primary outcome. All children who defaulted were followed up 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 Nutrition Service Delivery Assessment (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 (Ministry of Health, Uganda, n.d.) and using six pre-defined process indicators :1) correct diagnosis; 2) correct treatment; 3) correct complementary treatment; 4) correct evaluation of HIV; 5) correct patients' counselling; 6) correct exit outcome assignment.

- **Access to care**

Measured by the crude number of children accessing the nutritional service at HC. Equity in access to care we explored using a list of pre-defined patients' characteristics associated to wealth.

- **Cost effectiveness of SS**

Provider-perspective cost of providing SS to one health centre.
Incremental cost-effectiveness ratio per child cured.

4.6 Data collection and data entering

Data collection procedures

During intervention, data on each of the study outcome was collected prospectively.

Specifically, data on health outcomes, on quality of case management and on quality of data were collected prospectively for each child enrolled in the study, by six trained staff (each assigned to one HC). 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 (SOP) were developed to standardize the data extraction process and directly supervised by a nutritionist. Additionally, all children who defaulted were followed up to ascertain their living status.

Quality of nutritional services was measured at three time points (before the study, mid-term- end of the study) using the Nutrition Service Delivery Assessment (NSDA) tool, the official national instrument for assessing performance of nutritional services ("Nutrition Service Delivery Assessment Tool," 2015). It assesses the following 10 key capacity areas of nutrition service relevant at outpatient level: 1) general information on service implementation, 2) adequate human resources, 3) provision of nutritional services, 4) community linkage, 5) quality improvement activities, 6) materials and supplies, 7) nutrition unit requirements, 8) store management, 9) logistics management for commodities, 10) monitoring and evaluation. For each chapter, using strict criteria specified in the tool, a final judgment on the quality of the services is made and a final scoring is assigned in the form of one of four pre-defined 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 (Ministry of Health, Uganda, n.d.) and in the use of the NSDA tool ("Nutrition Service Delivery Assessment Tool," 2015).

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

extended to CHWs. We assumed that the total population in the coverage area did not change. Coverage was not estimated due to lack of a reliable estimate of the reference population for each HC.

Data on cost were collected from the accounting records of the implementing agency.

Stakeholder satisfaction and motivation is to be assessed at the final stakeholder meeting (July 2018) by dedicated pre-defined pilot-tested tools.

4.8 Data management and quality control

Strict quality assurance procedures were put in place to ensure accountability of data.

- Roles and responsibility were clearly distributed among the research team to ensure that all activities had a responsible team capable of carrying them out efficiently.
- Data were collected using pre-defined pilot tested tools
- Guidance material with clear and comprehensive operational instructions on how to collect data (such as case definition, inclusion/exclusion criteria) were developed and made available, in a user-friendly format.
- Data collection staff were trained, and their knowledge pre-tested, 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 validations rules and queries.
- Data were collected at fixed intervals, and entered in the databases in real time, by dedicated staff trained in data entering
- The databases were monitored at fixed intervals for completeness and internal consistency and any problems (such as missing data) were discussed in real time, and 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.

4.9 Data analysis

Data was analyzed with STATA 14. Categorical variables were presented as absolute numbers and proportions (95% 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 (MD).
To assessed the effect of possible imbalances in patients' characteristics, crude and adjusted Odds Ratio (OR) and 95%CI were estimated by forward fitting logistic regression models. We opted for a LOGIT model since is the more frequently used in medicine. The outcome was cured/not cured, and the covariates were baseline characteristics (ie, age group, sex, vaccination status, nutritional status and the randomization arm). Upon request of the funders we also performed PROBIT model, using the same variables, and calculating marginal effects.

All statistical tests were 2-sided. A p value of less than 0.05 was considered statistically significant. Results were interpreted looking both at the level of statistical significance and at plausibility and consistency of results across different outcomes.

4.10 Cost analysis

Key questions for the cost-effectiveness (CEA) analysis

With the CEA we aimed at answering the following questions:

1) What is the cost, form a provider perspective, of providing SS to one HC (with and without SS to CHWs) for one year?
2) What are the incremental cost-effectiveness ratios (ICERs) per children cured?

Model parameters

Measurement of effect

The cure rate, as directly derived from the Cluster RCT was the key outcome for this CEA. The effect comparison was the difference in cure rate before SS as compared to cure rates during SS, among the 3 intervention HCs. Details of the assumptions used for calculations of average number of children and estimated number of cured children are summarized in table 2.

Measurements of costs

Perspective

This was a provider perspective CEA focusing on only the additional cost of delivering SS and therefore zero cost for this activity were considered at baseline since SS had not been started. Two SS approaches were evaluated: 1) SS at HC level only; 2) SS at HC level including an extension to CHWs attached to the respective HCs. All estimates on costs were obtained from the project financial accounts and are presented in Euros (EUR) in accordance to these reports (Table 1). Costs were divided into: 1) start-up costs; 2) cost for delivering the intervention under steady state conditions. Start-up costs included: training of two supervisors, a coordinator (district nutritionist) and of the health facility staff (five for each HC) whose costs were based on the Ugandan daily allowance rate. The intervention running costs included: SS activities; fuel for transportation to the sites during SS; communication (phone calls airtime); equipment maintenance (which only comprised of replacing batteries of the electronic weighing scales); networking activities (workshops with the health facility staff meeting to discuss strategies to improvement of care and also share lessons learned).Other health care delivery related costs such as medications, HC staff or remuneration was not included because they were not specific to the intervention. Cost of developing the tools for SS were not included, since we assume these are developed at an early stage, at MOH level, and included in the national guidelines. Cost of coordinating the supportive supervisors were also not included, since this is already a duty of the district nutritionist (DN); however, training of the DN is 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 (Drummond et al., 2005), we opted not to discount costs given the overall short time horizon and the short time-frame between the intervention and the effect.

Table 2: Base parameters used for the CEA and assumptions

Parameter	Estimate	Range	Source
Average number of children treated per HC per year, Phase one	110	106 - 112	RCT results
Average number of children treated per HC per year, Phase two	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 one	54.3	23.3 – 85.1	RCT results
Estimated number of cured children at baseline in phase two	30.9	13.3 – 48.5	RCT results
During SS cure rate, %	83.8	71.0% - 96.6	RCT results
Estimated number of cured children during SS in phase one	78.8	66.7 – 90.8	RCT results
Estimated number of cured children during SS in phase two	111.0	93.7- 127.5	RCT results
Difference in number of cured children in phase one (SS to HCs only minus baseline)	47.9	42.3 – 53.5	RCT results
Difference in number of cured children in phase two (SS extended to CHWs minus baseline)	67	59.4 – 75.1	RCT results
Start-up costs			IA accounts
Training of two supervisors	120.0	102.0 – 138.0	
Training of a coordinator (DN)	60.0	51.0 – 69.0	
Training of the health facility staff	136.0	115.6 – 156.4	
Sub-total costs	316.0	268.6 – 363.4	
Running costs			IA accounts
Supportive supervision to the HC	391.7	333.0 – 450.5	
Fuel for transportation	60.0	51.0 – 69.0	
Communication and patients' follow up	206.0	175.1 – 236.9	
Equipment maintenance	3.7	3.2 – 4.3	
Print outs	2.8	2.4 – 3.2	
Networking activities	359.7	305.7 – 413.7	
Sub-total costs	1024.0	870.4 – 1177.6	
Supportive supervision to CHWs	308.16	261.9 – 354.4	IA accounts
Discount rate per year[1]	3.0%	0 – 6.0%	Drummond 2005
Assumptions			
• Final analysis results indicated that the cure rate significantly rose from 32.9% (95%CI: 14.1% – 51.6%) before SS to 83.8% (95%CI: 71.0% - 96.6%) during SS, p-value = 0.001. • The average number of children treated in 1 HC per year was calculated as follow: Mean number of children enrolled in the experimental group (considering the two phases separately) in each HC X time fraction in months out of a year, thus resulting in a) before SS to CHWs in (165/3) x (12/6) =			

110 children (95%CI 106 - 112); b) with SS 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 cost of delivering the intervention, with a provider perspective.
- The costs of trainings included the daily allowances (as per the local government official daily allowances) and, when appropriate, meals (from local service providers in Arua).
- Cost estimates included a day allowance to the DN and CHW members as per the local government guidelines, and fuel for transportation Abbreviations: IA: implementing agency
- Other health care delivery related costs (such as medication, staff remuneration etc) were not included. Cost of activities which 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, media coverage.
- Cost of developing the tools for SS were not included, since we assume these are developed at an early stage, at MOH level, and included in the national guidelines.
- The key outcome evaluated is the primary outcome of the study, ie. cure rate
- Following the study aims, costs are calculated per HC with a time horizon of 1 year, based on the data provided from the study.
- We assumed that, as in the RCT study that a total of 4 SS visits to the HC staff were delivered biweekly for the first 2 months, then monthly, for a total of 4+10=14 total visits in a year.
- Personnel involved in the SS visits included two supervisors; costs are calculated based on the Ugandan daily allowance rate
- Cost of coordinating the supportive supervisors are NOT included in the primary analysis, since this is already a duty of the DN; however, training of the DN is included under start-up costs.

[1] Discount rate not applied due to the short time duration of the study.
Abbreviations: IA: implementing agency

Incremental cost effectiveness analysis

The incremental cost-effectiveness ratios (ICERs) for phase one and phase two to determine the additional cost for every child cured under the two SS approaches were calculated using the formula;

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

where C_1 is the cost of SS and E_1 is the number of cured children for the two SS approaches:

1. Phase one ICER; where C_1 is the cost of SS delivered to only the HC staff and E_1 is the number of children cured during this phase
2. Phase two ICER; where C_1 is the cost after extending SS to CHWs and E_1 is the number of children cured during this phase

And C_0 and E_0 are the costs and effects estimated at baseline before delivery of SS in these facilities. Since only additional SS costs were considered, the C_0 was taken as zero, for both phases because SS had not yet been started in these HCs.

4.11 Possible sources of bias and strategies to reduce them

- Externalities and spill overs were not expected, since: a) children from the same family were expected to access the same HC and received the same type of treatment
- Contamination in regard to the delivery of the intervention was minimized, by using the HC as a unit of randomization and not the health workers. The intervention was delivered at HC level, i.e. all staff in each HC received the same intervention. Health workers did not routinely rotate among HCs. Contamination among receivers (such as mothers migrating from one HC to another HC) was prevented by checking patients' residence.
- Blinding: children and their families were blinded to the characteristic of the intervention and to the allocation group; blinding of receiver 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 is an objective outcomes) lack of blinding should only affect the study with minor risks of bias (51).
- Hawthorne effects was 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/unnatural "study setting". This "pragmatic design" was chosen because the study aimed at exploring 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 result section).
- John Henry effects, in the given context, cannot be ruled out: after discussion with local professionals, it is possible that staff in the "control HC" actively work harder to overcome the "disadvantage" of being in the control group.

4.12 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, as described below.

- General setting: Arua district is characterized 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; mid-level of security; urban/peri-urban context.
- Population: It is reasonable to think that this sample is not significantly different to the broader populations of children with malnutrition in other refugee settings in Uganda, as well as 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. Potentially, a similar intervention could be implemented in other similar settings.
- Control: control was standard care (no intervention).
- Outcomes: health outcomes are the classical health outcomes utilized for the evaluation of nutritional programs. Case definitions were based on the National IMAM guidelines.
- 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.

4.13 Ethical considerations

Institution Review Boards

The study was submitted to competent ethical authorities including the Uganda National Council of Science and Technology, School of Public health Makerere University Ethical committee, and the Ethical Committee of the IRCCS Burlo Garofolo. Ethical clearances were received on 6th June 2016 from the Uganda National Council of Science and Technology (UNCST), on 27th April 2016 for Makerere University School of Public health ethical committee, and on 1st April 2016 for the ethical committee of the IRCCS Burlo Garofolo, Italy. 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 et al., 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 (ClinicalTrials.gov: NCT02001116).

Informed consent

Approval from local leaders was sought before beginning activities in Arua district. Prior to starting the study, the team conducted awareness activities to secure commitment, and encourage participation from stakeholders at the local level. Health authorities were informed of the authorisation received to carry forward the study. At the cluster level, staff was informed on the objectives and methods of the study, and their written consent was obtained. At the individual level, children and their parents/guardians where informed, and enrolled if providing written consent to participation 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 and 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) and a translator was used if necessary. During the consent discussions, each section of the consent form was read exactly as it is written either by study personnel or by the translator, and then further explained to the participant or parent/guardian if necessary. All participants and parents/guardians were informed that participation in the study was completely voluntary and that they may withdraw from the study at any time. If the person asked to provide consent was unable to read or write, their fingerprint substituted for a signature, and a signature from a witness to the informed consent procedures was obtained.

Confidentiality

To ensure that confidentiality was maintained, all information gathered was treated as private by the study personnel, and records were kept securely in locked filing cabinets and offices. For all data collected as part of the study, participants were assigned a unique identification number. No personal identification information such as names was used in any reports arising out of this research. All project staff were trained on procedures for maintaining confidentiality.

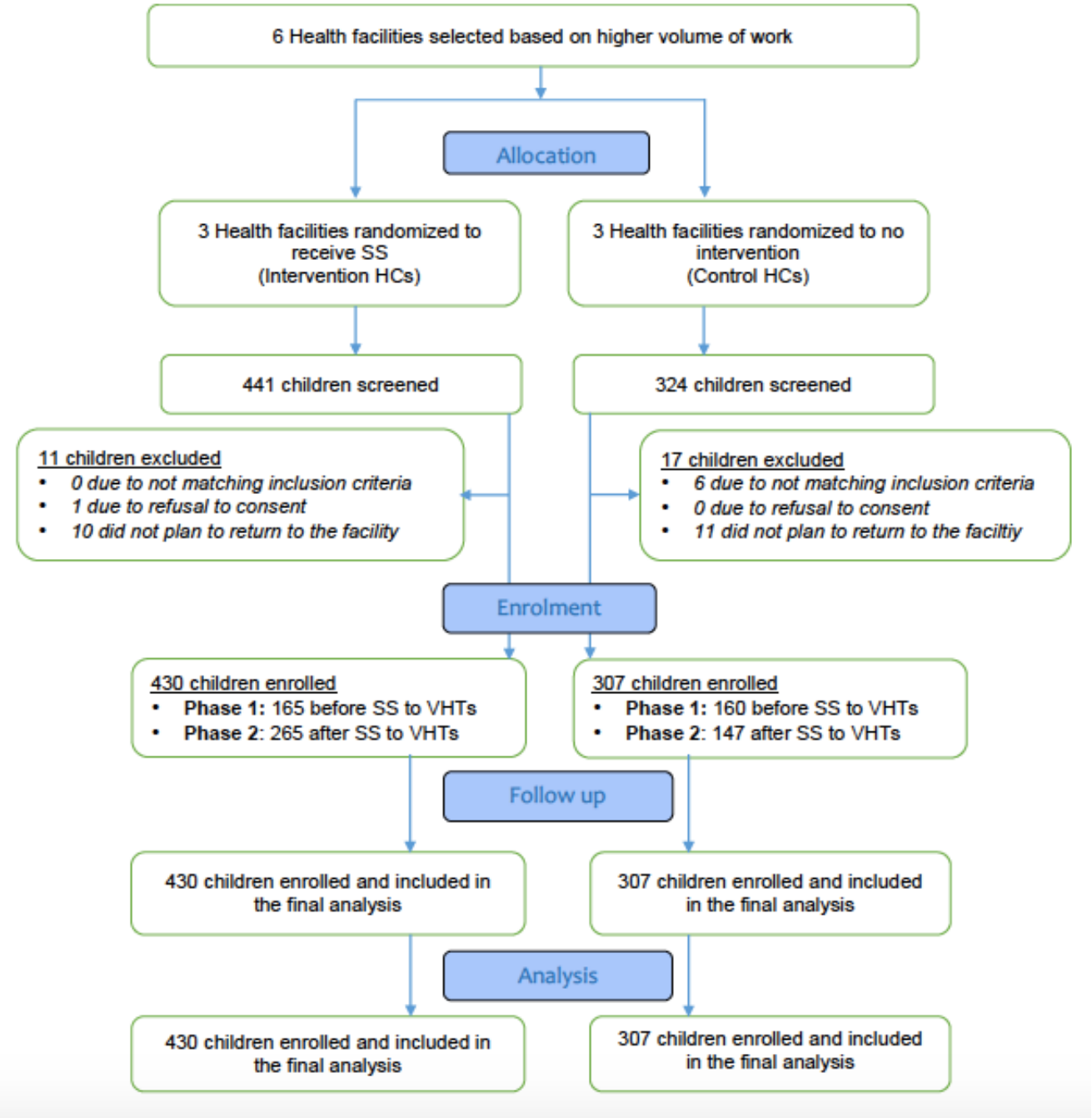
5. Impact analysis and results of the key evaluation questions

5.1 Characteristics of enrolled children

Baseline characteristic of HCs did not show significant differences. Children enrolment flow is shown in Figure 1. 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 to control.

Figure 2: CONSORT Flow diagram



Characteristics of enrolled children are reported in **Table 3.** 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 such as age, sex and vaccination status were not statistically different between the two arms.

Table 3: Children characteristics at enrolment

Variable	Randomisation arm		Chi p-value
	Intervention N = 430	Control N = 307	
Age categories (months)			
6 to 12	203(47.2)	122(39.7)	
12 to 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 B/F	7(1.6)	0	
Replacement feeding	0	0	
Mixed feeding	5(1.2)	4(1.3)	
Complimentary feeding	241(56.1)	201(65.5)	
No longer B/F	**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 4 presents the health outcomes during the intervention phase of the study. In the HCs receiving SS the cure rate was significantly higher than in the control facilities [83.8% (95%CI 71.0-96.6) vs 44.9%(95%CI 38.2-51.6)], mean difference 38.9% [RR = 1.91 (95% CI 1.56 to 2.34), p=0.010]. On the other side, defaulting rate was significantly lower in the intervention HCs compared

to control facilities; [1.4% (95%CI 1.1% to 1.8%) vs 47.2% (95%CI 37.3% to 57.1 %)] in the control, mean difference - 45.8% [RR = 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.

Overall less than five percent of children had any of the other outcome (non-responder, OTC transfer, ITC transfer, dead), and for these outcomes there were no statistical significances differences among allocation groups.

Table 5 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 the odds in the control arm [AOR = 7.6(5.3-10.9), p = 0.001]. There was trend of increasing odds of being cured with increasing child's 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] while children diagnosed with uncomplicated SAM had lower odds of being cured [AOR =0.5(0.3-0.7), p=0.001)]. Other variables such as sex and vaccination status did not have statistically significant effect on the odds of being cured.

Results of the PROBIT model are consistent with results of the LOGIT model. When corrected for baseline characteristics, being in the intervention arm increased the probability of being cured by 42% (95%CI 0.35 to 0.48), p=0.001. Having Sam rather than MAM decreased the probability of being cured by 12% (95%CI -0.18 to -0.06), p=0.001.

Table 4: Health outcomes

Health outcomes	Randomisation arm									
	Intervention HCs				Control HCs				Difference in mean %	p-vale
	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(-.3-1.1)**	-0.4	0.378

Table 5: Multivariate logistics regression results

Characteristics	Patient cure status		Crude OR (95% CI)	Adjusted OR (95% CI)	p-value
	Cured N=492	Not cured N=245			
	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**

5.3 Quality of case management

Table 6 presents process outcomes on case management (as the mean proportion and 95%CI). Six process outcomes measured quality of case management as 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, RUTF 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% (95%CI 43.2 to 74.3) of control facilities, compared to 94.0% (95%CI 83.7% to 100%) of intervention facilities (RR= 1.52 [1.40-1.67], p=0.001).

Table 6: Quality of case management

Process outcomes	Randomisation arm									
	Intervention HCs				Control HCs				Difference in mean %	p-value
	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			
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(1000	**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	-

5.4 Data quality

Ensuring high quality of data was essential for the study. **Table 7** presents data quality, as measured by three pre-defined indicators (data completeness, consistency and accuracy). During the intervention phase, the proportion of cases with data of good quality was over 99% in both groups, for all indicators.

Table 7: Data quality

Data quality	Randomisation arm									
	Intervention 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)**	**Difference in mean %**	**p-value**
	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

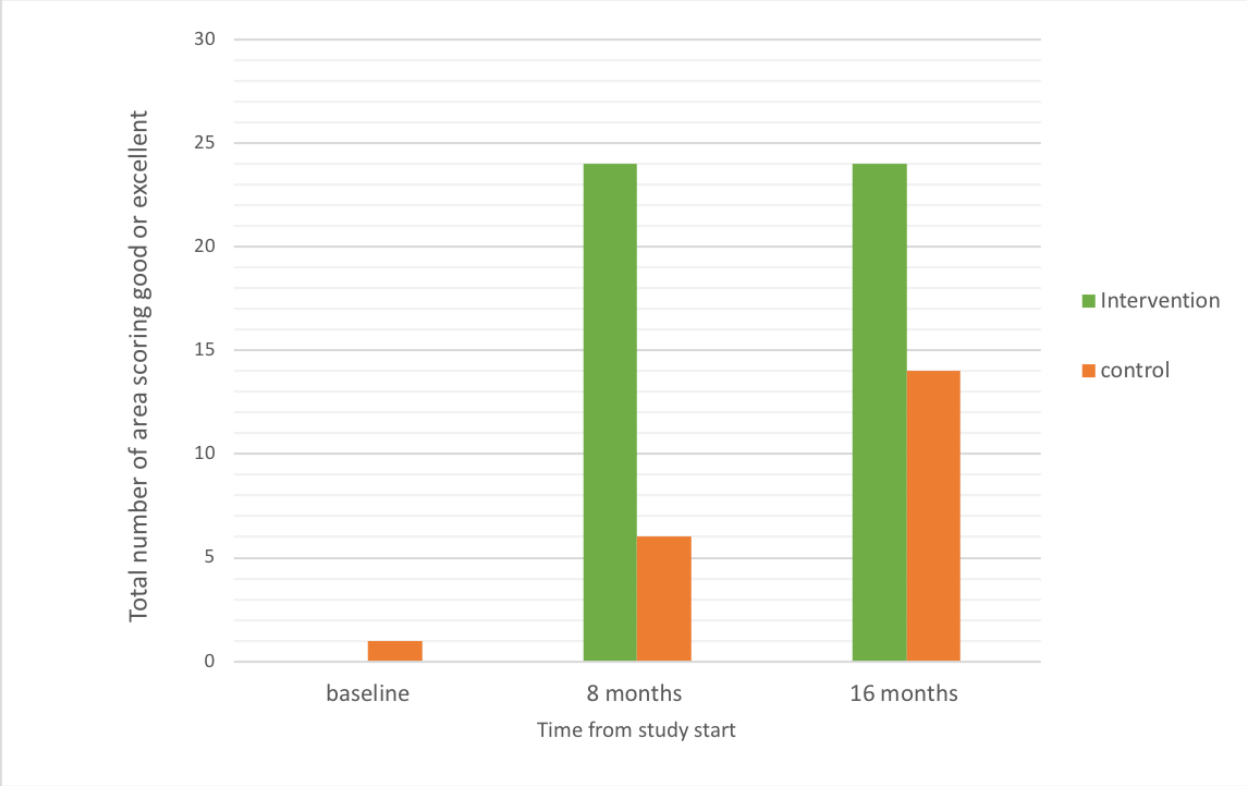
Quality of nutritional services was measured at three time points (baseline before the start of the intervention, mid-term, end of the intervention phase), using the national tool (NSDA tool). The tool provides, through predefined checklists, a summary score of the quality of 10 key capacity area (see section 1.8) using four pre-defined categories (poor, fair, good excellent). **Table 8** summaries quantitative results, while figure 3 presents details of the summary of scores at three time points. As reported in table 8, at baseline, all facilities except one scored either poor or fair under all the 10 assessment areas of the NSDA tool, and there was no statistical significance between the intervention and control for good or excellent score (p= 0.313). At the end of the intervention phase both groups had increased the number of area scoring either good or excellent, with a significant difference between intervention and control arm [24/30 (80%) vs 14/30 (46.6%), RR = 1.7 (95%CI 1.1 to 2.6), p = 0.007].

Table 8. 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 phase 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 objectives of the study was to increase access to care. In order to accurately evaluate the effectiveness of the intervention, the study period was split in two phases: in phase 1 (up to March 2017), SS was delivered only to HC staff, in phase 2 (from April 2017), SS was extended to community health worker (CHWs). As reported in **Table 9**, before the extension of SS to the CHWs the number of children enrolled in each group was not significantly different (in Phase 1:165 in intervention vs 160 children in control). After the extension of SS to the CHWs there was a significant 38.6% more children accessing nutritional care in the intervention arm compared to control (Phase 2: 265 in intervention group vs 147 in control arm, RR=1.26 [95%CI 1.11 to1.44], p=0.001). This explains the difference in the total number of children enrolled (430 in the intervention group vs 307 in the control).

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

Table 9: Effect of SS of Village Health Teams

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

5.7 Cost effectiveness analysis

Cost of delivering supportive supervision

The total cost of delivering SS in phase one to a single HC in one year was estimated at € 1,340.0 (range 1,139 to 1,541) with running costs contributing up to 75% of this cost (Table 10). The three largest expenditures in the running costs were: supportive supervision visits (€391.7), networking activities (€359.7) and communications and patients' follow up (€206.0)
When SS was extended to CHWs, this additional activity that was estimated to cost € 308.2, raised the cost of delivering SS in phase two in a single HC in one year to € 1,648.2 (range 1,401 – 1,895).

Table10: Costs of delivering SS in phase 1 and phase 2

Intervention Phases	**Cost in euros**	**Percentage cost contribution**	**15% variation in cost**
Phase 1: SS to HC staff only			
Start up costs	316.0	23.6	268.6 – 363.4
Running costs	1024.0	76.4	870.4 – 1177.6
Total costs	**1,340.0**		**1,139 – 1,541**
Phase 2: SS to HC staff + extended to CHWs			
Start up costs	316.0	19.2	268.6 – 363.4
Running costs	1024.0	62.1	870.4 – 1177.6
SS to CHWs	308.2	18.7	261.9 – 354.4
Total costs	**1,648.2**		**1,401 – 1,895**

Base incremental cost effectiveness ratio

The base ICER estimates are presented in table 11. The incremental effect of SS on number of cured children in phase one was 56 children and the incremental cost was €1340.0. This resulted into an ICER of €23.9, the additional cost required for every additional child cured as compared to the baseline.

When SS was extended to CHWs in phase two, 90 children were estimated to have been cured and the incremental cost was €1648.2. This resulted into an ICER of € 18.3, the additional cost required for every additional child cured in this phase as compared to the baseline.

Table 11: Base incremental cost effectiveness ratio results

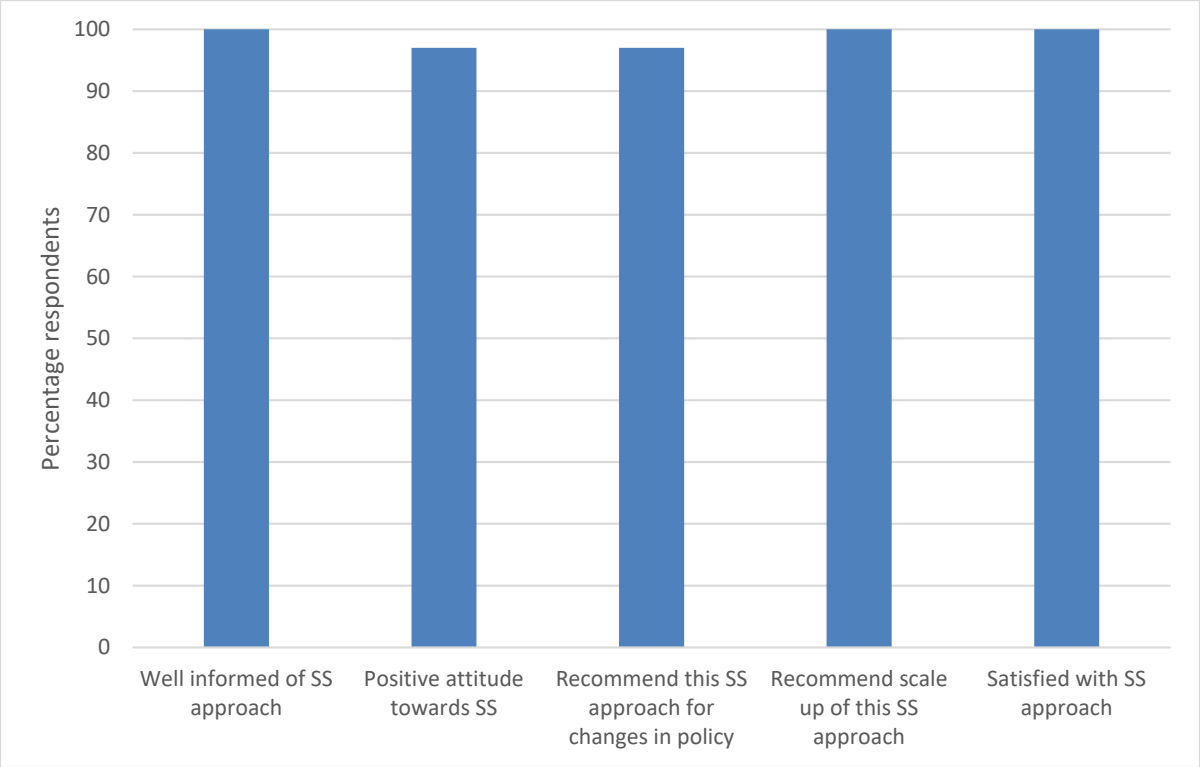
Phases	**Effectiveness**			**Cost**		
	Cure Rate	**Effect** *(No. of cured children)*	**IE**	**Total cost**	**IC**	**ICER**
Phase one comparison						
SS to HC staff only	83.8%	92		1340.0		
Baseline	32.9%	36	56	0	1340.0	23.9
Phase two comparison						
SS to HC staff + extension to CHWs	83.8%	148		1648.2		
Baseline	32.9%	58	90	0	1648.2	18.3

IE: Incremental Effectiveness, IC: Incremental Cost, ICER: Incremental Cost Effectiveness Ratio

5.8 stakeholder satisfaction and motivation

Three stakeholder dissemination workshops were held: a workshop in Trisete among the project partners; a workshop in Arua district (the study setting) involving local team, staff of the HC involved in the study, and local health authorities and partners; a large national restitution workshop in Kampala involving national stakeholders. The aims of both workshops were to present the final results of the study to all key district and national stakeholders.
During these meeting, there were also detailed discussions of the possible strategies to facilitate evidence uptake and sharing of study communication products such as the policy brief.
Additionally, we also conducted a stakeholder satisfaction and motivation assessment whose results are presented in **figure 4.** Overall, 37 stakehollders were interviewed. Of these, most were either very satisfied (51.4%) or satisfied (48.7%) with the study and the SS approach. One of the stakeholders suggested that this approach could be piloted in a program setting to strengthen the evidence generated in the study before it could be scaled up.

Figure 4: Graph showing parameters for stakeholder satisfaction of SS approach



6. Discussion

This cluster randomized control trial has shown that enhanced nutrition SS as delivered in this study (ie. high intensity) was a low-cost intervention able to significantly improve cure rates among 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 of the defaulters' rate, and a significant improvement in quality of case management, quality of data, general nutritional service delivery, and access to care. Other studies in low and middle income countries suggested that SS can be an effective strategy to improve quality of case management and health outcomes of mother and children at hospital or outpatient level (Hoque DM et al., 2014; Lazzerini et al., 2017; McAuliffe E et al., 2013). However, this is the first study that specifically tested SS to improve health outcomes of malnourished children. The study was conducted in a humanitarian setting with very low resources, were baseline quality of care was highly substandard. In these settings identifying effective intervention capable to improve health outcomes, especially for malnourished children who have a very high risk of death, is crucial.

As such, study findings are extremely relevant: this study adds to the previous knowledge that, in a setting with very low resources, SS may be a highly effective strategy for improving the health of malnourished children.

Notably, despite the control group did not receive SS, we observed in this group a relative

improvement in several outcomes (cure rates, quality of case management, quality of data and general nutritional service delivery), notwithstanding that the intervention facilities performed better. This may be explained as a “study effect” (ie, it is plausible that the presence at facility level of well-trained nutrition data collectors affected positively the overall performance of the health facility staff.)

Of note heterogeneity in quality of care at baseline was observed in our sample, despite no significant differences in the mean cure rate among groups. Heterogeneity in quality of care, even among nearby facilities is in the same setting, is a common finding (*Primary health care supervision manual.*, 2009; Rohde J., 2006) and should not be perceived as unusual. Most importantly, this study showed that SS can reduced heterogeneity in health outcomes.

Obviously, SS 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” (eg adequate human resources) irrespective of the intervention is not surprising. Some improvements (such as having adequate human resources) require economic resources, and actions from the district and central government authorities, activities that go beyond SS, and beyond the actual mandate of the supervisors.

The finding that SS also increased access to care is extremely important, since delay in accessing care may imply the death of vulnerable children as the malnourished one. The collaborative SS encouraged CHWs to conduct better their activities, such as 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 somehow recommended in the Ugandan guidelines, as well as in other guidelines, but more often not formalized 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 SS, and this model proved to be effective, and even more cost-effective than providing SS only at HC level. Future studies may test whether providing to CHW an economic incentive plus SS is more effective that providing only an economic incentive.

We acknowledge some limitation of this study. First, accountability of baseline data on health outcomes, essentially represented by historical data in the HMIS and in the nutritional registers, may be sub-optimal. However, these are the official data and no other data is available. Study finding showed that there was a clear improvement in outcomes according to the before and after comparison, but also when comparing the intervention to the control group, thus suggesting that the intervention is actually effective.
Imbalance among groups in patient characteristics did not favor a positive effect of the intervention, thus resulting in a possible under-estimation, and not in an over-estimation, of the treatment effect.
Although the study sample may be regarded as relatively small, the included HCs contributed with over 45% 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 beside the intervention, such as 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 SS was actually effective.
This study was conducted with well-trained, highly motivated local staff and the supervision was conducted at high frequency (two-to-four weeks' interval). These characteristics may be difficult to replicate in a "real setting", where absenteeism, high staff turn-over, lack of coordination (Kiwanuka et al.,2008) and resources are frequent problems. However, still the study brings as lessons that when the above-described factors are present, quality of care can be achieved.

Strength of the study include the cluster randomized trial design, and the quality assurance procedures used to ensure data quality. Quality of data was over 99% on all indicators (data a completeness, accuracy, consistency), in both groups. Even though the study was not blinded, the use of objective outcomes measures should have limited the potential for assessment bias.

Results of the study may be generalizable to other similar settings. Importantly, characteristics of the intervention may have affected results: in this study SS 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 weeks' intervals. Future studies aiming at exploring effectiveness of SS in other settings should both take into account context factors, and intervention characteristics.

7. Specific findings for policy and practice

Study findings bring an important lesson both for researcher and policy makers. In conclusion the study suggest that SS may be an effective and reasonably low-cost intervention to improve health outcomes of malnourished children at outpatient level in a setting with very low resources. This approach also may improve access to health facility, quality of case management and quality of data.

Future studies should explore effectiveness of SS in other settings, and confirm these results.

In terms of policies, the SS approach as proposed in this study may be scaled up in other similar districts in Uganda, as well in other similar settings. Currently Uganda guidelines, despite recommending SS, do not detail specific activities or tools to be used in this regard. This study provided a specific model of SS, with defined activities and tools, and as such may be used to improve national guidelines. The use of locally available staff as SS providers who are already under district employment and the use of local guidelines as reference standard should facilitate the sustainability of the intervention.

8. Translation of evidence into policies

8.1 Collaborations that make it likely for this study findings to inform policy

The collaboration between the WHO CC and CUAMM dates back more than 20 years, through a

number of different projects in different countries in Sub-Saharan Africa (Uganda, Tanzania, Ethiopia, Mozambique, Burkina, Togo and others). In 2014 a request was explicitly made from CUAMM to WHO CC to collaborate in evaluating the quality of care for children with malnutrition in the CUAMM ongoing projects. The opportunity to do an impact evaluation on SS in West Nile was discussed with partners (CUAMM) and found immediate agreement. The evaluation questions, and the methods of the evaluation were developed in collaboration with CUAMM and other local stakeholders. They reflect the current main area of interest of CUAMM (malnutrition/HIV/Maternal and Child health/Quality of Care) and of other stakeholders (UNICEF, MOH, local health authorities, local community etc).
CUAMM is working in collaboration with UNICEF and MOH, and local health authorities in other quality improvement projects in Uganda.

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

8.2 Current expectations

Locally there is great interest with respect to the results of this project. The importance of for this impact evaluation is highly perceived form both local policymakers and implementing agencies, considering that: a) prevalence of malnutrition in children in West Nile Region Uganda is high and b) beneficiaries of the intervention of quality improvement are large segments of the population, probably the poorest.

All of the relevant stakeholders, such as the Office of the Prime Minister, Ministry of Health, Ministry of Education, Local Government, UNICEF and the Academia have shown satisfaction of the intervention and almost all would recommend this for change of policy and scale up. Most importantly, all key stakeholders undersigned a support letter. This positive attitude is important especially at a time when the Ministry is reviewing and updating the national IMAM guidelines for which such evidence can be considered to fill the gaps related to conducting an effective supportive supervision.

As is the case in many low and middle income countries, the inadequacy funds allocated to supervision activities by the MoH was also discussed as a limitation to scale up. However, stakeholders suggested that in such instances, this study finding provide evidence and a platform for funding advocacy beyond what has been the norm (provision of supplies, materials and human resources etc).

A number of recommendations was made from different stakeholders to foster scale up included; targeted dissemination meetings and engagement with policy makers, developing a policy brief summarizing the study findings and recommendations for wider dissemination, developing a supportive supervision package (including tools and checklist) that could be piloted in a smaller region (possibly those over seen by the implementing partner – CUAMM) to strengthen this study's evidence and through scientific publications. The study team and implementing partner are already in the process of carrying forward these recommendations.

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