A comparative study on the effects of Ready to Use Therapeutic Food + PUR® in the management of severe acute undernutrition in children under 5 years



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Democratic Republic of Congo

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P&G
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1 Executive Summary

Bandundu province is situated in the west of the Democratic Republic of Congo (DRC). Although there exists little armed conflict the province has suffered significant socio-economic slowdown since the 1980s highly affecting the local population. The lack of public services and the linked rural exodus have led to areas being particularly vulnerable to malnutrition. The Health Zone of Popokabaka, located 400km from Kinshasa is one of these areas with a population of 168,546 people. The target population of this study (children between 6 - 59 months) was estimated at 28,652 (17% of the total population) (National Census, 1984[1]).

The general objective of the study was to compare, within the framework of the national protocol of the Ministry of Health (MoH) for Integrated Management of Acute Malnutrition (IMAM), the efficiency of using Ready-to-use-Food (RUTF) + PUR® versus RUTF alone in the nutrition treatment of SAM children under the age of 5 years without medical complications.

Previous to the study, two hypotheses were developed and justified:

1. **SAM cases without medical complications consuming RUTF + PUR® have a lower prevalence of waterborne diseases during the course of their treatment.**
   Populations living in the intervention area use water collected from unprotected rivers, wells and other water points, which expose them to waterborne diseases such as diarrhoea, intestinal worms, dysentery, typhoid or cholera. The population and children in particular, are thus more prone to be affected by waterborne diseases (ACF, 2009). As such, the integration of PUR® into the standard treatment would reduce or prevent the occurrence of these diseases.
2. **SAM children consuming RUTF + PUR® have better outcomes in terms of treatment time (shorter) and weight gain (higher).**
   There will be an absence or reduction of occurrence of waterborne diseases due to the treatment of SAM children with RUTF + PUR®. Consequently, this will shorten the length of stay in the OTPs and increase their daily weight gain (given that the length of stay is a denominator while computing the weight gain).

The study was rolled out in seven health centers, divided into two groups - in the South for the control group and in the East for the intervention group. The study data collection began on December 2012 and ended in March 2013. A total of 207 children were included in the study and followed until discharge within a period of four months.

The study used the regular nutrition protocol follow-up systems to gather data from the children included in the study. At the weekly Nutrition centre sessions, care takers were asked about the occurrence of any clinical symptoms since the last visit, anthropometric measurements of the child were taken, and the child underwent a complete physical examination.

[1] Last census - 1984 // Population estimates done based at 1% population growth per year

At the household level, every two weeks a questionnaire on dietary consumption, hygiene practices and the use of PUR® (intervention group) was facilitated. A second visit was conducted to ensure the proper application of RUTF and PUR®.

A total of 207 children were enrolled in the trial, of these 105 in the intervention group and 102 in the control group. Upon admission, the two groups were statistically similar with respect to age, sex and breastfeeding status. The intervention group had a slightly worse nutritional status with respect to weight-for-height z-score (-3.14 intervention vs. -2.93 control, p=0.02), but had larger MUACs (116.5mm vs. 114.2mm).[2]

With respect to household characteristics, children in the intervention group came from smaller households with an average size of 6.0 members, as compared to 7.0 in the control group (p<0.001). Children in the intervention group were also from households with lower levels of parental education: 16.2% of the intervention group had parents that had completed secondary schooling compared to 31.4% of the control group (p=0.04).

Significant differences were observed between the two groups with respect to the water sources. The majority of households in the intervention group (67%) relied on unprotected springs as a water source, whereas control households primarily relied on other surface water (88%). Water quality testing found an average residual chlorine level of 0.26-0.34 in intervention households. Based on the findings, there is a strong acceptance of the intervention group, with 95% - 100% of usage.

Children in the intervention group had a significantly shorter mean length of stay as compared to children in the control group (26.4 days vs. 30.4 days, p=0.06). Average daily weight gain was also higher among the intervention group than in the control group, at 7.3g/kg/day and 6.6g/kg/day respectively, however this difference was not statistically significant (p=0.13).

With a decrease of 4 days in the average treatment time, the average cost of the intervention group using PUR® for 26.4 days, amounted to a total of 36.96USD per child and treatment (31.68USD for RUTF and 5.28USD for PUR®). The cost of 4 days of RUTF is calculated at 4.8USD. With a cost of 5.28USD for the PUR® per treatment course of 26.4 days, this indicates that the reduction of 4 days treatment time would be able to cover 90.90% of the supplementary cost.

The study results concluded that while the study showed significant results towards the reduction of average length of stay, additional studies to improve results validity need to be facilitated:

- Further studies should have larger sample sizes and should be conducted in areas with high levels of untreated drinking water;
- Further studies should be applied in contexts with longer average nutrition treatment time;
- Further studies should reduce the data collection to avoid data-overload; and
- Further studies should include additional alternative intervention options to improve water quality and household water chain management through e.g. local water

[2] Children with WHZ > -2 met the MUAC inclusion criteria.

treatment products, water storage containers, etc.

2 Context of Study

2.1 Geographical and Demographic data

Bandundu province is situated in the west of the Democratic Republic of Congo (DRC), a province which is the bread basket of the country and provides Kinshasa, the capital, with most of its agricultural commodities. Even though there is no ongoing significant armed conflict, there has been a socio-economic slowdown since the 1980s affecting the local population. The lack of public services, as well as a decline in agricultural production linked to the rural exodus has led to certain areas becoming particularly vulnerable to malnutrition – isolated areas being the most affected.

The Health Zone of Popokabaka in Bandundu, located 400km from Kinshasa is one of these areas. The Popokabaka Health Zone covers an area of 6,949 km² with a population of 168,546, of mostly Yaka ethnicity, and an average population density of 24 inhabitants per km². The target population of this study (children between 6 - 59 months) is estimated at 28,652 (17% of the total population) (National Census, 1984[3]).

The Health Zone's climate is tropical with three seasons: a dry season from mid-May to the end of August, a rainy season from September to mid-May, which is interrupted by a short dry season in January. Its geography consists of hills, plains and valleys of clay, and sand rich soil. Its vegetation is principally made up of woody savannah and some river-bank woods. On a hydrographic level, the zone is crossed by the Kwango, Wamba, and Twana rivers as well as some smaller streams.

This Health Zone is accessible by road from the Bukanga Lonzo road in the direction of Kasongo Lunda, and by river (along the river Kwango).

2.2 Socio-economic situation and food security

The population's principal economic activity is subsistence farming. Small business, livestock rearing, as well as poultry, artisanal fishing, hunting, and wild food collection (especially insects) are the primary sources of income. Some seasonal activities (harvesting termites and mushrooms) and panning for diamonds are less lucrative activities.

According to an ACF nutrition survey in 2010, the vast majority of households practice agriculture. The most important crops include cassava, maize, groundnuts, black eyed peas, sesame and pumpkins/squash. The majority of the crops are either sold or exchanged for manufactured products (e.g. clothes, sanitary products, etc). Maize is mainly used to produce a local beer. Squash, plantain, and palm oil are produced in insufficient quantities to cater for the district's needs.

Small businesses mostly sell agricultural products (cassava, maize, groundnuts, beans and black eyed peas), as well as insects, sold or exchanged by farmers. Markets are held twice a week within the district, and there are a few small shops and pharmacies. Villages, far from the

[3] Last census - 1984 // Population estimates done based at 1% population growth per year

Health Zone's centre, benefit from trade with the bare necessities and pharmaceutical products.

Cassava is the staple food, eaten as porridge and generally accompanied by vegetables and leaves, in particular cassava leaves. The typical diet rarely includes protein, which comes mainly in the form of vegetables (groundnuts, black eyed peas) and/or animals (from hunting and fishing, wild foods and insects). Often the later are seasonally produced in small quantities and are sold.

Small livestock and poultry rearing are carried out by the majority of the households. These products are generally sold and rarely eaten, and the income from sale is used for a variety of costs (e.g. school fees, medical expenses, family arrangements, etc.). Large livestock farming is mostly carried out by local Jesuit fathers. The meat is exchanged at local markets for other agriculture produce, or sold to Kinshasa. Fishing is carried out on small scale in the Kwango, Wamba and Twana rivers. The best season for fishing is the dry season and generally the fish caught is sold or exchanged on the local market.

Hunting of game in the forest is carried out during the dry season with the application of traps, lines and shotguns. Hunting is limited due to the rarity of certain species, frequent bush fires, deforestation for agriculture, and a lack of hunting equipment. Hunted game is mostly used for family consumption.

Panning activities for diamonds has had a destabilising effect on the local communities, causing internal migration and exodus until 2006, with consequential lack of available manpower for agriculture cultivation, which continues to persist today along the border with Angola. Though, this phenomenon has slowed down as conditions for the Congolese workers are not as favourable as they were before 2006.

The district is affected by two annual lean seasons (from August to November and from March to May) when household food insecurity reaches its peak, the nutritional status of the population is affected, and the prevalences of undernutrition increase. During these periods, adults of the households are busy preparing the fields (ploughing and sowing) during the day and hence have less time to care for their children. Additionally, meal consumption and frequency reduces to one meal per day.

This study was carried out at the end of the lean season and beginning of the harvest, a critical period from a nutrition perspective, with undernutrition prevalence slowly subsiding with the new harvest being available for consumption.

2.3 Nutrition and Sanitary Conditions

The Health Zone of Popokabaka is comprised of one general referral hospital, 25 Health Centres, and 23 clinics, all ensuring that essential medical care is provided to the local population.

The most frequent medical problems encountered by children under five years of age in this zone are malaria and intestinal parasites. Table 1 provides more details on the case load reported between December 2012 and Feb 2013.

Table 1: Disease caseload of children < 5 years old (Dec 2012 - Feb 2013, MoH Health Zone Statistics)

Diseases	# of Cases	%
Malaria	316	41%
Intestinal Parasites	160	21%
Acute Respiratory Infection	83	11%
Diarrhoea	67	9%
Others	137	18%
TOTAL	**763**	**100%**

An anthropometric nutritional survey carried out in June 2011, by the *Programme National Nutritionel* (ProNaNut), showed elevated rates of acute malnutrition: global acute malnutrition (GAM) of 15.3% (CI 10.9% - 21.0%) and severe acute malnutrition (SAM) of 4.3% (CI 2.3%-7.8%). A provincial survey was undertaken by ProNaNut in May 2013, showing prevalences of GAM 10.4% (8.2%-13.1%) and SAM 1.6% (1.0%-2.6%) (ProNaNut, May 2013). While there is a notably slight improvement of the prevalence, this is likely due to the different seasons during which the data was collected, rather than substantial structural change and improvement in the area.

Identified undernourished children are referred to one of the 11 health centres for special treatment; including 10 outpatient therapeutic programs (OTP) and one stabilization centre (SC) for cases with medical complications, which are all implemented through the MoH structure with support from ACF. This support includes nutritional treatment for SAM cases that is available as part of the Health Centre's basic routine activities. As part of the nutrition treatment protocol, admitted children are provided with Vitamin A supplements and are dewormed with Mebendazole.

There is a limited supply of safe drinking water in the district, where just one water source is set up within the Health Zone but it is not yet connected to the town's water supply system. Moreover, REGIDESCO (the water distribution company for DRC) has no presence in the district. Therefore the local people collect water from unprotected sources, like rivers, streams, rainwater collection systems, etc. This lack of access to safe drinking water is a cause for waterborne diseases affecting the local population.

Hygiene practices and sanitation facilities also remain poor, even if taking into account a satisfactory level of access to mostly improved latrines (76% of the population has access to a latrine). Nevertheless, 34% of the population generally defecate out in the open. Local village level cleanliness and sanitation is limited, and UNICEF along with the Health District have begun a campaign to sanitise villages and schools, which started in 2012 and already covers 20 villages.

This study was implemented over a period of 20 months (August 2011 to March 2013) and was carried out within 7 of the 10 Health Centres, each of which provide OTP services.

2.4 Map of Popokabaka Health Zone



3 Study Model and Hypotheses

Given the local context in Popokabaka, and the limited access to safe drinking water, the ACF nutrition and water and sanitation teams considered the absence of safe drinking water as one of the key underlying causes of undernutrition in the area. The initial research question for the presented study was therefore formulated around the improvement of the effectiveness of available SAM treatment in link with the provision of safe drinking water - what would be the impact of PUR® in addition to the standard SAM treatment protocol RUTF on the nutritional recovery of children, without medical complications, suffering from SAM? To define the research further, the following models and hypotheses were developed.

3.1 Applied products

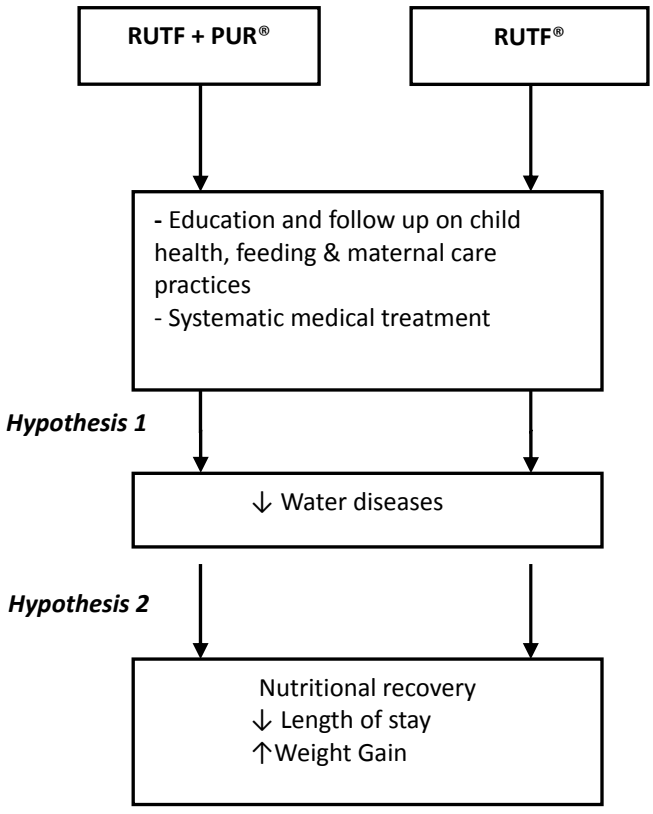
For the implementation of this research study, two key products are relevant to be introduced. The **Ready-to-Use-Therapeutic Food** (RUTF) used in outpatient therapeutic care, is a groundnut based paste, fortified with minerals and vitamins, with a high energy and protein content, which is used to treat SAM. A variety of commercial products are available (e.g. Plumpy-nut®, EZpaste®, etc.), but for ease of use, this study report will refer to RUTF as a generic term.

Additionally, the study will be using **PUR®**, which is a point-of-use water treatment product produced and provided by Procter & Gamble (P&G). The P&G Water Purifier is a flocculent-disinfectant applied at household level. For ease of use, this study report will refer to PUR® throughout the report.

3.2 Theoretical Model

For children affected by SAM (identified by anthropometric measurements) and admitted to an Outpatient Therapeutic Program (OTP), the standard treatment protocol encompasses an RUTF ration and medical treatment. Throughout the treatment process, the caretakers of SAM patients attend a variety of education sessions on health, hygiene and nutrition. A SAM patient is regarded as cured, or having recuperated, once anthropometric target indicators have been reached, i.e. a defined target weight, upon which the child is discharged. The length of stay and weight gain during this period vary depending on a case-by-case basis and may be influenced by different variables. This study is meant to assess if the addition of PUR® to the standard treatment has positive effects on the efficiency of the nutritional recuperation of SAM children, through the reduction of waterborne diseases which would consequently translate into a reduction of treatment time and an acceleration of weight gain. Figure 1 describes the theoretical model of the study.

Figure 1: Theoretical Model of the Study



3.3 Study hypotheses

Following the above reflection, two hypotheses were formulated and have guided the overall study:

a) Hypothesis 1

SAM cases without medical complications consuming RUTF + PUR® have a lower prevalence of waterborne diseases during the course of their treatment.

Justification of Hypothesis 1: Populations living in the intervention area use water collected from unprotected rivers, wells, and other water points, which expose them to waterborne diseases such as diarrhoea, intestinal worms, dysentery, typhoid or cholera. The population and children in particular, are thus more prone to be affected by waterborne diseases (ACF, 2009). As such, the integration of PUR® into the standard treatment would reduce or prevent the occurrence of these diseases.

b) Hypothesis 2

SAM children consuming RUTF + PUR® have better outcomes in terms of treatment time (shorter) and weight gain (higher).

Justification of Hypothesis 2: There will be an absence or reduction of occurrence of waterborne diseases due to the treatment of SAM children with RUTF + PUR®. Consequently, this will shorten the length of stay in the OTPs and increase their daily weight gain (given that the length of stay is a denominator while computing the weight gain).

3.4 Objectives of the study

The general objective of the study was to compare, within the framework of the national protocol of Integrated Management of Acute Malnutrition (IMAM), the efficiency of using RUTF + PUR® and RUTF alone in the nutritional treatment of SAM children under the age of 5 without medical complications.

The defined specific objectives of the study were the following (See Annex 1 for further details on the study timeframe):

a) to describe the socio-demographic characteristics of children admitted in both comparison groups;
b) to examine the relationship between the quality of water used in the households and the occurrence of waterborne diseases during the management of SAM children;
c) to determine the links between the consumption of PUR®, the occurrence of waterborne diseases, and the weight gain/length of stay of cured children;
d) to describe the use and acceptability of PUR® in the intervention group; and
e) to evaluate the cost effectiveness of providing PUR® as part of the standard SAM treatment package.

4 Study Methodology

4.1 Technical support

The faculty of the Center for Refugee and Disaster Response at Johns Hopkins Bloomberg School of Public Health provided technical support to the study for the definition of the overall study methodology, sampling and the analysis of the collected data. CRDP/JHU has been involved in discussion around the conclusions and the recommendations for further study needs.

4.2 Study context

Populations living in Popokabaka, Bandundu, are provided with limited public infrastructure for clean drinking water therefore collect water from unprotected sources like rivers and traditional wells which increases their exposure to waterborne diseases. A nutrition survey carried out in January 2011 showed a GAM rate of 15.3% and a SAM rate of 4.3%, which is above the emergency thresholds as per the World Health Organisation (WHO). A provincial survey was undertaken by ProNaNut in May 2013, showing prevalences of GAM 10.4% (8.2%-13.1%) and SAM 1.6% (1.0%-2.6%) (ProNaNut, May 2013). While there is a notable slight improvement in the prevalence, this is likely due to the different seasons during which the data was collected, rather than substantial structural change and improvements in the area. Neither the availability nor accessibility to food are a particular issue in the area, therefore the high rates of acute malnutrition are most likely due to poor access to clean drinking water, as well as proper hygiene and sanitation conditions. These conditions increase incidences of waterborne diseases, and subsequently lead indirectly to an increased prevalence rate of malnutrition.

4.3 Study Type

The study was a controlled trial comparing the effectiveness of two separate independent variables. These were divided into two groups: an intervention group (RUTF + PUR® - following the IMAM national protocol) and a control group (only using RUTF – following the IMAM national protocol) and assessed their effects on dependent variables such as the length of stay and the weight gain of a child.

4.4 Population and Sample Size

The study population was composed of SAM children, under five living in Popokabaka, having been admitted to OTP services. Sample size calculations were based on a variety of considerations:

- the average documented length of stay in the nutrition program (29.4 days, SD=8.8);
- a ≥15% reduction in the mean length of stay in the program (to ≤25.0 days) as this would be the point at which the introduction of PUR into the treatment protocol becomes cost-effective; and
- an assumed power (1-β) of 90% and significance level of α=0.05.

A sample size of 85 participants per group was determined to be the minimum requirement in order to detect a ≥15% reduction in the mean length of stay. A sample size of at least 102 per group was recommended to account for potential follow-up loss of up to 20%. As such, the research team decided to use a sample size (according to available resources) totalling 207 SAM children aged 6 to 59 months: 105 children in the intervention group and 102 children in the control group.

There are 10 OTPs supported by ACF in the health zone of Popokabaka. In order to reduce the risk of group contamination, the OTPs were divided into two groups: one group of four centres admitting the intervention group (RUTF + PUR®), and one group of three centres, admitting the control group (RUTF only – regular nutrition treatment protocol). The distribution of these centres is shown in Annex 2.

4.5 Inclusion and Exclusion Criteria

The treatment was offered to the first 207 children who arrived to the two groups of OTPs. Children were included in the study according to the following criteria:

- ✓ Children aged between 6 to 59 months;
- ✓ Diagnosed for the first time for SAM according to the national protocol;
- ✓ Absence of medical complications requiring inpatient (stabilisation centre) management; and
- ✓ Parents agreeing to remain in the study area during the whole duration of treatment including weekly OTP follow ups.

Similarly, and equally important, the following exclusion criteria were defined:

- Children with chronic diseases associated to acute malnutrition such as HIV or tuberculosis etc;
- Newly discharged cases from OTPs coming from the inpatient stabilisation centres (hence previously medical complicated cases)[4]; and
- Children with oedema.

Once the child was admitted to the OPT, his/her file was given to the study team to judge whether the child corresponded to the inclusion criteria. If the child fell within the study criteria, the team presented the study to the care takers, with the support of a consent form (Annex 3) translated into *Kiyaka*, to enable care takers the opportunity to fully understand the study, and to ensure a uniform message across all Health Centres. At the end of the study, a review confirmed that there was no refusal from care takers when asked to participate in the study.

4.6 Discharge criteria

Children were considered cured according to the standard discharge criteria of the national nutrition protocol applied in the various health centre OTPs: a Z score ≥ - 2 and/or MUAC measurement ≥ 125 mm.

Children who were not recovered as expected were judged as such according to the OTP criteria, and were discharged following unchanged weight for three consecutive weeks. Additional discharge criteria for the study were:

- If absent for more than three consecutive weeks, despite home visits by the team and/or the fact that the child's weight has reduced; and
- If the child was transferred to the SC from the OTP due to deteriorating medical condition.

4.7 Study variables and their measurements

Four variables supported the implementation of the study. These included the dependent, intermediate, independent and control variables, as shown in the Table 2 below.

[4] Children who received treatment in the Stabilization Centers, have already received RUTFs, antibiotic treatment and deworming which means that they are no longer comparable with a child who has been newly admitted to an OTP without having had any previous treatment.

Table 2: Types of study variables

Type of variable	Name of the variable
Dependent variables	• Length of stay • Average weight gain • Recovery rate
Intermediate variables	• Quality of water used in the households • Use of PUR® • Occurrence of diarrhoea
Independent variables	• RUTF + PUR® • RUTF only
Control variables	• Sex • Age • Socio-economic status • Systematic medical treatment • Diet and/or food consumption • Mean weight for height z-score • Mid-upper-arm-circumference (MUAC)

4.8 Dependant Variables

The length of stay: The length was the total number of days spent in the programme, from admission of the child to the discharge of a cured child. Children were considered cured once their target weight was achieved according to the IMAM national protocol. In order to measure the cure date, anthropometric measurements were systematically taken once per week during OTP follow-up. The average length of stay for all children in each group = [total number of days of cured children] / [number of cured children].

The average weight gain: The weight was taken by a Salter® weighing scale. A measuring board helped measure the child's length/height (children under 87cm are measured lying down, children above 87cm are measured standing up). The average weight gain was documented only for children discharged from OTP and considered cured, using the following formula:
The weight gain (g/kg/day) = [weight (g) at discharge – minimum weight (g)] / [Duration from minimum weight to discharge] * [minimum weight (kg)].
The average weight gain (g/kg/day) for each group = [Sum of weight gains of cured children] / [total number of cured children].

Recovery rate: This rate was a dichotomous variable regarding whether a child admitted to the program was cured or not. A child was considered successfully cured upon the achievement of his/her recovery target weight, as defined by the IMAM national protocol.
The recovery rate for each group = [Total number of cured children] / [total number of children].

4.9 Intermediate Variables

Quality of water used in the households: The quality of water was determined by measuring the residual chlorine levels and pH value. Water samples were collected in the households and their analyses was done on site.

Use of PUR®: During household visits the use of the product was assessed through direct observation and residual chlorine testing. Empty PUR® sachets were collected from the households (caretakers) and the presence of chlorine in the water was measured using a pool tester, DPD 1 tablets and Phenol Red tablets. There was no access to chlorine in the health zone on the local market; consequently the presence of chlorine indicated use of PUR.

Occurrence of diarrhoea: Occurrence and prevalence of diarrhoea were determined by interviewing care takers during follow-up visits at the OPT sites and at home.

4.10 Independent Variables

RUTF: The quantity of RUTF consumed by each SAM child was determined according to his/her admission and target weight, according to the national nutrition protocol. The corresponding quantities were distributed once a week. As defined in the national protocol, used RUTF sachets were collected from caretakers at weekly OTP sessions in order to ensure they were not sold.

PUR®: On average each family member uses three litres of water per day for drinking and cooking. A sachet of PUR® was used for purifying 10 litres of water. The quantity of PUR® corresponding to the household size was distributed once a week to each family. For instance, two sachets were used daily in a household of six persons. As with the used RUTF sachets, used PUR® sachets were also collected from caretakers at weekly OTP distributions in order to ensure they were not sold on the local market.

4.11 Control Variables

Sex: Sex is a dichotomous variable that was recorded as "male" for boys and "female" for girls. It was recorded systematically during the OTP admission process.

Age: The age was determined by asking care takers about the date of birth of the child. This was recorded in month; the information was recorded systematically at OTPs upon admission.

Socioeconomic situation: This variable concerned the marital status of the care taker, their profession, their level of education, food access, diet diversity, water source, volume of water utilized daily, etc. These indicators were followed as part of a questionnaire administered to the caretaker at one point during the time spent in the program. This was done at OTP sites or at household level.

Dietary diversity: Information on the child's Individual Dietary Diversity Score (IDDS) was asked to the care taker of the child. The IDDS classified the food into 8 groups and provided a variable with an amplitude ranging from 0 to 8, based on the consumed food groups. The tool uses a 24 hour recall period. This information, was gathered at three different times during home visits, and provided information of the nutritional quality of the child's diet.

Systematic medical treatment: This is the medical treatment applied according to the national nutrition protocol and is recorded as part of the OTP weekly follow-up.

Mean Z-score at enrolment: This is systematically taken at OTP admission and recorded as part of the child's database.

Mid upper-arm circumference (MUAC) at enrolment and at discharge: The MUAC is systematically taken at OTP admission and recorded as part of the child's database.

5 Study Implementation

The seven health centres were divided into two groups - one in the South for the control group and one in the East for the intervention group of the study (See Annex 2 for OTP repartition). Each group was monitored weekly by the study supervisors. The study data collection began on December 2012 and ended in March 2013. During the study implementation a number of activities were followed in preparation and at implementation phase, as well as at OTP sites and households levels.

5.1 Timeframe

Data collection and analysis lasted six months as it was dependent on admission rates which fluctuated during the study period. When considering the admission trends in nutrition centres, the 207 children were estimated to be included in the study and followed until discharge within a period of four months. See Annex 4 for more information on the location and frequency at which the variables were measured

5.2 Ethical Considerations

Both study protocols, RUTF + PUR® and RUTF alone, did not include any additional risks for the treated children. The use of RUTF was applied according to the national nutrition protocol for the treatment of SAM. Children in both groups received systematic medical treatment according to this protocol. For equity reasons, participants of both groups received nutrition, health and sanitation education messages. Both groups received equal follow-up visits and monitoring at household level. SAM children diagnosed with chronic diseases were referred to the appropriate health centres for adequate care.

In order to minimize risks for the children, the survey team and the health centres in charge were appropriately trained and made aware on how to implement the study and their respective tasks. Verbal or written consent (Annex 3) was obtained from caretakers before inclusion of the child in the study groups. The study took place after ethical approval from the ProNaNut, the nutrition branch of the Ministry of Health in the DRC (Annex 5).

5.3 Study team and training

Seven study supervisors and 14 Community Health Volunteers (CHV) were recruited through an application process including written (general knowledge about malnutrition, education, health and mathematics) and practical tests (utilization of MUAC and the water tester).

The staff from the seven Health Centres who took part in the study attended an awareness training held by the ACF team at the beginning of the study in November 2012. Within each

Health Centre, the study team presented the following information:

- The aim of the study;
- The protocol of the study;
- The expectations for collaboration between health centre and study team; and
- The clarification on the scope and additional work load of the study (no additional workload for the health centre staff, due to additional team members following up on home visits).

Additionally, all supervisors and CHVs underwent a two day training in Popokabaka, in order to minimize potential measurement errors. Staff for both groups (intervention and control) were trained together, and at the end of the training, each group received printed copies of materials and necessary field tools, e.g. questionnaires, water testers, bicycles, bags, office supplies, etc.

Direct supervision by the supervisors and close collaboration with the CHVs for data collection on OTP and household level, allowed for: clarification, broadening, and continuous correction of questions and data collection.

5.4 Activities at the OTP level

All children either referred from other health posts or not, admitted to the OTP during the study period, underwent a complete clinical examination and recording of anthropometric measurements by the referent nurse . The children who met the inclusion criteria were included in the study after the care takers' consent was received. These children then received the standard nutrition and medical treatment according to the national protocol, with the exception that the intervention group was additionally provided with PUR®. Demonstrations on the use and application of PUR® at home was provided to the care taker. Necessary equipment for applying the demonstrations at household level was provided. Each family included in the study at the time of entering the study received:

- a bucket of 15 litres
- one storage container of 20 litres
- a filter cloth and a stirrer to facilitate the application of PUR® for water treatment and storage
- three 70 g pieces of soap
- two 50 ccl cups - at enrolment for the intervention group and at the discharge for the control group, in order to promote and facilitate acceptance of hygiene practices demonstrated to both groups

During the regular follow-ups, the following information was collected:

- At the weekly OTP session, care takers were asked about the occurrence of any clinical symptoms since the last visit, anthropometric measurements of the child were taken and the child underwent a complete physical examination; and
- At household level, every two weeks, care takers were given questionnaire on dietary consumption, hygiene practices and the use of PUR® (intervention group). A second visit was conducted to ensure the proper application of RUTF and PUR®.

5.5 Activities at Community and household level

Sensitization and active screening: according to the national nutrition protocol, Community Health Volunteers (CHV) are in charge of raising the community's awareness about malnutrition, undertaking active screening, and ensuring household follow-up of children admitted in the OTPs. ACF currently supports 10 out of 25 health centres in Popokabaka health zone. For each supported health centre/OTP, 20 CHVs implement community mobilization activities in the surrounding villages. Generally, active screening is done once a month by all CHVs. For the present study, they were mobilised to do active screenings twice a month in order to reach the expected 207 children within a four month period.

Seven ACF monitoring agents were hired to support the OTPs data collection during the time of the study. The CHV of each OTP was invited to carry out household follow-ups and awareness activities. For the seven OTPs, 13 CHVs supported the activities for the entire time of the study, from the first to the last child's enrolment.

Application of nutrition and health education: Household follow-up activities consisted of ensuring that nutrition treatment, nutrition and health education, along with guidance on how to use PUR® were all given to and well applied by each family.

Use and acceptability of PUR®: The use and acceptability of the product was assessed by asking care takers about attitude of children and the other family members when consuming water treated with PUR®. In order to gather acceptance for the use of PUR®, PUR® was introduced as being part of the child's treatment.

Anthropometric measurements: Once a week, each child included in the study was clinically examined in the OTP.

Quality of water used in the households: Water stored and used in each household was measured and a sample was collected for analysis. A total of 621 samples were collected, corresponding to the 207 children of the study. Three analyses were carried out during the enrolment period to detect the presence of chlorine in the 207 samples – a total of 621 analyses done.

6 Data management

6.1 Data Collection

The preparatory study phase consisted of training of the study trial team on data collection. The team was comprised of the trial manager, a research assistant, supervisors, survey agents, and the CHV. Annex 6 presents a matrix that briefly describes the role of each team member involved in the study implementation.

The data collection tool (the two questionnaires) were developed according to the objectives and the identified variables of the study. One questionnaire focused on the overall general study content, and one questionnaire focused in particular on the PUR® and information related to its application and acceptability (Annexes 7 and 8).

The questionnaires were pre-tested in two OTPs of Popokabaka; in Kabangu (25 km from the ACF base) and Imuela (45 km from the ACF base). Randomly selected care takers of

malnourished children were interviewed during field visits in both health centres. The questionnaire was adjusted accordingly for its final study use and application.

6.2 Data file validation

In the field, each file was checked by the data collector and the supervisor to make sure that all items were included – the questionnaires, OTP data sheets and consent form. Each file was consolidated either by printing the photo (front and back) of the child's OTP sheet or photocopying the original. The OTP sheet remained the reference document in the study file on criteria for admission, discharge, and for monitoring of the child during the period of the nutrition treatment. Each file controlled for different elements:

a) Weight/height inclusion criterion cross-checked with the z-score or MUAC table
b) Number of packets of RUTF received during the child's treatment
c) Systematic application of nutrition treatment protocol
d) Standard clinical examination
e) Standard appetite and malaria tests
f) Weight progression (stagnant, weight loss)
g) Regular presence and presentation at the OTP
h) Correlation between the information given on the OTP sheet and the separate study file (inclusion of date, weight, height, age, etc.)
i) Consistency of the information in the study file (composition of the household, water treatment, hand-washing practices, measurement of residual chlorine, IDDS)
j) Occurrence of transfer, abandonment, death, etc.
k) Verification of criteria and anthropometric data of discharged children with standard indicators

6.3 Excluded files

After this first checking process, a certain number of files were systematically excluded from the study. The table below provides some of the exclusion criteria that appeared after the first checking. The data problems shown in this table were identified when the data was checked during data entry, see section 6.4 below.

Table 3: Summary of rejected files

OTP site / *Criteria*	*KK*	*KA*	*PO*	*IW*	*IN*	*IM*	*KN*	NC	Total
Inclusion error	4	3	3	3	5	0	3	0	**21**
Age inconsistencies	1	0	0	0	0	2	0	0	**3**
Child not cured	0	0	0	0	1	0	0	0	**1**
Abandonment	5	0	2	1	0	0	0	0	**8**
Death	0	0	1	2	0	0	0	0	**3**
Transfer	0	1	0	1	0	0	0	0	**2**
Monitoring stopped	0	2	2	0	0	0	0	0	**4**
Weight loss	0	5	0	0	0	0	0	0	**5**

Stagnant weight	3	1	0	0	0	0	0	0	**4**
Number of RUTF sachets	3	0	0	0	0	0	0	0	**3**
No reason	0	0	0	0	0	0	0	1	**1**
Total rejected files	16	12	8	7	6	2	3	1	**55**

6.4 Data entry and verification

The collected data was entered in Microsoft Excel, Sphinx Survey Plus V5 and ENA software. Filled questionnaires were verified daily by the supervisors and weekly by the research study manager to ensure completeness and coherence. A process of data entry, double entry and data verification was facilitated in two steps explained below: for the first 30% of entered data, and for the remaining 70%.

6.4.1 Data verification of 30% of the questionnaires

The general and PUR® questionnaires (Annexes 7 and 8, respectively) were entered twice, once by the study supervisor and the second by the assistant. The data was entered simultaneously into the following software applications:

a) **Microsoft Excel**: date and the patient's weight at inclusion, minimum weight, date of the cured patient's weight at release, the criterion for admission, and the patient's mid-upper arm circumference at release.

Two results emerged from this information: weight gain and length of stay.

b) **Sphinx:** the full questionnaire, including the weight gain and length of stay obtained from Excel, where entered into this software.

c) **ENA:** anthropometric data was entered into ENA software for anthropometric nutrition surveys.

The verification of the general questionnaire involved 62 of the 207 files received after validation. 162 potential variables of each questionnaire were verified in two steps. In the first step, 24 files or 11% of the data was entered. To cross-check each data entry, staff member's data file input on Sphinx, the files were exported to Excel. Data entry staff exchanged copies of their lists in order to cross-check the entered copy of each file. Anomalies were identified on Excel and then corrected on Sphinx. Once mistakes were corrected, 38 additional files were entered amounting to 30% of the data entered via double entry. The first step was repeated in the same way.

This verification of the PUR® questionnaire involved 33 of the 105 files received. 106 potential variables of each questionnaire were verified. 33 files or 31% of the data were entered for this questionnaire. To cross-check each data entry staff member's data file input on Sphinx, the files were exported to Excel. Data entry staff exchanged copies of their lists in order to cross-check the entered copy of each file. Anomalies were identified in Excel and then corrected in the Sphinx database.

6.4.2 Data verification of the remaining 70% of the questionnaires

The verification of the general questionnaire involved 145 of the 207 files received after validation. 162 potential variables of each questionnaire were verified. The questionnaire was divided between the two data entry staff members. For the final input, each member exported his/her Sphinx data to Excel. The members then exchanged their data sets in order to check the validity of the data by using the paper copies of the questionnaires to check 110 of the 162 variables, the most sensitive questions and indicators. Anomalies were identified on Excel and then corrected on Sphinx.

This verification of the PUR® questionnaire involved 72 of the 105 files received. 106 potential variables of each questionnaire were verified. The questionnaire was entered by a single staff member. For the final input, the staff exported his/her Sphinx data base to Excel and submitted the set to the other staff member, to double check using the paper questionnaires, checking the validity of all 106 potential variables. Anomalies were identified on Excel and then corrected on Sphinx.

6.4.3 Additional data consistency checks

A number of data checks were done very early in the data collection process, to guarantee maximum data quality of the birth date or age and the anthropometric data, as the two inclusion criteria were of utmost relevance to the study outcomes.

Birth date or age **-** In DRC, exact birth date and age are often pieces of information too complicated to obtain, especially in remote rural areas like Popokabaka. According to the health zone, the percentage of children having a birth certificate or who are registered at the health centre can vary from 23% to 94% amongst the seven health centres included in the study. To make this information as coherent as possible, recorded birth date and age were entered in the study inclusion document, and crosschecked with the OTP admission sheets.

Anthropometric data **-** The anthropometric indicators of height, weight and MUAC are very precise and exact measurements, therefore a few millimetres of difference in the measurement can often change whether a child is included in a program or not. Including or excluding a child in a nutrition program is an ongoing challenge as there is constant pressure from the community to admit a child. The anthropometric data report edited by the ENA software provided two important pieces of information: a) a slight tendency to round the weight to 0 and 500 grms; and b) a strong tendency to round the height to 0 and 5 mm. In order to limit and identify these inconsistencies early, two safeguards were put in place instantly:

1. Anthropometric measurements were taken in the presence of the data collector who participates in the measurements or assisted the health personnel. If the data collector was not present in this operation, he/she had to retake the measurements; and
2. The relationship of the anthropometric/birth date or age data was analyzed with the ENA software to identify children with irregular or inconsistent data according to the standard growth indicators of WHO.

6.5 Data analysis

A number of statistical tests and analysis steps were applied to the data set. A short description is provided below:

- A univariate analysis describes the characteristics of children included in each group, such as the size, minimum, maximum, average, and standard deviation for continuous variables and proportions for the qualitative variables;
- Bivariate analysis through the use of chi-square tests helps to compare the two groups in cross tables, with the Fisher Test in case of small subsamples;
- Multivariate regression contributes to control key differences in the comparison group which were observed at baseline and needed to be controlled for;
- The «intention to treat» approach is used during analysis in both groups;
- The Student t-test helps to compare the changes observed before and after the intervention within each group, and between both groups; and
- The statistical significance threshold applied is 0.05 (5%).

The data review and analysis was supported by the Faculty of the Center for Refugee and Disaster Response at Johns Hopkins Bloomberg School of Public Health, Baltimore, USA.

7 Limitations and Bias of the study

7.1 Study challenges and limitation

A number of limitations were observed during the study implementation. For most of them the study team was able to implement certain safeguards and adjust their respective supervisory functions. Nevertheless, some of the limitations might have impacted the quality and consistency of the data collection, and hence the overall study validity.

Sampling design - A group randomized design was important to decrease the risk of contamination between the two comparison groups. However, this likely resulted in important differences between the comparison groups. Some of these are discussed and controlled for in the analysis, but not all factors that could potentially influence study outcomes were addressed.

Study design - The study was not blinded which might have influenced outcomes or resulted in bias.

OTP - Nutrition Interventions - The Health Centre run OTPs, despite the supervision by ACF, depended entirely on the abilities and motivation of the Health Centre staff. Difficulties faced had essentially to do with RUTF supply, home monitoring, respecting the need to take anthropometric measurements, admission and treatment in accordance with national nutrition protocol. Therefore, the study team monitored the RUTF study stocks and those of the nutrition programme, weekly, to make sure their availability. Similarly, during the supervisory visits, the anthropometric measurements were regularly controlled and equipments checked and calibrated. When faced with the problem of incorrect admissions as according to national nutrition protocol, the study team would discuss with the OTP supervisory team to improve compliance with the protocol and its application. A large number of documented cases were excluded from the study on the basis of incomplete and low quality data sets.

Accessibility - The Health District of Popokabaka is large and a difficult area to access. Generally even relatively short distances take a long time to overcome, hence the study team spent a lot of time reaching health centres and households. Supervision was carried out on the basis of a weekly visits lasting one day within the Health Centre. Some centres benefitted from a longer period of supervision when more significant difficulties were encountered.

Water quality - Water sources in the study area included rivers, ponds, springs, and rain water. Water sources were not improved or treated and variations in water quality would be expected across sources and over time. It would have been ideal to rigorously monitor water source quality.

Understanding and interpretation of the questionnaires - After receiving the first data questionnaires, it appeared that certain questions were not completely filled or were misunderstood. Therefore, a follow-up information meeting and training was facilitated with all staff members involved in the study, to overcome uncertainties and/or misunderstandings. Some remaining questions might have persisted after these efforts, and could potentially have influenced the interpretation and recording of the information collected.

Follow ups - More frequent complete data follow-up, weekly as compared to bi-weekly, would have been ideal in the context of the trial because length of stay could have been measured with greater precision. Additionally, the study was supposed to be as realistic as possible, hence implementation was as close to the conditions normally followed during regular OTP services.

7.2 Deviations from the initial methodology

Throughout the study, observations were made and changes occurred with regards to the methodology of the study. Some observations might induce a potential bias to the data set and results of the study.

The inclusion criteria – height for weight ratio and MUAC measurement showed that according to the results for the length of stay, the children included on the basis of the mid upper arm circumference were more critically undernourished and therefore required more time to reach the discharge criteria.

Home visits – Each child was to be monitored once every two weeks at home. They were eventually monitored every week with different elements: every other week a questionnaire was administered on dietary diversity, hygiene, and the use of PUR® (for the intervention group). During the week when the questionnaire was not administered, a visit was made by the ACF team to assure the proper use of RUTF and PUR® packets. This provided more follow-up time than initially intended or provided during standard OTP activities.

PUR® questionnaire – The questionnaire was intended to collect information on the use of PUR® and to detect difficulties in the procedures. However, the questionnaire in its original version did not allow the data collector to do this, hence it was adjusted. Therefore the early data collection during the study period might have been presented differently compared to the later period of data collection, therefore the final data was not fully comparable.

7.3 Study bias

In the final field phase, it appeared that certain practices in the field might have directly or indirectly influenced the data and hence the results obtained.

Anthropometric data – According to the analysis of the anthropometric measurements and birth data, the report edited by the ENA software indicated occurrence of rounding on the numbers provided for the weight and height measurements of the children. This might have influenced the inclusion of children in the study, which by correct measurement would not have been included. Although a bias, this aspect was consistent between the two comparison groups.

Water testing – Reading the pH value and residual chlorine is generally a delicate operation and requires supervision. Considering the values reported, it appeared that the results were difficult to read for some data collectors, therefore the information collected on the PUR® application might not be entirely coherent.

Birthdates – With regard to birthdates, as mentioned above, despite the different levels of checking and cross-checking, it is difficult to be certain about the accuracy of the data therefore leading to potential inclusion errors for children older than 5 years.

Contamination of the study groups – A possible bias comes from contamination of the groups, because the study was not a blind controlled trial. In order to minimize its occurrence, the seven OTPs were grouped into two groups for intervention and control group. The distance between the groups reduced the risk for the participants to share PUR®.

8 Results

The study determined the importance of promoting PUR® as part of the standard nutrition treatment of SAM children without medical complications, in areas with difficult or no access to clean drinking water. The results contribute to improved operational management of nutrition programs targeting SAM children in the DRC and potentially other contexts.

The results section is structured along the objectives which were initially set to be researched and documented. Conclusions and recommendations are considered, following the results section.

8.1 Socio-demographic profile of children in the study

A total of 207 children were enrolled in the trial, of these 105 in the intervention group and 102 in the control group. Individual and household characteristics of the two groups at entry to the trial are summarized in Table 4 below. Upon admission, the two groups were statistically similar with respect to age, sex, and breastfeeding status. The intervention group had a slightly worse nutritional status with respect to weight-for-height z-score (-3.14 intervention vs. -2.93 control, p=0.02), but had larger MUACs (116.5mm vs. 114.2mm).[5]

With respect to household characteristics, children in the intervention group came from smaller households with an average size of 6.0 members, as compared to 7.0 in the control group (p<0.001). However, there was a similar number of children under the age of 5 years in

[5] Children with WHZ > -2 met the MUAC inclusion criteria.

households of both comparison groups. Children in the intervention group were also from households with lower levels of parental education: 16.2% of the intervention group had parents that had completed secondary schooling compared to 31.4% of the control group (p=0.04).

Table 4: Characteristics of study participants upon admission

	Intervention (n=105)	Control (n=102)	p-value*
Individual Characteristics			
Sex			
Female	52.4%	54.9%	0.72
Male	47.6%	45.1%	
Age (months)			
Mean (SD)	27.2 (16.2)	23.7 (16.2)	0.12
Median (range)	22 (6-59)	16.5 (6-59)	
Breastfeeding at time of admission			
Yes	52.4%	60.4%	0.25
No	47.6%	39.6%	
Nutritional status at enrollment – Mean (SD)			
WAZ	-3.88 (0.09)	-3.82 (1.17)	0.64
HAZ	-3.25 (1.66)	-3.20 (1.95)	0.82
WHZ	-3.14 (0.61)	-2.93 (0.66)	0.02
MUAC (mm)	116.54 (8.02)	114.18 (8.20)	0.04
Household Characteristics			
Household size (total)	6.0 (0.2)	7.0(0.2)	<0.01
# of children age 0-5	2.2 (0.1)	2.2(0.1)	0.67
# of children age 6-18	1.7(0.2)	2.3(0.2)	0.01
Highest level of parent education			
No education	39.1%	32.4%	0.04
Grade school	44.8%	37.2%	
High school	16.2%	31.4%	
College	0.0%	0.0%	
*t-test for continuous variables; chi-square for binary variables			

8.2 Water quality and the occurrence of waterborne diseases

Monitoring information on water sources, water treatment and free chlorine levels of stored drinking water are presented in Table 5. Also see Annex 9 for further information on the PUR monitoring protocol. Significant differences were observed between the two groups with respect to the water sources. The majority of households in the intervention group (67%) relied on unprotected springs as a water source, whereas control households primarily relied on other surface water, including rivers, ponds, and streams (88%). Water treatment differed significantly between the two groups as anticipated with almost no reported treatment in the control group and reported treatment levels >95% in the intervention group. Water quality testing found no residual chlorine in control households and an average residual chlorine level of 0.26-0.34 in intervention households. The proportion of intervention households with residual chlorine levels >0.5mg/L ranged from 39-48%, suggesting that the application and frequency of water treatment and water testing was not synchronized. To note here is that residual chlorine levels in stored water decrease over time, hence while the households did treat the water with PUR® (95-100% treatment indication), the household stored the treated water and by the time the ACF team came to test the water, the residual chlorine levels had already decreased.

Table 5: Water Source, Treatment and Quality by Intervention Group*

	Two weeks			Four weeks			Six Weeks		
	Int' (n=103)	Control (n=69)	p-value	Int' (n=55)	Control (n=54)	p-value	Int' (n=18)	Control (n=26)	p-value
Water source**									
River/pond/stream	44% (45)	88% (61)	<0.01	46% (25)	87% (47)	<0.01	33% (6)	85% (22)	<0.01
Unprotected spring	67% (69)	19% (13)		56% (31)	15% (8)		67% (12)	23% (6)	
Protected spring	1% (1)	1.5% (1)		4% (2)	4% (2)		0% (0)	0% (0)	
Rain water	5% (5)	22% (22)		0% (0)	9% (5)		0% (0)	0% (0)	
Water treatment **									
None	1% (1)	100% (69)	<0.01	0% (0)	98% (54)	<0.01	0% (0)	100% (26)	<0.01
Boil	3% (3)	0% (0)		2% (1)	2% (1)		0% (0)	0% (0)	
PUR	95% (98)	0% (0)		98% (54)	0% (0)		100% (18)	0% (0)	
Free Chlorine Levels***									
Mean (mg/L)	0.33	0	<0.01	0.34	0	<0.01	0.26	0	<0.01
Percent with >0.5mg/L	48% (49)	0%	<0.01	55% (30)	0% (0)	<0.01	39% (7)	0% (0)	<0.01

*The number of children enrolled in each comparison group at the time point was used as a denominator because timing of household visits did not correspond with follow up visits to OTP clinics. According to the study protocol, all enrolled households should have three home visits and water quality tests during the study period.

** Water source and water treatment information only reported for households receiving water quality tests.

***Water quality data at 8 weeks was reported for 22 households; findings are not reported in the table because of the small sample size.

During the follow-up visits, information on the occurrence of diarrhoea during the previous week was recorded. At baseline, both comparison groups had 10 cases of diarrhoea each during admission (i.e. 9.5% and 9.8% of the intervention and control group respectively). During the follow-up weeks, both comparison groups had an equal number of diarrhoea cases with one case in week two, and no cases in the following weeks.

8.3 Length of stay and weight gain

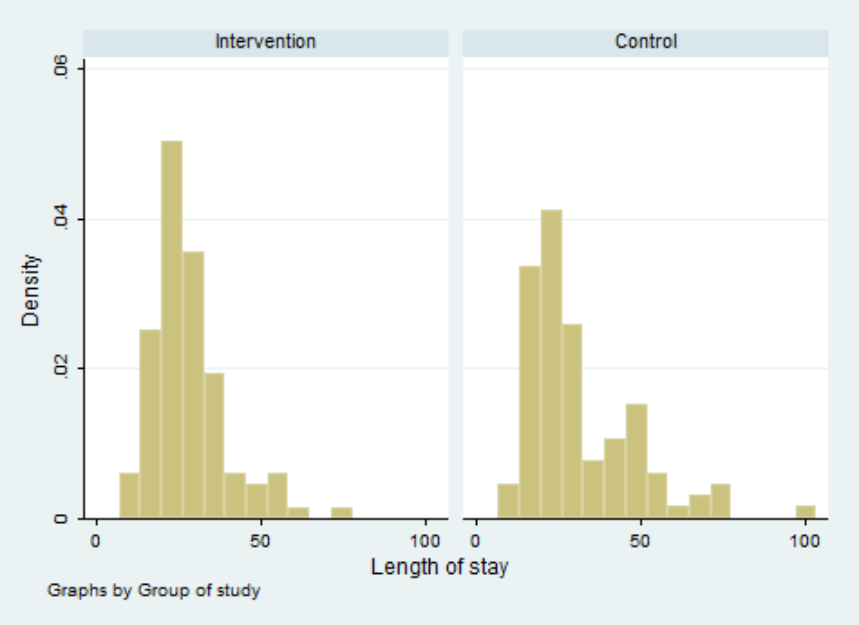
Feeding program effectiveness indicators are summarized by comparison group in Table 6. Children in the intervention group had a significantly shorter mean length of stay as compared to children in the control group (26.4 days vs. 30.4 days, p=0.06). Figure 2 presents frequency distributions for the length of stay by comparison group and illustrates differing distributions between the two comparison groups. The distribution of the intervention group is narrower and less skewed, with fewer children having extended lengths of stay as compared to the control group. Average daily weight gain was also higher among the intervention group than in the control group, at 7.3 g/kg/day and 6.6g/kg/day respectively, however this difference was not statistically significant (p=0.13). Upon discharge from the nutrition treatment programme, children in the intervention group and control group had similar mean WHZ scores of -1.31 and -1.21, respectively (p=0.36). All children in both the intervention and control groups were discharged from the program as cured.

Table 6: Feeding program effectiveness by comparison group

Indicator	Standard	Intervention (n=105)			Control (n=102)			p-value*
		Median	Mean	Range	Median	Mean	Range	
WHZ at entry	≤ -3	-3.24	-3.15 (0.61)	(-4.64, -0.74)	-3.03	-2.93 (0.66)	(-5.23, -0.81)	0.02
WHZ at exit	≥ -2	-1.45	-1.31 (0.75)	(-2.15, 2.56)	-1.37	-1.21 (0.81)	(-2.10, 1.83)	0.36
Length of stay	<30 days	21	26.4 (12.3)	(7,77)	21	30.4 (17.7)	(7,97)	0.06
Weight gain	g/kg/day	6.7	7.3 (3.2)	(2.0, 17.9)	6.0	6.6 (3.6)	(1.3, 23.0)	0.13

*t-test

Figure 2: Length of stay by comparison group



8.4 Usage and acceptability of PUR® in the intervention group

Based on the findings, there is a strong acceptance of the intervention group, with 95% to 100% of usage. The use is confirmed by the water quality analysis, showing residual chlorine in water samples at the household level. However, only 39-55% of the samples showed residual chlorine equal or above the recommended standard of 0.5mg/L. This could be due to a decrease of residual chlorine over time at the moment of measurement, or a lack of compliance with dilution recommendations, but it is clear that the intervention group has used the product over time. No family of the intervention group indicated, when asked about their use of PUR®, that they had any difficulties with the application of the product. During week 2 follow-up, 8.57% of the PUR® users declared dissatisfaction with the taste, and 2.86% reported discomfort when drinking the water, mainly through occurrence of vomiting. During week 4 follow-up, only 5.45% declared a taste problem, and only one respondent continued to report discomfort. Overall, this shows a large acceptance of the product in the area, especially as it was reported that in all cases (100%), the entire family was drinking from the treated water.

This was correlated with observations made during the various surveys, as members of households and health centre personnel inquired about where they could buy PUR® after the end of the treatment study.

8.5 Cost effectiveness of providing PUR® as part of the SAM treatment package

The introduction of the PUR® water purifier into the standard nutrition treatment protocol for the intervention group was reviewed under a cost effectiveness calculation. For easy facilitation, the calculation has concentrated on the simple cost of supplies of RUTF and PUR®. Additional costs of human resources, supervision and logistics exist, but would not be significantly different

in a programme run with or without PUR®. This assumes the standard nutrition treatment protocol application without home visits and simple regular follow-ups at the nutrition/health centres.

The standard cost of RUTF is 0.4USD per sachet with an average of 3 sachets per child per day is necessary for a SAM treatment course (1.20USD/day). During the treatment time, each child was provided with PUR® to purify 20 litres of portable water per day, with a cost of 0.01USD for each litre treated, hence 0.20USD per day.

The average length of stay in the nutrition treatment programme of 30.4 days was considered for the cost effectiveness calculation. With a sachet cost of 0.4USD, the total RUTF cost amounts to 36.48USD per child and treatment, at a total of 91.2 sachets of RUTF. During the treatment time, each child was provided with PUR®, to purify 3 litres of portable water per day per household member. With an average of six household members, two sachets where provided per day for each child in treatment.

With a decrease of 4 days in the average treatment time, the average cost of the intervention group using PUR® for 26.4 days, amounted to a total of 36.96USD per child and treatment (31.68USD for RUTF and 5.28USD for PUR®). The cost of 4 days of RUTF is calculated at 4.8USD. With a cost of 5.28USD for the PUR® per treatment course of 26.4 days, this indicates that the reduction of 4 days treatment time would be able to cover 90.90% of the supplementary cost.

Additionally, a benefit which is difficult to evaluate a cost for is the benefit to the overall family. PUR® was provided in sufficient quantity to ensure purified water to the whole family (3liters per family member), as compared to providing PUR® for the malnourished child only. This calculation would need to consider frequency of illness with productive and non-productive family members, cost of treatment at health centre or traditional healer, cost for transport, income loss due to illness, etc. Over a treatment time of 26.4 days, the family benefits would need to cover 0.48USD, 0.02USD per day, which would most likely be easily covered.

If for practical operational reasons, the calculation of 90.90% of cost covered through shortened treatment time is used, this indicates that an additional supplement of 0.48USD per child treated in the nutrition centre with PUR® would be necessary, if this was to be rolled out as part of the standard nutrition treatment protocol. Given the DRC's relatively short overall average treatment time (29.4 days) it is nevertheless an important achievement, and application in contexts with longer treatment time (e.g. Pakistan 59.9 days, South Sudan 58.9 days) must be considered to provide additional evidence for the consideration in policy influencing and making.

8.6 Additional analysis and modelling

Individual dietary diversity – To better understand the food intake of the children in the nutrition treatment, information on their individual dietary diversity (IDD) was collected. IDD information is collected using a 24hrs recall of the consumption of eight food groups. Table 7 below shows an overview of the two comparison groups and the IDD of the study children.

Three food groups - other fruits, eggs and fat/oils - were significantly different in their consumption between the two comparison groups, during week 2 and week 4 follow-up. This indicates that the children in the intervention group might have received a diet with more fruit and animal protein as compared to the control group, therefore potentially having an influence on the recovery of the children.

Table 7: Individual Dietary Diversity

IDD	Two weeks			Four weeks			Six Weeks		
	Intervention (n=105)	Control (n=102)	p-value	Int. (n=54)	Control (n=77)	p-value	Int. (n=19)	Control (n=28)	p-value
Cereals	98.1%	94.1%	0.138	98.2%	100%	0.231	100%	100%	1.000
Food rich in vitamin A	88.6%	91.2%	0.535	100%	98.7%	0.396	88.9%	100%	0.071
Other fruits	45.7%	35.3%	0.127	63.6%	27.6%	0.000	72.2%	48.2%	0.109
Meats	74.3%	74.5%	0.971	83.1%	74.55%	0.229	77.8%	78.6%	0.949
Eggs	7.6%	8.8%	0.752	12.7%	2.6%	0.023	5.6%.	3.6%	0.747
Vegetables or legumes	68.3%	73.5%	0.406	70.4%	75.3%	0.528	77.8%	75.0%	0.829
Milk	56.2%	51.0%	0.452	56.4%	53.3%	0.723	72.2%	60.7%	0.424
Fat/oils	88.6%	70.6%	0.001	92.7%	79.22%	0.033	77.8%	82.1%	0.716

*The number of children enrolled in each comparison group at the time point was used as a denominator because timing of household visits did not correspond with follow up visits to OTP clinics. According to the study protocol, all enrolled households should have three home visits and water quality tests during the study period.

Modelling – A linear regression was conducted as a means of accounting for differences at the baseline between the intervention and control groups. In simple linear regression models, statistically significant predictors of length of stay included weight-for-height z-score at enrolment and child age in months ($p<0.05$). Marginally significant predictors include intervention group and household size ($0.05<p<0.10$); but child sex and parental education attainment were not significantly associated with length of stay. A multivariate linear regression including the four significant and marginally significant predictor variables from simple linear regression was developed. In the final multivariate model, weight-for-height z-score remained the only significant predictor (5.53, CI: 2.30-8.75; $p<0.01$) and age in months was marginally significant (-0.12; CI: -0.25-0.01; p=0.62). Both, intervention group and household size were not significantly associated with length of stay in the final multivariate model (p=0.46 and 0.10, respectively). Findings from the multiple linear regression model should be interpreted with caution because the model fit was poor (adjusted R-square=0.09) and the sample size was likely to be too small to see a significant difference using this analysis approach.

8.7 Discussion of results

Upon entry into the feeding program, children in the intervention group were significantly more wasted than controls when assessed by weight-for-height z-score. These children had a shorter average length of stay in the feeding program (26.4 days vs. 30.4 days; p=0.06) and a higher rate of daily weight gain (7.3 g/kg/day versus 6.6g/kg/day; p=0.13, not statistically significant). Basic descriptive analysis suggests that despite worse nutritional status at enrolment (measured by WHZ), children in the intervention group were discharged in a shorter time period than children in the control group with an average reduction in length of four days.

Multiple linear regression models controlling for baseline differences in the comparison groups suggest that other factors may contribute to the observed difference in length of stay, however, given the small sample size and the limited model fit, the pertinence of the multiple linear regression model is not fully applicable.

In conclusion, a marginally significant reduction in length of stay was observed in the intervention group. This result is not supported by additional analysis and the multiple linear regression models. Natural differences between the comparison groups at baseline were noted. Especially the difference in education levels (p=0.04) of parents in the intervention and control group might have had an influence on family behaviour on hygiene and water handling, and hence child performance in the nutrition treatment programme.

9 Conclusions and Recommendations

The context of this study was very particular with its setting and current nutrition programme implementation, i.e. the mean length of stay which is already quite short. Additional studies of the effectiveness of safe drinking water in SAM treatment protocols are warranted based on this initial pilot test. A number of considerations for similar studies in additional contexts can be applied in planning:

- Further studies should pay attention to their set up and framework, with focus on sampling and admission of study participants. This would provide a larger opportunity to ensure a more coherent and comparable sample of families and children.

- Further studies should have larger sample sizes and should be conducted in areas with high levels of untreated drinking water.

- Further studies should be applied in contexts with longer average treatment time to establish the validity of the current findings on the overall treatment of SAM.

- Further studies should revise the necessary questionnaires to focus on the relevant information and avoid collection of supplementary additional information and indicators which add unnecessary data-overload.

- Further studies should carefully define and appropriate the follow-up schedules and plans on household and health centre level, to ensure that implementation during the study is as close to nutrition treatment programme reality as possible.

- Further studies should consider a more detail cost-efficiency calculation, acknowledging the cost of the family benefits to the purified water on household level, as compared to child level only.

Lastly, further studies should include additional alternative intervention options to improve water quality and household water chain management through e.g. local water treatment products, water storage containers, etc.

Annex 1: Study timeframe

Activity	2012					2013				
	Jan.	Feb.	Oct.	Nov.	Dec.	Jan.	Feb.	Mar.	Apr.	May
Literature review										
Submission of 1st draft of literature review and methodology	05									
Adjustment and submission of the review and methodology										
Activities in DRC										
Meetings with partners in DRC (MSP, ACF, etc.)										
Ethical approbation acquisition										
Implementation sites visits										
Hiring and training of agents carrying out the study										
Purchase of needed material for the study										
Adjustment of final protocol										
Briefing of Trial Manager										
Trial commencement and follow-up of beneficiaries										
Data entering and data control										
Pre-analysis of data										
End of data gathering										
Detailed data analysis										
Drafting of the report of the study										
Article drafting and submission										

Annex 2: OTPs repartition in both study groups

RUTF + PUR® Group	Distance to ACF base	RUTF only Group	Distance to ACF Group
Kiamfu Kinzadi	75 km	Cité Popokabaka	3 km
Kangwezi	80 km	Kabangu	25 km
Intenga	52 km	Imwela	45 km
Imbela	110 km		

Annex 3: Consent form (sera traduit en kiyaka la langue locale)

FORMULAIRE DE CONSENTEMENT POUR LE GROUPE DE CONTROLE

Titre du projet de recherche: étude comparative des effets du Plumpy'Nut® + Pur® versus Plumpy'Nut® dans la prise en charge d'enfants de 6 à 59 mois souffrant de malnutrition aiguë sévère sans complications médicales dans la zone de santé de Popokabaka, République Démocratique du Congo
Investigateur principal: Action Contre la Faim - USA

Introduction :

Nous vous demandons de participer à une recherche menée par Action Contre la Faim - USA. Ce formulaire de consentement explique l'étude de recherche à laquelle il vous est demandé de participer. Merci d'écouter attentivement et de poser des questions au sujet de l'étude avant d'accepter d'y participer. Vous pouvez également poser des questions à tout moment. Si vous acceptez de participer à cette étude, nous allons vous laisser une copie de ce formulaire.

Objectif du projet de recherche:

Le but de l'étude est de savoir si le traitement de l'eau de boisson à une influence sur la durée de prise en charge et le gain de poids d'un enfant malade de Malnutrition Aiguë Sévère (MAS) suivi dans une Unité de Nutrition Thérapeutique Ambulatoire (UNTA).

Procédures:

Si vous acceptez de participer à cette étude, votre enfant sera prise en charge selon le protocole national de nutrition (PCIMA) en vigueur et votre foyer sera visité une fois par semaine pour savoir si votre enfant qui est suivi au centre de santé a eu de la diarrhée, des vomissements, un problème d'appétit et de répondre à toutes questions que vous pourriez avoir.

Vous devrez **vous présenter au centre de santé avec votre enfant chaque semaine au jour fixé** par l'infirmier titulaire, afin qu'il soit examiné, que vous rameniez les sachets vides de Plumpy'Nut® afin d'en recevoir de nouveaux. Par ailleurs, le **Plumpy'Nut® donné pour soigner votre enfant ne devra pas être partagé avec les autres membres de la famille**.

Risques :

Nous ne donnerons aucun traitement supplémentaire, la seule chose que nous vous demandons, c'est votre temps. Les questions que nous poserons ne vous prendront que quelques minutes.

Avantages:

Il n'y aura pas de retombées directes pour vous. Cependant, pour vous remercier de votre participation nous fournirons à votre foyer : un bidon de 20 litres, un seau de 15 litres et un entonnoir pour le stockage de l'eau de boisson seulement.

Alternatives à la participation:

Vous pouvez choisir de ne pas participer, et cela n'affectera pas votre droit à des traitements

médicaux dans le centre de santé ou tout autre droit que vous avez en tant que citoyen congolais, y compris la prise en charge de votre enfant malnutri. Si toutefois, vous acceptez de participer, vous pouvez si vous le souhaitez arrêter à tout moment.

Confidentialité :

Tout ce que vous nous direz sera confidentiel.. Au cours des quatre prochains mois, toutes les informations que vous nous direz seront conservées dans nos locaux à Popokabaka, puis seront transférées à Kinshasa.

Compensation:

Il n'y a pas d'argent prévu pour y prendre part.

Libre arbitre:

Votre participation à ce projet de recherche est entièrement volontaire. Vous avez le droit de vous retirer de l'étude à tout moment. Même si vous ne voulez pas participer à l'étude, ou si vous souhaitez vous retirer de l'étude en cours, votre enfant recevra toujours la même qualité de soins médicaux dans votre centre de santé local. Vous pouvez me demander des précisions sur toutes les points que nous avons abordez. Dans l'avenir, si vous ne comprenez pas quelque chose, s'il vous plaît n'hésitez pas à nous poser vos questions à tout moment. Lorsque nous aurons terminé et scruter toutes les données nous tiendront informé l'infirmier titulaire de ce que nous avons trouvé et les recommandations qui s'en dégagent.

Personnes à contacter:

Si vous souhaitez parler à une personne de cette étude parce que vous pensez ne pas avoir été traité équitablement ou pensez avoir été blessé en joignant votre enfant à l'étude, ou si vous avez d'autres questions sur l'étude. Merci de prendre contact avec *Franck Gressard* ou *Patrick Kazadi* au bureau ACF à Popokabaka, Tel. 0820 141 363. Ces personnes se feront un plaisir de répondre à vos questions dans nos locaux. Action Contre la Faim - USA n'a pas prévu d'indemnisation à vous proposer si vous veniez à être blesser ou subir des effets indésirables qui ne sont pas la faute des investigateurs.

Avez-vous des questions au sujet de cette étude?
Acceptez-vous que votre ménage pour participer à cette étude? ☐ Oui ☐ Non

Intervieweur doit remplir la section suivante
Numéro unique :
Nom, prénom du parent:
_____

_____ / / _____
Signature de la date de consentement de la personne obtention Date

_____ / / _____
Témoin du consentement si le parent ne sait ni lire ou écrire Date
(Doit être différent de la personne qui obtient le consentement)

Annex 4: Location and frequency of essential variables gathering

Variable	Gathering frequency	Gathering location
Weight	Weekly	OTP
Height	At enrolment and discharge	OTP
Weight gain	Weekly	OTP
Length stay	Weekly	OTP
Water diseases	Weekly	OTP
Sex, age, socio-economic status	Weekly	OTP
RUTF consumed	Weekly and at random	OTP and at household
PUR® consumed	Weekly and at random	OTP and at household
Education on good feeding, maternal, healthcare and hygiene practices	Weekly	OTP
Quality of water consumed at the household	Weekly	At household
PUR® utilization	Weekly	At household
PUR® acceptability	Weekly	At household
Education messages follow-up	Every other week	At household

Annex 5: Ethical approval and MoU with ProNaNut, the nutrition branch of the Ministry of Health in DRC

République Démocratique du Congo
Ministère de la Santé

PRONANUT

ACF

PROTOCOLE D'ACCORD
Programme national de nutrition / Action Contre la Faim - l'étude comparative des effets du Plumpy'Nut® + PUR® versus Plumpy'Nut® dans la prise en charge des enfants de 6 à 59 mois souffrant de Malnutrition Aiguë Sévère dans la zone de santé de Popokabaka, province du Bandundu

Entre : Le **Programme National de Nutrition** (PRONANUT), sise sur 35 Avenue du Comité Urbain, Kinshasa Gombe représenté par **Prof. Dr Banea MAYAMBU**, Directeur National

Et : **Action Contre la Faim USA** (ACF-USA) représenté par **Anne KRÖNING**, Chef de mission ACF-USA RDC Ouest

ARTICLE 1 : OBJET DU PROTOCOLE

1.1 **Objet du protocole** : ce protocole a pour objet d'établir et définir les conditions et modalités générales de la collaboration entre les parties en ce qui concerne *l'étude comparative des effets du Plumpy'Nut® + PUR® versus Plumpy'Nut® dans la prise en charge d'enfants de 6 à 59 mois souffrant de Malnutrition Aiguë Sévère dans la zone de santé de Popokabaka, province du Bandundu.*

Les parties conviennent de conjuguer leurs efforts et de maintenir des relations de travail étroites en vue de réaliser une prise en charge satisfaisante et conforme aux recommandations du Programme National de Nutrition en Vigueur.

1.2 **Portée du protocole** : *12 novembre 2012 au 30 avril 2013* (durée de 6 mois).

ARTICLE 2 : ATTRIBUTIONS ET RESPONSABILITES

2.1 Chaque partie choisit la personne qui exerce en son nom l'autorité et la responsabilité ultime pour le projet et en communique l'identité à l'autre.

2.2 Les parties se tiennent mutuellement informées de toutes les activités concernant le projet. Une entrevue mensuelle ou un mémorandum d'état de l'avancement avec les parties à ce protocole sera organisée afin de discuter de l'avancement du projet, des difficultés rencontrées et des perspectives à venir. La réunion aura lieu une fois par mois.

2.3 Une réunion extraordinaire pourra être convoquée selon les besoins.

ARTICLE 3 : CADRE SPECIFIQUE

3.1 **Engagements d'ACF-USA** :

1. ACF-USA versera une enveloppe de cinq cents dollars (500$) au PRONANUT sise sur 35 Avenue du Comité Urbain, Kinshasa Gombe afin de couvrir les frais administratifs, d'enregistrement de l'étude et d'autorisation.

2. ACF-USA versera un perdiem à la personne du PRONANUT selon le protocole d'accord de partenariat entre le programme national de nutrition et Action Contre la Faim pour l'exercice juillet 2011 à juillet 2016 signé le 1er juillet 2011, lors :

- de la visite initiale à Popokabaka pour la présentation du projet d'étude aux autorités sanitaires de district et de zone, prévue pour une durée de 4 jours.
- de la visite de supervision qui s'effectuera à mi-étude, prévue pour une durée de 6 jours.

3. **ACF-USA**, au travers d'un mémorandum ou d'une entrevue, partagera mensuellement des informations sur l'état d'avancement de l'étude avec le partenaire (PRONANUT).

3.2 **Engagements du PRONANUT** :

1. Le **PRONANUT** facilitera les relations d'ACF-USA avec les autorités locales médicales et administratives pour la mise en place et le bon fonctionnement de l'étude. Notamment : l'autorisation de réaliser l'étude au sein des centres de santé impliqués dans la zone, l'implication des aires de santé dans les activités de prise en charge et d'inclusion des enfants répondant aux critères retenus par le protocole de recherche, etc.
2. Le **PRONANUT** aura un regard sur l'étude durant la visite terrain à mi-étude et lors des points mensuels et pourra faire des recommandations sur le déroulement de l'étude,

ARTICLE 4 : ACCORD ET BONNES PRATIQUES

Par la signature du présent protocole, le PRONANUT consent à la réalisation de la présente étude dans la zone géographique précitée et confirme que la présente étude est conforme aux bonnes pratiques de la recherche et donc aux règles éthiques de la recherche en vigueur dans le pays.

ARTICLE 5 : PROPRIETE INTELLECTUELLE

Le PRONANUT convient que l'étude, les idées, la méthodologie, la documentation et toute information contenue dans l'étude constituent un élément de propriété intellectuelle dont Action Contre la Faim est le titulaire. Action Contre la Faim, titulaire de ces droits, est le cas échéant, protégé par le droit civil et pénal, ainsi que par les lois sur la protection des droits d'auteur.

Après publication des résultats, ACF-USA mettra à la disposition du ProNaNut l'ensemble des données et conclusions en lien avec cette étude.

ARTICLE 6 : RESILIATION ANTICIPEE

Chaque partie a le droit de mettre fin à cet accord dans un délai de trente jours après l'envoi d'une notification préalable écrite :

(1) Si l'autre partie n'est pas capable, n'est pas disposée ou est empêchée de s'acquitter de ses obligations et de responsabilités définies dans le présent accord, ce qui aurait pour conséquence de compromettre la réalisation des objectifs de l'étude.

(2) En cas de mauvaise gestion de ressource mise à disposition pour les activités du présent projet.

ARTICLE 7 : FORCE MAJEURE

7.1 Les parties se réservent le droit, en cas de force majeure, de modifications imprévisibles des conditions d'exécutions de ce projet ou d'arrêt de financement des bailleurs de fonds, d'aménager le présent protocole par le biais d'un amendement ou de mettre fin au présent protocole.

7.2 Si les conditions de sécurité ne permettent pas à ACF- USA d'accéder dans sa zone d'action, ACF- USA se réserve le droit de suspendre ses activités, et donc de mettre fin aux obligations énoncées dans le présent protocole.

ARTICLE 8 : ARBITRAGE

Tout différend, controverse ou réclamation découlant du présent accord doivent être soumis, sauf arrangement à l'amiable, aux voies de négociations directes prescrites par la loi congolaise en vigueur.

ARTICLE 9 : AMENDEMENT AU PROTOCOLE

9.1 Toute modification au présent protocole devra être discutée et approuvée au préalable entre les deux parties et débouchée sur un avenant signé conjointement et qui fera partie intégrante au présent protocole.

9.2.Le présent protocole d'accord prendra effet à la date de signature par l'ensemble des parties.

Pour commun accord, fait à Kinshasa, le 12 novembre 2012

Pour le PRONANUT

Prof. Dr Banea MAYAMBU
Directeur National

Pour ACF-USA/R.D.C Ouest

Anne KRÖNING
Chef de Mission

Annex 6: Brief description of roles of personnel and duration of their assignment in the implementation of the study

Title	Number	Role	Duration in months
Trial Manager	1	-Coordinate and ensure the smooth roll-out of the study -Ensure the quality of the data -Analyze the data -Draft the report and the article for publication	7 months, including 5 at Popokabaka
Research assistant	1	-Supervise field supervisors -Ensure data gathering and follow-up -Enter data in software and ensure its quality	6 months at Popokabaka
Field supervisors	2	-Supervise survey agents -Ensure data gathering	
Survey agents	7	- Implement the protocol in each of OTP -Gather data in OTP and at households -Ensure the quality and completeness of data	
Community Health Workers	14	- Gather data in OTP and at households - Ensure the quality and completeness of data	4 months at Popokabaka
Consultant	1	-Coach the trial manager -Assist the trial manager in the analysis and the reading of data and in the drafting of the report -Participate in the article drafting	Remote and intermittent intervention
Biostatistician	1	-Support data analysis and result reading	Remote and intermittent intervention

Annexes 7 and 8: General and PUR Questionnaires

Questionnaire d'étude commun aux 2 groupes

dec 2012 - mars 2013 - ACF

Etude Pur® - zone de santé de Popokabaka - RDC

Informations générales

1. Aire de santé
○ 1. POpokabaka ○ 2. KAbangu
○ 3. INtenga ○ 4. ImWela
○ 5. Kianfu Kinzadi ○ 6. KaNgwenzi
○ 7. IMbela

2. Groupe d'étude
○ 1. Contrôle ○ 2. intervention

3. Référence d'inclusion

4. Date d'inclusion

5. Nom de l'enquêteur qui inclut

6. Nom de l'infirmier qui a admit l'enfant

7. Nom et prénom de l'enfant

8. Numéro unique

9. Nom du Père ou de la mère

10. Adresse du domicile

11. Temps de marche entre la maison et le centre de santé

12. Date naissance de l'enfant
Expression régulière : jj/mm/aaaa

13. Âge en mois

14. Sexe
○ 1. Fille ○ 2. garçon

15. Mode d'admission
○ 1. dépistage au centre ○ 2. dépistage RECO
○ 3. venue spontanée ○ 4. rechute

16. Statut vaccinal selon l'âge de l'enfant
○ 1. Complet ○ 2. Incomplet ○ 3. ne sait pas

Anthropométrie à l'admission

Entourer le critère avec lequel l'enfant a été admis

17. Poids à l'admission

18. Taille à l'admission

19. Périmètre brachial (PB) à l'admission
La réponse doit être comprise entre 70 et 115.

20. Indice poids / taille en Z-score à l'admission

21. Poids cible Pur(r) de sortie de l'étude

Examen clinique à l'admission

22. Diarrhée simple (plus de 3 selles liquides / j)
○ 1. oui ○ 2. non

23. Vomissements
○ 1. oui ○ 2. non

24. Fièvre
○ 1. oui ○ 2. non

25. Toux
○ 1. oui ○ 2. non

26. Test d'appétit admission
○ 1. positif ○ 2. négatif

27. Test du paludisme à l'admission
○ 1. positif ○ 2. négatif ○ 3. non réalisé

28. Autres problèmes (utiliser des mots clés)

Traitement administré à l'admission

29. Amoxicilline
○ 1. oui ○ 2. non

30. Mebendazole
○ 1. oui ○ 2. non

31. ACT (Combinaison Thérapeutique à base d'Artémisinine)
○ 1. oui ○ 2. non

32. Vitamine A
○ 1. oui ○ 2. non

33. Vaccin rougeole
○ 1. oui ○ 2. non

34. Nombre de sachets d'atpe Plumpy'Nut® donnés à l'admission

35. Autres traitements
○ 1. oui ○ 2. non

36. Si oui : nom du médicament date et dose

Informations générales - semaine 2

37. Nom et prénom de l'enfant

38. Adresse

39. Date de venue à domicile

40. L'enfant est-il toujours sous allaitement maternel ?
○ 1. oui ○ 2. non

41. A quel âge les aliments ont été introduits (sevrage partiel) ?

42. A quel âge l'allaitement maternel a pris fin (sevrage complet) ?

43. Profession de la personne travaillant dans le ménage ?

44. Niveau d'instruction de la personne interrogée ?
○ 1. sans instruction ○ 2. primaire ○ 3. secondaire
○ 4. universitaire

45. Personne répondant au questionnaire
○ 1. mère ○ 2. père ○ 3. autre membre de la famille

46. Etat civil des parents de l'enfant
○ 1. marié(e) ○ 2. élève seule l'enfant ○ 3. en couple
○ 4. autre

47. Combien de personnes vivent dans votre ménage ?

48. Combien d'enfants de 0 à 5 ans vivent dans votre ménage ?

49. Combien d'enfants de 6 à 18 ans vivent dans votre ménage ?

50. Combien d'adultes de plus de 18 ans vivent dans votre ménage ?

51. Avez-vous reçu des messages sur les signes d'alerte qui doivent vous conduire à amener votre enfant au centre de santé ?
○ 1. oui ○ 2. non

52. Si oui, lesquels ? (en demander au moins 3)
☐ 1. convulsions
☐ 2. respire difficilement
☐ 3. refuse de têter ou de manger ou de boire
☐ 4. a des selles liquides avec du sang
☐ 5. est inconscient
☐ 6. fièvre
☐ 7. autres
Vous pouvez cocher plusieurs cases.

53. Avez-vous reçu des messages sur les signes de la malnutrition ?
○ 1. oui ○ 2. non

54. Si oui, lesquels (en demander au moins 3)
☐ 1. perte de l'appétit
☐ 2. pertubations affectives
☐ 3. apathie
☐ 4. oedèmes
☐ 5. pertes de poids massive
☐ 6. peau fine
☐ 7. changements d'aspect des cheveux
☐ 8. autres
Vous pouvez cocher plusieurs cases (7 au maximum).

55. Avez-vous reçu des messages sur les recommandations de l'alimentation du Nourrisson et du Jeune Enfant en fonction de son âge ?
○ 1. oui ○ 2. non

56. Si oui, lesquels (en demander au moins trois)
☐ 1. Avant 6 mois allaitement exclusif
☐ 2. Après le 6e mois, l'enfant a besoin de manger des bouillies en plus du lait maternel
☐ 3. A 8 mois, ajouter toujours de l'huile de palme rouge crue à la fin de préparation de la bouillie
☐ 4. Après 12 mois, continuer à donner les bouillies, introduire au moins 2 fois / jour les aliments du plat familial en plus du lait maternel
☐ 5. Après 2 ans, l'enfant mange la même nourriture que la famille et continue si possible l'allaitement maternel
☐ 6. Donnez régulièrement des fruits
☐ 7. Autres
Vous pouvez cocher plusieurs cases (6 au maximum).

57. Avez-vous reçu des messages sur les recommandations sur l'hygiène corporelle?
○ 1. oui ○ 2. non

58. Si oui, lesquels (en demander au moins trois)
☐ 1. lavage des mains au savon
☐ 2. se laver avec du savon 2 fois / jour
☐ 3. laver au savon les plaies ou blessures
☐ 4. porter des habits propres
☐ 5. laver les enfants avec du savon tous les jours
☐ 6. se brosser les dents tous les jours (kélélé)
☐ 7. laver les cheveux des enfants
☐ 8. couper court les cheveux des enfants
☐ 9. peigner les cheveux des enfants
☐ 10. autres
Vous pouvez cocher plusieurs cases (7 au maximum).

59. Avez-vous reçu des messages de recommandations sur l'hygiène des aliments?
○ 1. oui ○ 2. non

60. Si oui, lesquels (en demander au moins 3)

- ☐ 1. bouillir l'eau avant de la boire
- ☐ 2. consommer de préférence des aliments cuits
- ☐ 3. laver les aliments à consommer cru ou à cuire
- ☐ 4. couvrir les aliments
- ☐ 5. se laver les mains avant de manger ou de préparer à manger
- ☐ 6. manger équilibrer (énergie, construction et protection)
- ☐ 7. autres

Vous pouvez cocher plusieurs cases (6 au maximum).

Utilisation de l'eau - semaine 2

61. Où allez-vous chercher l'eau ?

- ☐ 1. Rivière ou mare ou ruisseau
- ☐ 2. Source aménagée
- ☐ 3. Source non aménagée
- ☐ 4. Puit protégé
- ☐ 5. Puit non protégé
- ☐ 6. Eau de pluie

Vous pouvez cocher plusieurs cases (2 au maximum).

62. Quel récipient utilisez-vous pour transporter l'eau ?

☐ 1. Seau ☐ 2. Bidon ☐ 3. Bassine

Vous pouvez cocher plusieurs cases.

63. Dans quel récipient stockez-vous l'eau de BOISSON ?

- ☐ 1. Bidon fermé
- ☐ 2. Bidon non fermé
- ☐ 3. Seau couvert
- ☐ 4. Seau non couvert
- ☐ 5. même récipient que pour le transport
- ☐ 6. Celui donné par ACF

Vous pouvez cocher plusieurs cases (5 au maximum).

64. Quel traitement appliquez -vous à l'eau avant de la boire ?

- ☐ 1. Aucun
- ☐ 2. Bouillir
- ☐ 3. Filter
- ☐ 4. Chlorer
- ☐ 5. Pur
- ☐ 6. Aquatabs
- ☐ 7. Par gravité

Vous pouvez cocher plusieurs cases (6 au maximum).

65. L'eau de boisson est-elle servie dans des gobelets propres ?

○ 1. oui ○ 2. non

Pratiques d'hygiène - semaine 2

66. Une latrine est-elle présente à domicile ?

○ 1. oui ○ 2. non

67. A quels moments de la journée vous lavez-vous les mains?

- ☐ 1. Avant manger
- ☐ 2. Après avoir nettoyé les selles de mon enfant
- ☐ 3. Après avoir été au toilette
- ☐ 4. En rentrant du travail ou du champ
- ☐ 5. Avant de préparer à manger
- ☐ 6. Avant de donner des soins à mon enfant
- ☐ 7. autres

Vous pouvez cocher plusieurs cases (6 au maximum).

68. Comment vous lavez-vous les mains?

- ☐ 1. Avec de l'eau sans savon
- ☐ 2. Avec de l'eau et du savon
- ☐ 3. Avec de l'eau qui coule
- ☐ 4. Avec de l'eau dans un récipient

Vous pouvez cocher plusieurs cases.

69. Que faites-vous des selles après avoir changé votre enfant?

- ☐ 1. Je laisse les selles là où elles sont
- ☐ 2. J'évacue les selles dans les latrines
- ☐ 3. J'évacue les selles dans les latrines, puis je me lave les mains avec du savon
- ☐ 4. Autres

Vous pouvez cocher plusieurs cases.

Qualité de l'eau de boisson - semaine 2

70. Quand l'eau de boisson a-t-elle été mise dans le bidon la dernière fois ? ☐

71. Heure du prélèvement ☐

72. Quelle est la couleur de l'eau prélevée ?

○ 1. Translucide ○ 2. Brune

73. Quel goût à l'eau dans le gobelet ?

○ 1. Pas le goût de chlore ○ 2. goût de chlore

74. Quelle est la valeur lue du pH ? ☐

La réponse doit être comprise entre 6.6 et 8.2.

75. Quelle est la valeur lue du Chlore résiduel ? ☐

La réponse doit être comprise entre 0 et 6.

Diversité alimentaire individuelle (IDDs) - semaine 2

Quels sont les différents aliments que votre enfant suivi dans l'étude PUR a mangé depuis hier (dernières 24 heures) pendant la journée et la nuit. SEULE la personne qui prépare le repas de l'enfant doit répondre. Sélectionner les groupes d'ingrédients:

76. Céréales, racines et tubercules (maïs, riz, sorgho, pain, pâtes de millet, manioc, pomme de terre, patate douce, sésame, banane plantin ou autre)

○ 1. oui ○ 2. non

77. Aliments d'origine végétale riches en vitamine A (carotte, tomate, banane douce, sauce feuilles, ngaingai, bilolo, pointe, piment rouge séché ou autre)

○ 1. oui ○ 2. non

78. Autres fruits et légumes (mangue, ananas, papaye, fruits ou légumes de la cueillette)

○ 1. oui ○ 2. non

79. Viande, volaille, abats, poissons, chenilles (boeuf, chèvre, mouton, porc, poulet, dinde, poissons fumés ou salés ou frais)

○ 1. oui ○ 2. non

80. Oeufs
○ 1. oui ○ 2. non

81. Légumes secs, légumineuses, noix (haricots, niébé, arachide ou autres)
○ 1. oui ○ 2. non

82. Lait, allaitement maternel, laitages (lait de vache ou chèvre ou de mouton, allaitement, lait en poudre ,yaourt, fromage, lait d'arachide ou autre)
○ 1. oui ○ 2. non

83. Aliments cuits avec de l'huile (banane plantain, viande, feuilles...)
○ 1. oui ○ 2. non

Précisions IDDs - semaine 2

Merci de reporter ci-dessus pour chaque repas des dernières 24 h, chaque plat et sa composition -> exemples : repas du soir : riz (cuisiné avec de l'huile, des tomates et des sardines), petits pois (cuisiné avec de l'huile) et poundou (feuilles et huile)

84. Avez-vous détaillez les ingrédients de chaque plats ?
○ 1. oui ○ 2. non

Questionnaire de suivi à domicile groupe Pur - semaines 2 - 4 - 6 - 8

déc 2012 - mars 2013 - ACF

Etude Pur(r) - zone de santé de Popokabaka - RDC

Observation de l'utilisation du Pur(r) - semaine 2

1. Date du passage à domicile

2. Nom de l'enfant

3. Référence d'inclusion

4. Aire de santé

O 1. POpokabaka O 2. KAbangu O 3. INtenga
O 4. InWela O 5. Kianfu Kinzadi O 6. KaNgwenzi
O 7. IMbela

5. Nom de l'enquêteur qui fait la visite

6. Le sachet du produit est-il ouvert de manière hygiènique (avec des ciseaux ou une lame) ?

O 1. oui O 2. non

7. Le contenu du sachet est-il ajouté dans un seau propre contenant 10 litres d'eau ?

O 1. oui O 2. non

8. La poudre est-elle vivement mélangée avec l'eau pendant environ 5 minutes ?

O 1. oui O 2. non

9. Le mélange est-il laissé au repos jusqu'à ce que l'eau se clarifie durant environ 5 minutes ?

O 1. oui O 2. non

10. L'eau devient-elle claire et propre après que le processus de purification soit terminé ?

O 1. oui O 2. non

11. La matière solide s'est-elle accumulée et déposée au fond du seau ?

O 1. oui O 2. non

12. L'eau est-elle transvasée à travers un filtre de coton propre ?

O 1. oui O 2. non

13. L'eau purifiée est-elle conservée dans un bidon propre et couvert ?

O 1. oui O 2. non

14. L'eau purifiée est-elle consommée à l'aide d'une tasse ou d'un verre propre ?

O 1. oui O 2. non

15. Le matériel utilisé pour la préparation est-il le matériel fourni par ACF ?

O 1. oui O 2. non

16. Si 'non', pourquoi (utiliser des mots clés):

17. Les réponses (questions 6 à 16) collectées sont obtenues par OBSERVATION lors de la préparation de l'eau ou DEMANDEES (rapportée) en dehors de toute préparation ?

O 1. rapportée O 2. observée

18. Le matériel utilisé pour le stockage de l'eau de boisson est-il le matériel fourni par ACF ?

O 1. oui O 2. non

Acceptabilité du Pur(r) - semaine 2

19. Qui boit l'eau purifiée à la maison ?

O 1. Tout le monde
O 2. l'enfant suivi à l'UNTA seulement
O 3. les enfants seulement

20. Si différent de "tout le monde", pourquoi ? (utiliser des mots clés)

21. Une fois traitée la couleur de l'eau change t'elle ?

O 1. oui O 2. non

22. Si "oui" : est-ce important pour vous ?

23. L'odeur de l'eau vous dérange t-elle ?

O 1. oui O 2. non

24. Le goût vous dérange-t-il ?

O 1. oui O 2. non

25. Rencontrez-vous des difficultés pour utiliser le PUR® ?

O 1. oui O 2. non

26. Si "oui", lesquelles ? (utiliser des mots clé)

27. Avez-vous ressenti des effets indésirables après avoir bu l'eau traitée par PUR® ?

O 1. oui O 2. non

28. Si "oui", lesquels ? (utiliser des mots clé)

Annex 9: PUR MONITORING PROTOCOL – OUTPATIENT CARE FOR SAM CHILDREN

Weeks	week 1		week 2		week 3		week 4		week 5		week 6		week 7		week 8		week 9	
Days	d0	d1	d7	d10	d14	d17	d21	d24	d28	d31	d35	d38	d42	d46	d49	d52	d56	d59
Inclusion	X																	
Household visits																		
Reinforcement for PUR use		X		X		(X)		X		(X)		X		(X)				
Control of residual chlorine and pH levels				**X**				**X**				**X**				**X**		
Survey questionnaire				**X**				**X**				**X**				**X**		X
Montitoring the use of PUR and Plumpy'Nut		X		X		(X)		X		(X)		X		(X)		X		X
Health center visits																		
Appetite test	X		X		X		X		X		X		X		X		X	
MUAC	X		X		X		X		X		X		X		X		X	
Weight measurements	X		X		X		X		X		X		X		X		X	
Physical	X		X		X		X		X		X		X		X		X	
Release																		
W/H or MUAC depending on exit criteria for PUR					X		X		X		X		X		X		X	

Exit criteria for PUR® protocol

W/H in z-score ≥ -2 ET

MUAC ≥ 125 mm