Alive & Thrive Evaluation in Burkina Faso

[Version 3.4. 16th March 2015]

SPONSOR: London School of Hygiene & Tropical Medicine

FUNDING: Managed by FHI 360

LSHTM ETHICS REFERENCE: 9066

Protocol authorised by:

Name:	Veronique Filippi	**Role:**	Chief Investigator
Signature:		**Date:**	
Name:		**Role:**	Sponsor Representative
Signature:		**Date:**	

Main Contacts

Trial Management Group:

Chief Investigator: Dr Veronique Filippi

London School of Hygiene & Tropical Medicine

Keppel Street

London, UK. WC1E 7HT

Tel: +44 207 927 2874

E-mail: veronique.filippi@lshtm.ac.uk

Co-investigators: Dr Hama Diallo

Centre Muraz Research Institute

Ministry of Health

2054 Avenue Mamadou Konate, Bobo-Dioulasso, Burkina Faso

Tel: +226 76 78 94 15

E-mail: diallohama@hotmail.com

Dr Rasmané Ganaba

AFRICSanté

01 BP 298 Bobo-Dioulasso, Burkina Faso.

Tel: +226 20 986 368

E-mail: rganaba@fasonet.bf

Dr Sophie Sarrassat

London School of Hygiene & Tropical Medicine

Keppel Street

London, UK. WC1E 7HT

Tel: +44 207 958 8198

E-mail: sophie.sarrassat@lshtm.ac.uk

Dr Jenny Cresswell

London School of Hygiene & Tropical Medicine

Keppel Street

London, UK. WC1E 7HT

Tel: +44 207 927 2476

E-mail: jenny.cresswell@lshtm.ac.uk

Statistician:

Prof. Simon Cousens

London School of Hygiene & Tropical Medicine

Keppel Street

London, UK. WC1E 7HT

Tel: +44 207 927 2422

E-mail: simon.cousens@lshtm.ac.uk

Trial Co-ordination Centre:

For general queries, supply of trial documentation and queries relating to day-to-day collection of data please contact:

Dr Rasmané Ganaba

AFRICSanté

01 BP 298 Bobo-Dioulasso, Burkina Faso.

Tel: +226 20 986 368

E-mail: rganaba@fasonet.bf

Clinical Queries:

Clinical queries should be directed to Dr Hama Diallo who will direct the query to the appropriate person.

Sponsor:

London School of Hygiene & Tropical Medicine is the main research sponsor for this study. For further information regarding the sponsorship conditions, please contact Clinical Trials QA Manager:

London School of Hygiene & Tropical Medicine

Keppel Street

London, UK. WC1E 7HT

Tel: +44 207 927 2626

This protocol describes the Alive & Thrive evaluation in Burkina Faso and provides information about procedures for entering participants. The protocol should not be used as a guide for the treatment of other participants; every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study.

Problems relating to this trial should be referred, in the first instance, to the trial coordination centre.

This trial will adhere to the principles outlined in the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines, protocol and all applicable local regulations.

Contents

1. BACKGROUND

1.1 Introduction

'Alive & Thrive' is a nine-year (2009-2017) initiative to improve infant and young child feeding practices by increasing rates of exclusive breastfeeding and improving complementary feeding practices. In its first phase of implementation, 'Alive & Thrive' operated in Bangladesh, Ethiopia, and Vietnam. Originally planned to end in 2014, the Initiative received additional funding from several donors (Bill & Melinda Gates Foundation, Irish Aid, and Canada's Department of Foreign Affairs, Trade and Development) to support programs in additional countries. One of these additional countries is Burkina Faso.

This protocol describes the design of the impact evaluation of the 'Alive & Thrive' Initiative (A&T) in Burkina Faso, and the effective dissemination of its findings. The impact evaluation will take place in one province: Boucle du Mouhoun, although A&T will be implementing their activities nationally. This evaluation will complement and supplement ongoing research into the A&T framework in other countries [1].

1.2 Study setting: Boucle du Mouhoun

Boucle du Mouhoun is situated in the northwest of Burkina Faso. The region is divided into 6 provinces, 47 departments, 6 urban communes, 41 rural communes and 992 villages. The total population was estimated to be 1.7 million in 2013, including 380,000 women of reproductive age and 73,000 infants under 12 months [2]. The dominant ethnic groups in the region are the Bwaba, the Samo and the Marka.

Boucle du Mouhoun is organised into six health districts, each covering one province (**Figure 1**). These are: Boromo, Dédougou, Nouna, Solenzo, Toma and Tougan.

- DS Boromo (province Balé): 138 secteurs/villages
- DS Dédougou (province Mouhoun): 192 secteurs/villages
- DS Nouna (province Kossi): 269 secteurs/villages
- DS Solenzo (province Banwa): 105 secteurs/villages
- DS Toma (province Nayala): 111 secteurs/villages
- DS Tougan (province Sourou): 152 secteurs/villages

In 2013, public sector health facilities in Boucle du Mouhoun comprised one CHR (regional hospital), five CMA (district hospitals), three CM (CSPS with a doctor), 181 CSPS (health centre), 22 dispensaries, two maternity clinics, and seven "other" types of structure. In the region overall, 57% of the population live within 4km of a health facility, 23% live within 5 to 9 km, and 20% live 10km or further away [2]. The percentage of the population living more than 10km from a health facility ranges from 15% in Boromo to 24% in Nouna [2]. The radius of the average catchment area of a health facility in Boucle du Mouhoun is 7.3 km; this information stratified by health district is provided in **Table 1**.

Health personnel in Boucle du Mouhoun include 34 doctors of whom six are specialists, 121 "attaché de santé" (nurse-specialists), 639 nurses, 158 midwives, 266 auxiliary nurses and 303 auxiliary midwives. Overall 92% of CSPS meet the minimum required standard for staffing (i.e. have 1 nurse + 1 auxiliary midwife + 1 auxiliary nurse) ranging between 67% in Solenzo to 100% in each of Dédougou, Nouna and Toma.

Figure 1: Map of health districts in Boucle du Mouhoun. Taken from the "Carte sanitaire 2010".

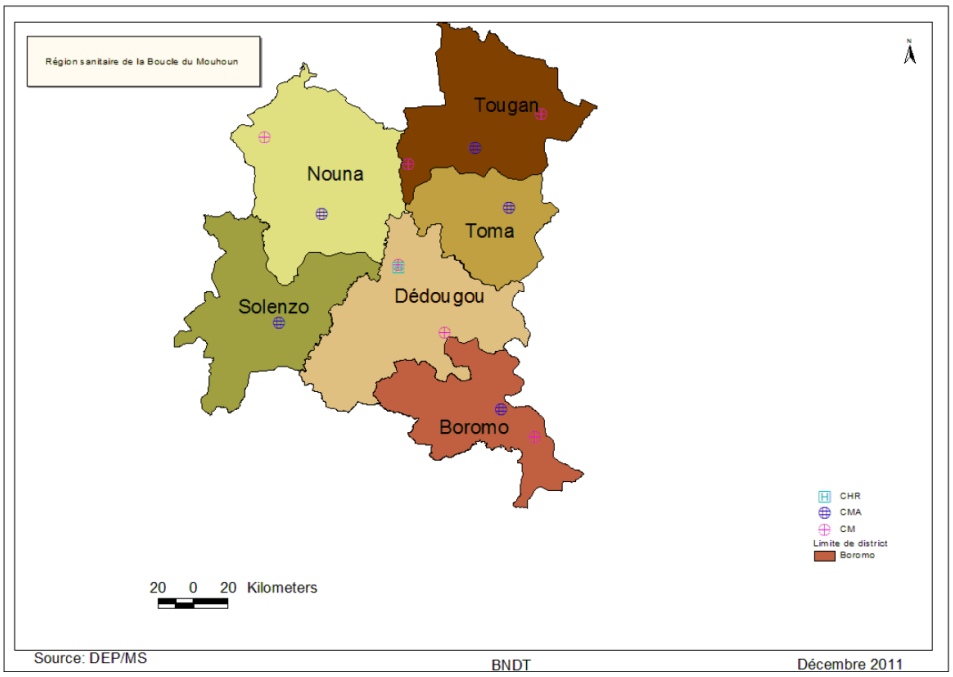


Table 1: Population and catchment of CSPS by health district. Data taken from the Annual Statistics [2].

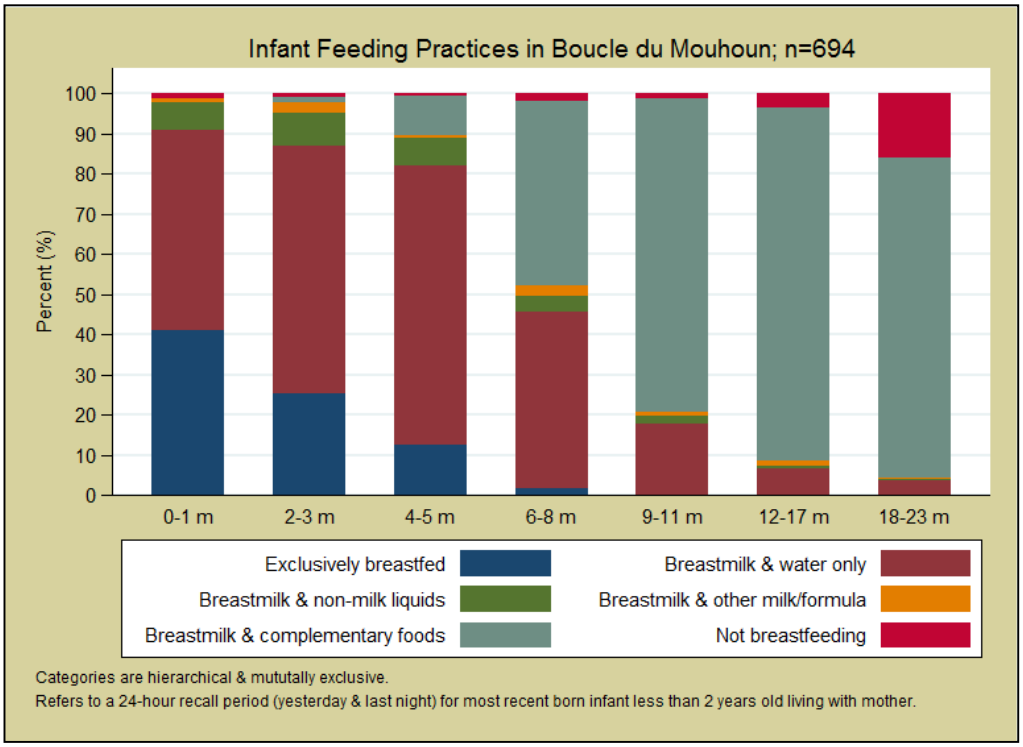
Health district	Women of Reproductive Age	Expected Pregnancies during 2013	Number of Health facilities*	Average Radius of Catchment Area in km	Ratio of Expected Pregnancies/ CSPS Catchment
Boromo	56,505	14,782	33	6.6	448
Dédougou	78,616	20,566	37	7.7	556
Nouna	72,644	19,004	42	7.5	452
Solenzo	71,016	18,578	33	7.5	563
Toma	42,522	11,124	27	6.6	412
Tougan	56,994	14,910	36	7.3	414
Boucle du Mouhoun	**378,297**	**98,962**	**208**	**7.3**	**476**

** Including CSPS, CM, maternity clinic & dispensary*

According to data from the 2010 DHS, in Boucle du Mouhoun 80% of women of reproductive age have no education, 13% have primary education and 6% have secondary education or higher. The predominant religion is Muslim (65% of women of reproductive age) followed by Catholic (22%) and Protestant (8%), with 5% following traditional religions.

Based on self-report, a majority of women attend antenatal care at least once (94%), whilst 64% deliver in a health facility [3]. In this region, 38% of infants initiated breastfeeding within one hour after birth (national average: 42%) and 84% initiated breastfeeding on the first day of life (national average: 81%) [3]. The median length of exclusive breastfeeding was 0.7 months (national median: 0.6 months). In Boucle du Mouhoun, 30% of infants less than 6 months old were exclusively breastfed during the 24 hours prior to interview (national median 25%). It is very common to supplement breast milk with plain water from birth (see **Figure 2**).

Figure 2: Infant feeding practices in the previous 24 hours in the region of Boucle du Mouhoun among most recent born infants less than two years old. Data source: DHS 2010.



Boucle du Mouhoun generally performs better on indicators of child nutritional status (under 5 years) compared to the national average, although in absolute terms there are still many children who are malnourished. In Boucle du Mouhoun 29% of children under 5 years are stunted (national average: 35%), and 12% are severely stunted (national average: 15%); 11% of children under 5 years are wasted (national average: 16%) and 3% are severely wasted (national average: 6%); 21% are underweight (national average: 26%) with 4% being severely underweight (national average: 8%).

In Boucle du Mouhoun the neonatal mortality rate is currently 33 deaths per 1000 live births; infant mortality is 69 deaths per 1000 live births and under-5 mortality is 135 deaths per 1000 live births [3].

1.3 Description of the 'Alive & Thrive' intervention

The stated objective of A&T in Burkina Faso is to increase the proportion of infants younger than six months who are exclusively breastfed to a minimum of 50% in A&T areas. This target may be revised by A&T after the baseline survey of the impact evaluation.

A&T's theory of change identifies five inter-related barriers which must be overcome in order to bring about changes in exclusive breastfeeding. These barriers include: (i) lack of political will and the low priority given to preventive nutrition services as opposed to the treatment of malnutrition; (ii) lack of motivated and well-supervised health workers with appropriate counselling skills; (iii) women's erroneous beliefs about water, colostrum and infant needs, as well as lack of skills; (iv) the lack of social support for women who might like to practice exclusive breastfeeding, as well as (v) a lack of community mobilisation around the importance of exclusive breastfeeding.

Table 2 describes the components of the A&T intervention. Some activities (national-level advocacy work and mass communication through radio broadcasts) will not take place within Boucle du Mouhoun and thus do not form part of the intervention package for this evaluation.

Table 2: Description of the components of the A&T intervention

A&T activities to be evaluated within Boucle du Mouhoun	A&T activities taking place outside Boucle du Mouhoun
Interpersonal communication component delivered by community workers and volunteers during home visits and at monthly mother's group meetings to: • Increase mother's knowledge about optimal breastfeeding and its benefits • Increase mother's self-efficacy related to breastfeeding Improve mother's perceptions about social norms relating to breastfeeding.	National level advocacy activities to: • Increase awareness among decision makers regarding the importance of improved breastfeeding practices. • Strengthen ways to motivate frontline workers in health services to counsel on infant feeding.
Community mobilisation activities to: • Raise awareness of the benefits of optimal breastfeeding among opinion leaders, and family members, and increase the support they provide to breastfeeding mothers.	Mass communication through radio to reinforce breastfeeding messages, and expand the reach to areas where A&T does not have interpersonal and community mobilisation activities.
Enhanced training of government health workers in infant and young child feeding and interpersonal counselling techniques to: • Improve their ability to support mothers and provide timely information about infant feeding.	

A&T has identified two partners who are in the final stages of contract negotiation for the local implementation and scale-up: *Terre des Hommes* for the component of interpersonal counselling at health facilities and in the community, and *Mwangaza Action* covering community mobilization activities.

The mass communication activities (taking place outside Boucle du Mouhoun) will be conducted by *DMI*.

2. STUDY OBJECTIVES

2.1 Overall aim

Our overall aim is to conduct an impact evaluation of the A&T, with a focus on testing A&T's primary objective in Burkina Faso of increasing the exclusive breastfeeding rate among infants younger than six months to at least 50%.

Using a cluster randomised trial design, our evaluation will seek to answer the primary research question: "What is the size of the effect of the locally-delivered A&T components on the prevalence of exclusive breastfeeding among infants up to six months old?"

2.2 Specific objectives

1. To conduct a cluster randomised trial in Boucle du Mouhoun to determine the impact of A&T locally-delivered components on the prevalence of exclusive breastfeeding among infants up to six months, and other secondary outcomes of interest in infants up to twelve months.
2. To conduct a complementary qualitative study to document: i) the implementation of A&T activities at the regional and local level, activities conducted by other agencies and the ways in which women receive information on breastfeeding in both the intervention and control areas; ii) the social determinants of breastfeeding in Boucle du Mouhoun.
3. To conduct a validation study in a sub-sample of mothers and infants up to six months comparing mother's reported breastfeeding to a reliable biochemical method (the dose to the mother deuterium oxide turnover technique).
4. To use the LiST tool to estimate Lives Saved by the A&T locally-delivered intervention components
5. To package our findings in a variety of formats appropriate for dissemination to different audiences.

3. STUDY DESIGN

Our evaluation will be a cluster randomised trial design, consisting of two independent, cross-sectional surveys. The baseline survey will take place in 2015; the endline survey will take place in 2017. The A&T intervention will be ongoing throughout 2015-2017.

Our evaluation will include complementary qualitative work to better understand the intervention and cultural norms surrounding exclusive breastfeeding in Boucle du Mouhoun; and a validation study to assess the reliability of self-reported breastfeeding behaviour.

There will also be an ongoing process evaluation of A&T activities throughout the period. Most of this data will be collected by the implementing partners through their own monitoring activities. This data will be shared with us so that we have knowledge about the intensity of the intervention.

3.1 Study outcome measures

Primary outcomes:

- The proportion of infants aged less than 6 months who have been exclusively breastfed since birth.
- The proportion of infants aged less than 6 months who were exclusively breastfed on the day preceding the interview.

Secondary outcomes:

- The proportion of newborns who were breastfed within 1 hour of birth.

- The proportion of newborns who were given colostrum.
- The proportion of newborns who receive no pre-lacteal feeds before breastfeeding was established or before breast milk production during the first 3 days after birth.
- The proportion of infants age 6 to 8 months who received semi-solid, solid or soft foods in the previous day.
- The proportion of infants aged 6 to 11.9 months who received a minimum acceptable diet (apart from breast milk) on the day preceding interview.
- Dietary diversity among infants age 6 to 11.9 months.
- The proportion of children aged 6 to 11.9 months who were fed breast milk on the day preceding the interview.
- Mother's accurate knowledge of:
    - Optimal timing of breastfeeding initiation
    - Optimal duration of exclusive breastfeeding
    - Benefits of optimal breastfeeding practices for the infant
    - Solutions to common difficulties, for example engorgement, cracked and sore nipples
    - Optimal timing to introduce complementary feeding
    - Optimal dietary diversity and frequency of complementary feeding up to 12 months
- Mother's self-reported breastfeeding practices, including asking her if she experiences any barriers or difficulties with breastfeeding such as engorgement, cracked and sore nipples, or breastfeeding when working outside of the home.
- Mother's perceptions and beliefs about breastfeeding (qualitative component).
- Knowledge, beliefs and perceptions of family members, such as mothers or mothers in law, community opinion leaders towards optimal infant and child feeding practices (qualitative component).

3.2 Cross-sectional surveys

Our design requires data collection from both A&T intervention areas and non-intervention (control) areas, both before and after the A&T intervention takes place. There will be two cross-sectional surveys one at baseline and one at endline. Each will be representative of the target population, but each sample is independent i.e. it is not the same individuals being surveyed.

Our target population is women of reproductive age with at least one live birth during the previous 12 months. As our primary outcome refers to infants under six months, we will design our sample so that we have sufficient numbers in this age group.

Inclusion criteria are:

- Gives informed consent
- Being aged from 15 to 49 years old (women of reproductive age)
- Has at least one infant less than 12 months old who is currently alive and lives with her.

Mother-infant pairs will be recruited through a household survey. We will select 3 villages per cluster with probability proportional to size and recruit 20 women from within each village (to balance achieving a geographical spread across the cluster with logistical feasibility). The fieldwork team will conduct a census of all households within selected villages to enumerate all eligible mother-infant pairs. Our sample will then be selected at random.

Information on the outcomes and exposures described in section 3.1 and exposure to the intervention (section 3.5) will be measured using a structured questionnaire. A comprehensive questionnaire previously validated in

Burkina Faso during the PROMISE-EBF trial [4, 5] will be adapted and pretested for use. A draft of the questionnaire is presented in Appendix 1. This questionnaire will be pre-tested before the main fieldwork begins.

PDAs will be used for data collection. This will have benefits for the completeness and quality of the data, as interviewer error is reduced (for example in skip patterns and permissible responses) and allows for regular interim data monitoring by the fieldwork co-ordinator. Time required for data entry is also eliminated.

3.3 Qualitative studies

This component will document:

- Implementation of A&T activities at the community level and regionally.
- The ways in which women in the intervention and control areas receive information on breastfeeding.
- Social determinants of women's breastfeeding practices.
- Strengths and limitations of A&T's activities.
- Nutrition-related activities carried out by other NGOs and the government at the regional and national levels.

The main target population for this component will be women age 15-49 years who are breastfeeding a child less than 12 months old. The secondary population will consist of decision makers and actors engaged in nutrition-related policies and programmes at the national, regional and local levels (such as village chiefs, opinion leaders, leaders of associations or NGOs promoting nutrition or health etc.) and the family members of women targeted by the A&T intervention.

Women will be identified by the study team and invited to participate after obtaining informed consent. During the study, the team will seek to achieve saturation level, both within each interview and overall in all interviews across respondents. The sample size thus is not known *a priori*, however the team hopes to reach saturation by conducting:

- 60 individual in-depth interviews with women (30 in the intervention areas and 30 in the control areas)
- Six focus groups with women (3 in the intervention areas and 3 in the control areas) including a total of 48-72 participants.
- Individual or group interviews with decision makers and key actors at the community level
- Eight focus groups with the husbands/partners and female members of households of women targeted by the intervention (4 in the intervention areas and 4 in the control areas) including a total of 64-94 participants.

Selection of participants will be opportunistic. The team will invite the same number of women in the control and intervention areas. In each area, respondents will be drawn from different localities in order to obtain a relatively heterogeneous group.

An interview guide will be developed for each category of respondents, which will identify the themes of interest for each group. The interview guide will be dynamic, that is it will allow for the exploration of new themes that may appear during data collection as rapid saturation of items may result in the reduction or elimination of topics from the guide.

Qualitative data will be collected by three investigators. Each interviewer will transcribe their own interviews. Interviews will be analysed manually. We will carry out a content analysis by simple categorisation; each theme will be covered sequentially. We will disseminate the results to the target population and other actors in the

field of nutrition to check the internal acceptability of our results using a "dissemination model of analysis"; this aims to present the analysis of the results to key stakeholders in order to confirm or refute the results and test the plausibility of the conclusions.

3.4 Validation study

As mothers' self-reported feeding practices are subject to errors of recall and social desirability bias [6, 7] especially relating to exclusive breastfeeding, and since our evaluation will be based only on two surveys (baseline and endline) unlike a cohort study (such as PROMISE-EBF), we will conduct a validation study in a sub-sample of mother-infant pairs where the infant is under six months. The aim of this work will be to determine the accuracy of mother's self-reported breastfeeding practices using a reliable biochemical method.

The dose-to-the-mother-deuterium-oxide turnover technique [8, 9] will be used in a sample of 120 mothers at baseline and in a sample of 224 mothers in control and intervention arms at endline (112 each). The bigger sample at endline will enable us to document potential reporting bias. This method estimates the intake of non-breast milk water. A sample of 2 ml of saliva from the mother and the child will be collected at day 0 in addition to height and weight; then, the mother will be given an oral dose of 30g of deuterium oxide. Deuterium oxide is water in which the hydrogen atoms are in the form of deuterium (i.e. they contain a neutron in the nucleus). Follow-up of this group of mother-infant pairs will be conducted to collect further 6 saliva samples from the mother and the child up to day 14. During this period the deuterium will pass from mother to infant through the breast milk. At day 0, before enrollment in the validation study, self-reported data will also be collected as part of the normal questionnaire administration for the trial baseline. At day 14, a shorter version of the questionnaire, on breastfeeding practices only, will be administered and these data will be compared to results from the validation study.

Date and time of saliva samples collection will be recorded and samples will be stored in ice box during transport and brought to the nearest lab of the region to be stored at -20°C until analysis. Deuterium enrichment of saliva samples will be measured using a Fourier transform infrared spectrometer (FTIR-8400S, Vienna, Austria) available at Centre Muraz. Qualified laboratory staff that are familiar with this technique are available to do the work in Burkina Faso. Samples will be destroyed after analysis.

The accuracy of mother's reporting will be done in two steps: first by examining the proportion on non-breast milk water intakes by mothers' self-reported breastfeeding status; and second by calculating the sensitivity and specificity, positive predictive value and negative predictive value. Because the sample is quite small, modeling might be necessary. If we find a high positive predictive value for exclusive breastfeeding self-reports (e.g. the proportion of babies reported to be EBF who had no intake of non-breast milk) and negligible non-breast milk water intake in the vast majority of women who report exclusive breastfeeding there will be no need to do this validation study again at endline except for assessing potential reporting bias between control and intervention arms.

3.5 Process evaluation

The implementation and intensity of the intervention will be monitored by data collectors external to the implementing partners, hired by A&T. We will request access to this data to inform the evaluation design and interpretation of findings. We might be particularly interested in accessing information on:

Geographic coverage of program activities: areas where the interpersonal component is taking place, community health worker and community mobilisation activities are implemented.

In these areas:

- Number of health workers and community health workers trained in infant and young child feeding practices
- Number of home visits
- Number of group meetings
- Number of food demonstrations
- Number of community mobilisation events.
- Number of refresher trainings.
- Monthly/quarterly meetings of health promoters and health workers

The list of process indicators will be finalised once details of the intervention package are available. We will also endeavour to collect information about other organisations who may be working in the A&T intervention and control areas and attempt to control for this if necessary. We will liaise with district health officials to identify such organisations in the first case.

In our surveys, we will record self-reported exposure to the intervention.

Exposure to government health worker counselling:

- Proportion of interviewed women reporting antenatal care, health facility delivery, , postnatal care (during their last pregnancy), health care seeking for childhood illnesses, child's immunisation visits with counselling on breastfeeding and/or complementary feeding.

Exposure to community health worker counselling:

- Proportion of interviewed women reporting a home visits by a community worker or volunteer
- Proportion of interviewed women reporting attending a monthly mothers' meeting

3.6 Timeline of activities

Figure 3: Timeline of activities

	2015				2016				2017	
	1	2	3	4	1	2	3	4	1	2*
	J-M	A-J	J-S	O-D	J-M	A-J	J-S	O-D	J-M	A-Jul
Finalise protocol with FHI & implementers										
Finalise dissemination strategy										
Prepare data collection tools										
Submit protocol & tools for ethical approval										
Data collection for baseline studies										
Analysis of baseline data										
Baseline interpretation workshop										
Qualitative interviews /activities monitoring										
Preparation for endline										
Data collection for endline										
Analysis of endline data										
Interpretation of results (including workshop)										
Drafting of final report, policy briefs etc.										

Dissemination activities										

* The final quarter has four months (finishes in July 2017).

4. INCLUSION CRITERIA

Inclusion criteria are:

- Gives informed consent
- Being aged from 15 to 49 years old (women of reproductive age)
- Has at least one infant less than 12 months old who is currently alive and lives with her.

5. RANDOMISATION

The randomisation unit will be a rural commune. There are 41 rural communes and 6 urban communes in Boucle du Mouhoun. The 6 urban communes will be excluded. The randomisation will be stratified by province to balance co-interventions and potential confounders associated to the provinces in the region of Boucle du Mouhoun.

6. STATISTICS AND DATA ANALYSIS

6.1 Sample size and power calculations

Primary outcome:

We assume prevalence of exclusive breastfeeding in the control arm to be 30%, based on the region-specific prevalence for Boucle du Mouhoun from the DHS (2010) data.

Our design has 20 clusters per arm (40 clusters overall) recruiting 30 mother-infant pairs where the infant is under 6 months, and an additional 30 mother-infant pairs where the infant is 6-11 months old per cluster. Thus our total sample size will be 2,400 mother-infant pairs.

Using the method of Hayes and Moulton this sample size will provide at least 90% power for us to detect a difference in exclusive breastfeeding prevalence between intervention and control clusters of 50% versus 30%, assuming a coefficient of variation of 0.4.

Secondary outcomes:

Our study is powered around prevalence of exclusive breastfeeding, the primary outcome. Given this sample size, we would be able to detect the following effect sizes for the secondary outcomes with 90% power, assuming a design effect of 5.

Table 3: Minimum effect size detectable for secondary outcomes with a sample size of 2,400

	Assumed Prevalence	**Minimum Detectable Effect Size**

	in Control Clusters	Change (+ / -)	Prevalence in Intervention Clusters
Initiation of breastfeeding within 1 hour	38% [1]	10%	48%
No pre-lacteal feeds in first 3 days	36% [2]	10%	46%
Use of colostrum	88% [2]	7%	95%
Continuation of breastfeeding alongside complementary feeding for infants 6-11 months	62% [3]	14%	76%
Adequate complementary feeding diet	2% [3]	4%	6%
Continued feeding of sick infants below 12 months (*Assuming 15% of sample have been sick in past 2 weeks so could answer questions on this behaviour*)	19% [1]	21%	40%

[1] *Based on DHS (2010) estimate for Boucle du Mouhoun*
[2] *Based on PROMISE-EBF control clusters*
[3] *Based on DHS (2010) national-level estimate*

Validation study:

Assuming a discrepancy of 50% between the prevalence of self-reported exclusive breastfeeding and the exclusive breastfeeding rate measured by the dose-to-the-mother-deuterium-oxide turnover technique, a sample size of 56 per arm is required to allow for a design effect of 1.3 and 80% power.

Table 4: Sample size for validation study

Exclusive Breastfeeding at 6 months				N per Arm	N per Arm allowing for a design effect of 1.3
Self-report		Deuterium technique			
Intervention	Control	Intervention	Control		
73%	22%	37%	11%	43	56

6.2 Analysis Plan

Baseline:

We will carry out a descriptive analysis of the baseline data to describe the characteristics of the study population. This information will be used to help assess the generalisability of the trial findings.

We will also assess the baseline comparability of the trial arms with respect to key outcomes and risk factors of interest, and identify any important imbalances. If we identify any variables that cause us concern we will consider including these as cluster-level baseline covariates in our endline analysis.

Endline:

Primary analyses will be performed on an intent-to-treat basis.

Our main analysis providing the overall trial finding will be an analysis of covariance using individual-level data. A binomial regression with the identity link will be used to compare the effect of the intervention and compare exclusive breastfeeding among infants less than six months between the intervention and control arms (which would give an estimate of the % point increase).

Individual-level analysis is generally the most efficient method where the number of clusters is 15-20 or more, as in this study. We will include cluster-level baseline prevalence of exclusive breastfeeding as a covariate in the model to account for any baseline variation between clusters and improve the precision of our estimates. Other covariates to be included in the model will be identified during the baseline analysis.

In addition, we will carry out a Difference-in-Difference (DiD) analysis on cluster-level summary data which will provide the absolute change in exclusive breastfeeding (% point change) from baseline to endline. This is a robust approach in a wide range of circumstances.

In each cluster, the proportion of infants less than six months being exclusively breastfed will be calculated at baseline and endline; subsequently the change in cluster-level prevalence from the baseline to endline surveys will be calculated and a DiD analysis will be performed adjusted for baseline behaviour prevalence to control for the phenomenon of regression to the mean, i.e. the cluster-level differences between surveys will be regressed on the cluster-level baseline prevalence and the intervention status of the cluster (intervention/control). A two-side t-test comparing the mean change in prevalence between arms will then be performed to test the null hypothesis of no intervention effect.

A similar approach will be taken to analysing each of the secondary outcomes listed in section 3.1 sequentially.

Calculation of Lives Saved:

The LiST tool enables one to estimate the number of lives that can be saved/deaths averted by changing the coverage of a wide range on interventions for child survival. The interventions available in LiST include feeding mode up to 1 year of age. We will use LiST to estimate the lives saved by the Alive and Thrive program using measured changes (from baseline and endline surveys) in exclusive breastfeeding between 0 and 5.9 months of age and of continued breastfeeding between 6 and 11.9 months of age.

7. RISK ASSESSMENT

There is no physical risk involved in participating in this study. However, the interviewer will ask some questions which can sometimes be sensitive, for example about socio-economic status. It will be explained to participants that their participation is entirely voluntary, that they may choose not to answer any question that they do not wish to answer and can stop the interview at any time.

A small sub-sample of women will be invited to take part in a validation study using the stable isotope (deuterium) technique, as described above. Only mothers with healthy infants will be invited to take part in this validation study. Mothers and infants will be offered a health check-up as an incentive to participate in this component.

Deuterium is a stable (non-radioactive) isotope of hydrogen which is consumed orally as deuterium oxide [10]. Deuterium oxide is water in which the hydrogen atoms are in the form of deuterium (i.e. they contain a neutron in the nucleus). It is metabolised in the body in the same way as water and eliminated from the body in as urine, saliva, or sweat. Stable isotopes have been used in human metabolic studies for over half a century [10]. The threshold for deuterium toxicity has been defined as 15%, which is far in excess of the concentrations conceivable in human studies (the amount of deuterium consumed in studies such as this trial will be of a

maximum of 0.1% in the mother and 0.05% in the infant). At this level, no adverse side effects have been reported [10].

8. REGULATORY ISSUES

8.1 Ethics approval

Ethical approval will be sought from the London School of Hygiene & Tropical Medicine, the National Ethical Committee in Burkina Faso (Ministry of Health) and Centre Muraz.

8.2 Consent

Informed consent will be obtained using a three steps approach (informing the community, seeking permission from husbands, obtaining informed consent from women): (i) we will inform the community that we are doing an evaluation of nutrition and maternal and child health practices and that we will visit households to identify women with young children, as this is standard practice in Burkina Faso and will enable us to identify whether they are particular concerns in the community vis à vis the research; (ii) in the household, we will first explain the reason of our visit to the household head or husband of the selected woman, and we will proceed to the interview if he agrees for her to participate; (iii) we will then proceed with obtaining informed consent from women either in writing, on the PDA, or using a thumb print.

The information provided to women to help them decide about their participation will be provided in writing or verbally using simple vocabulary. The information sheet will describe the broad aims of the research, the nature of the interview and the risk associated with the research. It will also emphasise the rights to withdraw at any time and the confidentiality of the information provided. The risks of the research are small as we will not use invasive procedures (except in the validation study). The nature of the intervention will also be described in broad terms in order not to bias the responses of women.

Obtaining consent from stakeholders will be a more straightforward procedure as we expect them to be mostly literate. They will be mostly concerned about the nature of the interview, its length and the confidentiality. Reports of qualitative data will not include names. Participants will be differentiated using their identification numbers.

8.3 Confidentiality

Identifying information (i.e. name of woman, names of compound and household head) will only be available to the member of the field team, his/her supervisor and any members of the research team directly involved in fieldwork procedures where access to such information is necessary (for example rescheduling interviews, cleaning data or selecting women to participate in the validation sub-study). Once these procedures have all been completed identifying information will be removed from the datasets and participants will be identified by an anonymous ID number only.

The importance of maintaining confidentiality is covered in the fieldworker training, so that all members of the team are aware of its importance. Once the data manager has collected the data from the field team, interviewers no longer have access to any data.

The data managers laptop will be password protected and their laptop will be wiped of any data at the end of the study.

Any paper documents containing potentially identifiable data (such as maps of household location) will be stored securely and destroyed at the end of the study.

Quantitative analyses will not present small sub-groups which might allow identification of individuals.

Qualitative data will be anonymised prior to publication.

8.4 Payments to participants

No cash payments will be made to participants; however participants will be offered a small locally-appropriate gift, such as soap or baby clothes, as a 'thank you' for their participation.

8.5 Other ethical issues

We have budgeted for referral to health facilities of very sick babies and mothers. A detailed procedure will be developed to facilitate decision making in the field by the clinical lead on this project (Dr Diallo).

Using a range of approaches (described in section 6), we will provide feedback on the results of the research to all those who have participated in the study. Community engagement and dissemination to stakeholders an essential component of ethical procedures.

8.6 Indemnity

London School of Hygiene & Tropical Medicine holds Public Liability ("negligent harm") and Clinical Trial ("non-negligent harm") insurance policies which apply to this trial.

8.7 Sponsor

London School of Hygiene & Tropical Medicine will act as the main sponsor for this study.

8.8 Funding

The A&T (including this evaluation) is funded by Bill & Melinda Gates Foundation with supplemental funding from the Governments of Canada and Ireland. The funding is managed by FHI360.

9. DATA USE & DISSEMINATION OF FINDINGS

In order to facilitate the use of the evaluation data, we will develop a more detailed communication strategy during the first 3 months of the project. It will include four aims:

1. Engage with A&T and FHI in order to make robustly interpreted findings available to all key audiences.
2. Present findings in the most suitable and tailored format to achieve maximum impact in policy and practices with key stakeholders, including providers, policy makers and programme managers at local, national and international levels.
3. Provide feedback of evaluation results to the communities and stakeholders who participated in the study as required in ethically conducted research.
4. Disseminate findings to the scientific community, who will further validate the findings through peer review processes and build on the evidence.

The detailed communication strategy will be based on the following principles (adapted from DFID):

1. Communication is a cyclical and interactive process of knowledge sharing leading to improved understanding.
2. Involving stakeholders at key stages of the project increases the probability that research findings will be relevant and used.
3. When possible, existing channels of communication will be used rather than the creation of new ones.
4. Communications activities are strategic and able to respond to emerging opportunities.

The strategy is supported and implemented by all evaluation collaborators.

Table 5 provides a description of the key target groups for sharing the evaluation results and provides examples of the possible tools that are most likely to reach them. We have identified a Burkinabé communications expert who will lead the dissemination. In addition, the London School of Hygiene & Tropical Medicine has an external relations team who can provide support.

Table 5: Dissemination strategy

Target Group	Main Objectives	Main Communication Activities
Internal		
A&T staff (HQ & in-country)	To facilitate interpretation of the results. To inform programme implementation.	- Face to face or verbal communication at key stages of the projects including planning, interacting with implementers, analysis of baseline, analysis of endline - One workshop in-country to discuss preliminary findings and their interpretation, and key messages for stakeholders.
Local/regional		
Research participants & their communities in Boucle du Mouhoun	To inform participating communities about the study's findings in an appropriate local language and format.	- Identify trusted sources (e.g. local leader, women's groups) in each village selected for the study. Describe study at the beginning of the project. Relay findings orally. Consider Theatre Forum. - Arrange for study findings to be reported on local radio stations in local languages

Health professionals responsible for providing MCH services in Boucle du Mouhoun	To provide useful information for their professional practice, e.g. identifying optimal ways to support and encourage breastfeeding mothers	- Send a one-page evaluation brief summarising key findings to each health centre in Boucle du Mouhoun in French. - Visit health centres in communities who have participated in trial to communicate findings verbally and practical implications that are relevant to their job
Policy makers & managers responsible for implementing breastfeeding policies in Boucle du Mouhoun	To provide advice and guidance on the evidence for best practice and infant and child feeding metrics in the local area.	- Invitation to dissemination workshop for regional and national policy makers - Face to face meeting(s) to present study and its findings at suitable / emerging opportunities, - Copies on all printed materials produced (1-page research brief, journal article etc.) provided.
National		
Health professionals in relevant specialities including public health, paediatrics, midwives etc. (national)	To transfer lessons learnt in Boucle du Mouhoun to other regions within Burkina Faso.	- Meeting with representatives of main professional organisations (such as SOGOB, ABSFM) to obtain feedback and agreement on practical implications of results. - Ask to include a short item in professional newsletters wherever possible. - Presentation at one emerging national/regional professional meeting in French. - Ensure findings also published in French language.
Policy makers and advisors (national)	To provide advice and guidance on the evidence for best practice and infant and child feeding metrics in Burkina Faso.	- Face to face meeting(s) to introduce study (during the planning phase in association with A&T), and explain study findings and discuss their implications at the end of the project - One policy brief with practical policy implications - Copies on all other printed materials produced - Invitation to dissemination workshop for national and regional policy makers

Other NGOs /UN organisations working on breastfeeding	To share evaluation results	Copies of all printed materials produced (1-page policy brief, journal article etc.) provided to A&T to share in relevant forum.
International		
Wider public health and scientific community	To contribute to the international evidence base on infant feeding practices. To validate our findings through the peer review process To feed into international technical guidance	- Presentation at two conferences (one local e.g. les journees scientifiques de Nouna); one international - Presentations at our institutions, for example the LSHTM Centre for Evaluation seminar series. - Manuscripts suitable for publication in a peer-reviewed, open-access journal. - Tap into existing list serves on relevant issues and social media for example MARCH or LSHTM twitter accounts, the Maternal Health Taskforce, the Partnership for Maternal, Newborn and Child Health

9. REFERENCES

1. Menon, P., R. Rawat, and M. Ruel, *Bringing rigor to evaluations of large-scale programs to improve infant and young child feeding and nutrition: the evaluation designs for the Alive & Thrive initiative.* Food Nutr Bull, 2013. **34**(3 Suppl): p. S195-211.
2. Ministere de la Sante, Secretariat General, and Direction Generale des Etudes et des Statistiques Sectorielles, *Annuaire statistique 2013*. 2014.
3. Institut National de la Statistique et de la Démographie and ICF International, *Enquête Démographique et de Santé et à Indicateurs Multiples du Burkina Faso 2010.* 2012, INSD & ICF International: Calverton, Maryland. USA.
4. Tylleskar, T., et al., *Exclusive breastfeeding promotion by peer counsellors in sub-Saharan Africa (PROMISE-EBF): a cluster-randomised trial.* Lancet, 2011. **378**(9789): p. 420-7.
5. Diallo, A.H., et al., *Perinatal mortality in rural Burkina Faso: a prospective community-based cohort study.* BMC Pregnancy Childbirth, 2010. **10**: p. 45.
6. Piwoz, E.G., et al., *Potential for misclassification of infants' usual feeding practices using 24-hour dietary assessment methods.* J Nutr, 1995. **125**(1): p. 57-65.
7. Medoua, G.N., et al., *Breastfeeding practices of Cameroonian mothers determined by dietary recall since birth and the dose-to-the-mother deuterium-oxide turnover technique.* Matern Child Nutr, 2012. **8**(3): p. 330-9.
8. Coward, W.A., et al., *Breast-milk intake measurement in mixed-fed infants by administration of deuterium oxide to their mothers.* Hum Nutr Clin Nutr, 1982. **36**(2): p. 141-8.
9. Haisma, H., et al., *Breast milk and energy intake in exclusively, predominantly, and partially breast-fed infants.* Eur J Clin Nutr, 2003. **57**(12): p. 1633-42.

10. International Atomic Energy Agency, *Stable isotope technique to assess intake of human milk in breastfed infants*. 2010, International Atomic Energy Agency: Vienna.