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Promoting hygienic weaning-food handling practices through a community based programme: intervention implementation and baseline characteristics for a cluster-randomized controlled trial in rural Gambia.

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Abstract

Objective: Contamination of weaning-food leads to diarrhoea in under-5s. Public health interventions to improve practices in low and middle-income countries are rare and often not evaluated using a randomised method. We describe an intervention implementation and provide baseline data for such a trial.

Design: clustered randomised controlled trial

Setting: Rural Gambia

Participants: 15 villages/clusters each of 20 randomly selected mothers with 6-24 months old children per arm

Intervention: To develop the public health intervention, we utilised (a) formative research findings to determine theoretically-based critical control point corrective measures and motivational drives for behaviour change of mothers; (b) lessons from a community based weaning-food hygiene programme in Nepal and a handwashing intervention programme in India; (c) culturally-based performing arts, competitions and environmental clues. Four intensive intervention days per village involved the existing health systems and village/cultural structures that enabled per-protocol implementation and engagement of whole villager communities.

Results: Baseline village and mother's characteristics were balanced between the arms after randomisation. Most villages were farming villages accessing health centres within 10 miles, with no schools but numerous village committees and representing all Gambia's 3 main ethnic groups. Mothers were mainly illiterate (61%), farmers (92%); 24% and 10% of children under-5 had mother's reported diarrhoea and respiratory symptoms respectively in the last 7 days (dry-season). Intervention process engaged

whole village members, and provided lessons for future implementation; culturally-adapted performing arts were an important element.

Conclusion: This research has potential as a new low-cost and broadly available public health programme to reduce infection through weaning-food. The theory-based intervention was widely consulted in the Gambia and with experts, and was well accepted by the communities. Baseline analysis provides socioeconomic data and confirmation of MICS data on the prevalence of diarrhea and respiratory symptoms in the dry season in the poorest region of Gambia.

[Abstract 298 words]

Article Summary - Bullet point of strengths and weaknesses:

Strengths:

- Strongly theory based community intervention
- Pragmatic public health intervention involving existing public health workforce, village and country leaders in rural Gambia (low cost and easy to replicate)
- Use of traditional Gambian performers/performing arts in the intervention (attractive to villagers and target mothers)

Weaknesses:

- For the trial, it is impossible to fully blind communities
- Villages selected from Primary Care Villages in the poorest region of the Gambia may pose a generalisability constraint
- Lack of full qualitative data from the villages on the process of intervention implementation

Trial registration: The trial was registered on the 17th October 2014 with the Pan African Clinical Trial Registry in South Africa with numberPACTR201410000859336.

Keywords: cluster randomised controlled trial, diarrhoea, pneumonia, behaviour change, weaning-food, hygiene, food preparation, community intervention, performing arts, dramatic arts, motivational drives, scalability, Africa.

Background

It is estimated that 2 billion episodes of diarrhoea annually occur among children under-5 years resulting in 1.2 million deaths globally.[1]The highest prevalence are in low and middle-income countries (LMIC) clustered around those aged 6–24 months[2]: the weaning age. Contaminated weaning-food[3] is an obvious source of infection but the emphasis for research and interventions has been on water hygiene.

In general, handwashing with soap by mothers can reduce infant diarrhoea by 47%.[4] A central element of safe food preparation is handwashing, but this is not the only component requiring improvement for weaning-food hygiene.[5,6] Two small individually randomised proof-of-concept efficacy trials with individual training and follow-up of mothers for a weaning-food hygiene intervention (in Mali[6] and Bangladesh[7]), and a recent community intervention evaluated in a small before-and-after cluster study in Nepal,[8] explored potential options. The former was too intensive to be scalable, while the latter needs to be evaluated in a larger trial and could be simplified further to become a model for a population-level intervention package.

Fundamentally, community-level interventions should be short, simple, culturally acceptable, low-cost and involve existing structures. In this paper we describe the intervention implementation and provide the baseline data for evaluating such an intervention in the Gambia, W. Africa. The Gambia has a high rate of childhood diarrhoea. To our knowledge, no recent studies or interventions have been conducted on weaning-food in the Gambia; however the observations and findings from our formative research[9] indicate that the practices and rates of contamination have not changed significantly since 1978.[10] We found that weaning-food samples collected immediately after preparation before feeding to the child, were significantly

contaminated with faecal coliform and that this contamination increased after more than 5 hours' storage.[9]

We describe here the intervention implementation phase of the complex public health community intervention with qualitative data from the team on success elements, and the baseline survey data for our cluster-randomized control trial (cRCT). We draw lessons from our intervention implementation for future expansion. The primary objective of the main trial is to investigate the effects of the complex public health community intervention that sought to improve mothers' weaning-food hygiene practices. We further sought to investigate the effect of the intervention on the level of microbiological contamination in food and in water ready for child's consumption; and to establish the prevalence of diarrhoea and respiratory symptoms, and diarrhoea admission, as reported by the mothers.

Methods/Design

Design

Thirty villages were the unit of randomization for this parallel cRCT. The 4-day community intervention was followed by a reminder visit after 5 months. Two cross-sectional samples were taken to measure baseline characteristics and outcomes: one before randomisation and the other 6 months post-intervention roll-out. There were no changes to the protocol after commencement.

Setting and population

The cRCT was conducted in the Central River Region (CRR), one of the 7 administrative regions in the Gambia. CRR is 48000 km^2 in area, organised into 11 districts with 659 villages, and a population of

201,506 of which 41,334 (20%) are under-5 years of age.[11] CRR was selected for the intervention as it has the highest incidence diarrhoea in the Gambia, particularly in children aged 6–24 months (26.5% of children under-5 had diarrhoea in the two weeks preceding the UNICEF Multiple Indicator Cluster Survey (MICS) in 2010, verses 17% nationally. The rates for ARI of children under-5 were 14.2% in CRR compared to 6% nationally). CRR is rural, with low literacy, and is economically the poorest region in the Gambia. Villages in the region differ in their access to facilities such as water supply and health care. A typical village has a head and a religious leader, but the size of individual settlements registered on the national population census (in 2013) ranges from as few as 27 to 1,800 population per village. This means that the mean village size for CRR was 357(SD+59).[12] As with the other regions in the Gambia, UNICEF and the Ministry of Health and Social Welfare (MOH) have selected a number of villages (158 in CRR) to become Primary Health Care villages where they have trained (for 4 weeks) a Village Health Worker (VHW) and a Traditional Birth Attendant (TBA) to provide health promotion and basic health support to the villagers.[13]

Inclusion criteria for study villages for the Intervention were Primary Health Care villages of 200–450 population within CRR. It was felt that such villages, with lay health workers, would be best able to support the programme given the available resources. The 200–450 population criteria per village was decided on 3 grounds: the requirement for a minimum of 20 families with children aged 6-24 months, a population close to the mean village size in CRR (375), and the need not to select a village that was too large given the size of the team implementing the intervention. Exclusions for the villages were those that were within 5km of already selected villages.

Inclusion criteria for households within the villages for the baseline were mothers with children aged 6-24 months; exclusions were those expecting to be resident in the village for the following 6 months. There were no other exclusions.

Recruitment

The villages were randomly selected by a UK epidemiologist from a list of all villages in CRR after applying the selection criteria. We provided written and oral information and sought informed consent from the village heads for the villagers' participation in the programme.

For the baseline, a list of all mothers with children between 6-24 months of age living in the village at the time was obtained from the maternal-child health register, and households were chosen randomly based on the study criteria. Mothers gave written informed consent. In case of illiteracy, the information was read out (and a written copy left behind), and a thumb print obtained in the presence of a family witness and the fieldworker.

Baseline measurement

During the initial recruitment visit (December 2014; dry season), after consent, we characterized all 30 villages and 20[1] randomly chosen mothers within them before randomisation, collecting the information detailed in Tables 5 and 6.

[1] **On-line annex: Trial Sample size:** Observations during the formative research indicated that the proportion of events in which correct behaviour was displayed (i.e. practices of heating stored food, hand washing with soap before food preparation, during food preparation if contaminated, and before feeding the baby (measured the first time activity occurred)) was 17/150 (11.3%). As this was to be a cluster RCT, we assumed an intracluster correlation coefficient (ICC) of 0.04[14] between villages and a coefficient variation of cluster size 0.22. With a significance level of 5%, we aimed to detect a minimum of 25% absolute increase in behaviour in the intervention compared to the control arms with 95% power. As we were able to recruit 15 clusters per arm, a minimum of 12 mothers per cluster was required.[22] We aimed to recruit 20 mothers within each village at outcome evaluation to guard against loss of mothers during

Randomisation

Randomisation took place after all village heads gave consent and the baseline data collection was completed. Randomisation was conducted by a statistician in the UK: the villages were grouped and randomised within strata (north or south of the river, and by quartiles of the population size of the village) into 15 control and 15 intervention villages.

Blinding

Blinding of the implementers of the intervention programme and of families who received it was not possible. However, the families exposed to the community intervention were unaware of the comparative nature of the intervention with a control village.

Intervention

The intervention components and delivery package were theory-based, and informed by the local context from our formative research, and by the lessons/tools from community interventions in handwashing studies in India[14]and weaning-food hygiene in Nepal.[8] The intervention took the form of a community-mobilisation campaign delivered to all the village and focussing on mothers of weaning babies and those with children under-5 years in each village. The intervention consisted of a team visiting each village on days 1, 2, 17 and 25 and was delivered between 16th February and 28th April 2015 (the dry season). A set of activities were conducted that involved mothers and a range of other village members through village-wide events, neighbourhood meetings, home visits, and further involvement of the village authorities and volunteers. A 5th visit after 6 months was included since we envisaged that if such a programme

the 8 hour observation by female fieldworkers during evaluation home visits. In a sensitivity analysis, assuming a larger ICC of 0.1, the power (84%) remained reasonable.

was to be implemented at scale, then for the behaviour change to be sustained, villages would require a reminder visit before or early in the diarrhoea high-risk rainy season (if several days after the initial 4-day campaign). [21] At this time mothers and their families are busy and hence more likely to forget weaning-food hygiene behaviour while distracted with farm work. The programme's daily schedule and tools, including their links with the motivational theory, are summarised in Tables 2 and 3.

We used two theoretical frameworks in designing the intervention: Firstly, Hazard Analysis and Critical Control Points (HACCP),[15,16] which is conventionally used in the food processing industry to reduce microbiological contamination, has been recommended by the WHO/FAO Expert Committee on Food Safety for use in homes in LMICs to provide insight into hazards in food preparation and remedial preventive measures.[16,17] Evidence from efficacy and a small population trial that weaning-food hygiene activities following the HACCP approach can help in identifying measures to improve weaning-food safety.[16] Table1 summarises the corrective measures that were prioritised following our formative research.[9]

Secondly, we used an applied motivational behaviour change model[18] that facilitated the application of identified corrective measures in a way that would add to knowledge and attitude and would motivate a change in mothers' behaviour. The model draws upon research in psychology that proposes ways of classifying various drivers of human behaviour. Our formative research found that Nurture, Disgust, Affiliation, Status and Purity were the strongest motivational drives for our village mothers.[9]

As with the India and Nepal programmes,[8,14] we focussed on the use of performing arts (using culturally ingrained styles of drama and songs),[19] competitions and environmental cues[20] to deliver the HACCP corrective measures and motivational drives. The details of our community

weaning-food hygiene programme designed by the research team at the University of Birmingham (which included a Gambian Public Health officer from MOH) was widely consulted with expert health promotion agencies who were represented on a Local Scientific Advisory Committee in the Gambia (MOH, UNICEF, WHO, University of the Gambia, National Nutrition Agency (NANA), and the MRC Gambia).

Subsequently, the material was translated into the 3 local languages (Mandinka, Wolof and Fula), field-tested and piloted iteratively by the intervention team in the CRR. This team, which also delivered the programme, comprised one literate male and one illiterate female traditional communicators (TC) with health promotion experience, 3 Public Health Officers (PHO) from the local Regional Public Health Department (2 with a Higher National Diploma graduates from Gambian College School of Public Health, one with an additional Masters in Public Health) and an illiterate driver (for 24 days of the 60 days visiting the villages, there were 2 PHOs in the team and for the remainder there were 3 PHOs). TCs are performing artists who use traditional African drumming, singing and acting to communicate messages. The team were deliberately chosen from the existing structures in rural Gambia to demonstrate replicability and scaling. The team were assisted by a female volunteer (usually a TBA) from each village who was trained for 2 weeks to assist the work programme during, and in-between, the team visits. The TBAs were encouraged to find one or more assistant volunteers by day 1 of the team's visit (3 in smaller villages ended with no assistants, 11 had one assistant, and one had 3 assistants).These were called "MaaSupervisors" and visited the families between team visits to recruit more mothers of young children, reinforce the target practices, and in doing so, help ingrain the practices in cultural norms of the community at large.

The intervention focussed on a central role model character the "MaaChampion", a mother who practised the key behaviours used in the messages (Table 1) and encouraged other mothers to do the same. Village mothers could achieve "MaaChampion" status if they managed to demonstrate the practices and knowledge, and encouraged two other mothers to do so. 'Funtu' (a derogatory noun for a discarded useless thing) was another character: a mother who did not practise any of the target behaviours and reaped the consequences with her family and other villagers. These two characters, described in the context of an average village, through story, drama and songs, demonstrated all key messages and motivational drives, and engendered a wish for behaviour change in village mothers as they identified with the characters' lifestyles and behaviours.

Other components such as competitions (for mothers of children <5 years), environmental cues (for mothers engaged in the competitions), and demonstrations, had an important role in embedding behaviour change. The programme's daily schedule and tools, including their link with the motivational theory, are summarised in Tables 2 and 3.

Overall, the aim was to apply theory, to use successful elements of two previous studies[8,14] while ensuring the intervention was as simple and cost-effective as possible, understandable and replicable by existing local health system/staff in the Gambia.

Implementation was staggered over 2 months. During implementation of the intervention, there were no diversions from the protocol. The intervention team logged significant events, comments and the overall participation of villagers/mothers in the programme to enable full evaluation of the intervention implementation. At the end of the intervention implementation, the intervention team were interviewed in a focus group discussion to explore the experience of the team during village visits and implementation, and identify successful elements and learning points. The interview was transcribed, and they were coded together with the log using inductive thematic

analysis to gather themes and sub-categories to guide future implementation. Qualitative assessment of the community or mothers was not possible.

Findings

Recruitment and baseline characteristics:

The trial flow chart (Figure 1) outlines how 15 clusters were recruited per arm with a total of 300 mothers in the intervention and 300 in control villages at baseline. No village or family refused to participate. The median village size was 351 (IQR 297-400) in intervention and 354 (IQR 282-406) in control villages. The background characteristics of villages and baseline families were well-balanced between the arms (Tables 4 and 5). The majority of villages had no school and no health facility within 5km; the main source of income for all villages was farming with only the 3 major Gambian ethnic groups represented. All villages had Development Groups and most had Women's Groups or Water Sub-groups indicating some village level organisation.

The majority of the mothers were farmers and illiterate. The structure of the houses and belongings provided a good indication of economic status and indicated that nearly half could be categorised as poor by rural Gambian standards with no cattle, and houses with thatched roof and mud walls.

Intervention development and implementation

Stories, songs, posters and animations from previous relevant programmes in India and Nepal were transferable from Asia to our African setting and the tools were easy to adapt within 6 weeks. (including staff training, refining of the material, field testing and piloting). Production of the material (banners, posters, flip charts etc.) took a further 4 weeks. Animations from South Asia were used unadapted and seemed to fully engage our target audience (live translation of spoken words was given during the showing).

For replicating the program in other settings, particular lessons were learnt for low-cost adaptation and replication of the material that are important for scaling such programmes. First, it was initially intended that the story booklets/flipcharts would have professionally drawn artist graphics (as per Nepal study), but the team found that printing photos of consented local women/actors in a local home performing the stories was superior for story flipcharts and other printed material compared to the artist's drawing. They could be done by the team members rather than professional graphics experts, thus lowering the cost.

Second, unlike the Nepal programme where each village visit detailed one theme/message, all messages/practices were discussed in all visits. This simplified the intervention and meant that the same tools, stories, songs etc. could be used more than once during village visits. Since there were only 4 core visits and one reminder visit, we found that villagers continued to be interested in the material: repetition brought familiarity which helped participants to understand the messages better in depth, and to relate the stories and songs to their lives. Qualitative data from team members (Table 6), who were experienced public health officers delivering government or UNICEF health promotion programmes, reveals that drama, animation, songs, stories, and handwashing demonstrations using GlowGerm[27] appeared much more effective than the traditional communication of messages with talks and flipcharts/posters which the team members had used in previous projects. The villagers seemed to adopt the stories and songs, calling/singing them out loud as the team walked around the village and between visits. Themes that emerged about successful or challenging elements of the project are summarised in Table 6. As the table indicates, on the whole the villagers welcomed the team and all components of the programme, including the competitions that increased peer-support, and which encouraged mothers of young children to achieve MaaChampion status. From the 1349 mothers of children

<5years in 15 villages, during the 4 visits there were 608 (44%) MaaFamboos (pledged), 501 (37%) MaaSawarr (sustained), and 459 (34%) MaaChampions (role-model). However, the emphasis was on mothers with 6-24 month old babies who were making exclusive weaning-food for the babies, and the majority of these mothers were in our target population. All villages reached the status of 'Weaning-food Hygiene Village' with a third of mothers of children under-5 years as MaaChampions. All levels of the community, including men, women of all ages and children, became involved in the programme as they attended meetings, encouraged each other to participate, sang the songs and hence fully participated.

Discussion

We summarise an intervention implementation and baseline data of the first African community-level weaning-food hygiene intervention programme. The baseline characteristics revealed satisfactory randomisation and villages and families that are typical compared to CRR as a whole.[12] Reported diarrhoea and ARI rates in our survey conducted in the dry season (best conditions for villagers), agreed with the 2010 MICS survey for CRR (26.5% and 14.2%, respectively).[12]

The intervention strengths include a strong theory base and application of replicable and transferable tools found to be relevant from Asian programmes. Furthermore, the use of culturally embedded performing arts was welcomed by communities, and the involvement of regional Public Health Officers, instead of research staff, provided a pragmatic and scalable intervention should it prove to be effective.

A possible limitation affecting generalisability of our intervention implementation is that we did not sample from non-Primary Health Care villages. However, during the evaluation process we observed that as the MaaSupervisors were from any background and as we trained them for 2 weeks, in reality we drew little on the training of TBAs and Village Health Workers. Thus we anticipate that this intervention could have been readily implemented in other non-Primary Health Care villages. Another limitation of the study is that a thorough formal qualitative evaluation process was not conducted, but documented observations from events during the programme implementation and a focus group with the project team shortly after the implementation provide evidence for our broad conclusions. The involvement of policy makers, public health managers and funders from the start, as well as local implementing agencies (as

part of the Local Scientific Advisory Committee) helped avoid potential bureaucratic or other threats to the programme. As the delivery method is low-cost, replicable and possible with the existing systems (Public Health Officers (PHOs), village organisations and traditional communicators(TCs)), the programme could be scaled-up even with relatively limited resources. If combined with on-going related programmes on child nutrition or Community-led Total Sanitation ran by UNICEF, NANA or MOH our intervention, if proven effective, could contribute towards strengthening health systems through training and utilisation of non-specialised staff unavailable in rural settings.

Performing arts, although used in health promotion campaigns, are rarely evaluated as instruments in themselves for community behaviour change. Although formal evaluation of their work was beyond the resources available, qualitative data concluded that any success of the programme and the involvement of young and old members of the community, and both men and women, are primarily due to the initial attraction offered by these traditional communicators. During team visits they engendered a joyous atmosphere, and their songs and stories became ingrained in daily village life as the children and villagers learnt and repeated them.

A controversial issue about the use of performing arts is the need to adapt the tools to different cultural settings. It is significant for expansion of this, or similar hygiene programmes, that we found tools from Asia (India and Nepal) that were easy to adapt to the style of communication used by African TCs and performing artists. There is a dearth of literature describing formal evaluations of the use of such TCs in song and drama during campaigns and we hope to contribute to this once the trial data is reported.

Conclusion

In conclusion, household and village data established a low socioeconomic population in CRR with high child morbidity on reporting from the mother that confirms data from MICS surveys. Weaning-food hygiene intervention programmes based upon HACCP and motivational theory, and using culturally engendered performing arts, may share elements that are transferable across cultural settings in LMICs. We have demonstrated, at the implementation stage, the successful active involvement of policy makers and public health service providers (Public Health Officers) as well as traditional performing artists and village authorities in a Gambian weaning-food hygiene intervention programme. This engagement was successful at the level of developing and implementing tools, leading to a low-cost intervention that was easy to deliver by existing public health structures and well-received by villagers in the lowest resourced region of the Gambia.

[Manuscript 3390 words without headings]

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Authors Contributorship Statement: All authors contributed to design of the study/study protocol and helped with drafting the manuscript (Dr Ensink contributed to draft of protocol and early versions of manuscript before his murder). The following specific contributions apply:

Buba Manjang – Trial Manager, contributed to design and development of the intervention and evaluation, implementation of the study in the field, data collection and data analysis, Co-PI;

Karla Hemming – Senior Trial Statistician and RCT design Co-I;

James T. Martin – Junior Trial Statistician contributing to analysis plan and analysis;

Sandy Cairncross and Jeroen Ensink – WASH experts contributed to design of the intervention and evaluation in the RCT;

Chris Bradley - water scientist contributed to the design of study in general pertaining to safe waters and testing;

Jama Sowe and Abdou Jarju - both Public Health officers, contributed to the development of the intervention and its implementation and study design;

Semira Manaseki-Holland – Trial Director, contributed to design and development of the intervention, evaluation, and the trial as a whole, implementation of the intervention, and completion of the data collection: Co-PI.

Conflict of interest: Authors declare no conflict of interest.

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Registration: The protocol was registered on the 17th October 2014 with Pan African Clinical Trial Registry with number; PACTR201410000859336 at South Africa.

Ethical approval: This study had full ethical approval from Gambia Government / MRC Joint Ethics committee (SCC 1385v2) and the University of Birmingham (ERN_14-0574). A written informed consent form was obtained from caregivers of children aged 6-24 months. All the information collected was kept strictly confidential.

Data sharing statement: This paper only documents the baseline data for a cluster randomised controlled trial. The remaining analysis is still not completed and will be done by our research team. Once this is complete the database is available for other researchers from the corresponding author after 5 years to allow for all required use by the primary research team.

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Figure 1: The trial flow chart.

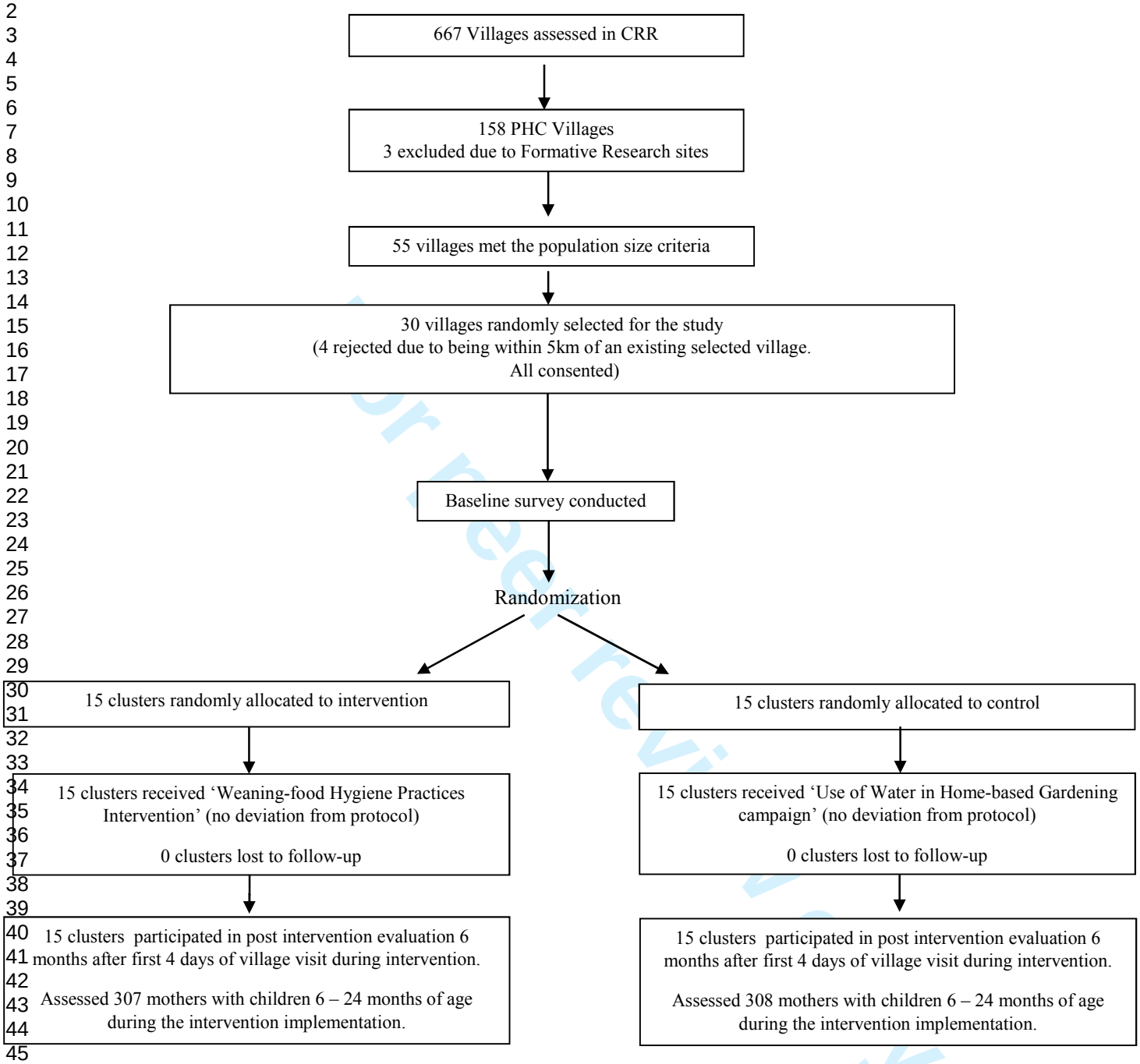

Table 1.Showing critical control points and corrective measures prioritised for the Gambia formative research. These became the target practices for the hygiene promotion campaign: 5 weaning-food hygiene and 1 infant drinking water hygiene practices.

Critical Control Points	**Corrective measures – behaviours the intervention aimed to improve**
Before food preparation	***Handwashing with water and soap before food preparation***
	Washing of pots and utensils before food preparation and drying on a clean (and cleanable) surface
Cooking	***Handwashing with clean water and soap when contaminated during cooking***
Food storage	***Reheating of pre-made food after storage before feeding***
Feeding practice	***Handwashing with clean water and soap before feeding child (mother) or eating (child)***
Water ready for drinking by child	***Boiling of water ready for drinking of child***

Table 2: Intervention activities during visits to intervention villages/cluster.

	EVENT	**ACTIVITY**	**WHERE**	**TIME**	**PURPOSE**
Day 1	Meeting Alkalo (village head)	- Traditional communicator's (TCs) play a song in praise of the Alkalo. - The team greet the Alkalo. - Explain purpose/project - Met village health worker (VHW) - Met Traditional Birth Attendant (TBA)	Alkalo's residence	20 min	- Alkalo is the entry point to village must receive a visit before start of work - Alkalo & wife have social status & their support motivates mothers
	Announce to village presence of team	-TCs invite villagers to afternoon meeting by drumming & campaign song with use of loud speaker.	Within whole village	2 hrs	- Create alert - Mobilise the community - Repetition of song & messages help memorisation
	Household visit	- House-to-house visit (invited household members to afternoon meeting) with TBA & VHW	Residence of each every household	3 hrs	- Social mobilisation to involve the whole community
	Take short video during household visits	- Video Alkalo & wife handwashing & reheating weaning-food (done at Alkalo's home after house-to-house visit) to show at the meeting later.	Alkalo's residence	15 min	- Alkalo & wife have social status & their support motivates mothers -Engender social norms
		-Drum/sing the 6 messages & pledging			-Inform the

	EVENT	ACTIVITY	WHERE	TIME	PURPOSE
	Afternoon event	song while village people arrive at meeting site. - Imam (religious leader) lead prayers for the gathering (Gambian cultural norm). - Alkalo gives the opening remark. - Introduction of project by PHO. - 2 Drama (MaaChampion & Funtu) by TCs. - Summary of drama by PHO. - Question & answer from village audience led by PHO. - Pledge song by TCs. - Play 'Choose soap' silent animation video. [14] - Show video of Alkalo (washing hands with soap) & his wife (reheated weaning-food). - Announce competition by PHO. - Invite mothers of children 6 to 30 months to pledge - Give pledged mother's plastic sheets for covering surfaces to enable drying utensils/pots on a clean surface & take a group photo for the honour/notice board. - Print & display pledged mothers & Alkalo's photos on honour board at the Bantaba. - Closing remark by PHO. - More drumming & songs (motivational).	Village "Bantaba" (a central place where villagers meets – usually under a large tree)	4 hrs	community/provide instructions - Model or demonstrate behaviour - Prompt identification with a role model - Target mothers for their pledge - Set graded tasks through competitions - Prompt intention formation - Engender all motivational drives – particularly nurture and affiliation
	Community volunteers training	- Train new assistant MaaSupervisors by village volunteers/trained MaaSupervisors, supervised by PHO.	Village Bantaba	2 hrs	- Enable encouragement of mothers and competition success
Day	Meeting Alkalo	- Greet Alkalo formerly. - Inform Alkalo of our presence in village.	Alkalo's residence	10 min	As Day 1
	Announce to village the presence of team	As Day 1	As Day 1	2 hrs	As Day 1
	House-to-house visit with MaaSupervisors	- Engage MaaSupervisors with household visits & boost their confidence. - Assess/encourage pledged mothers for progress to next stage.	Residence of each pledged mother	3 hrs	- Prompt practice of key behaviours - Provide feedback - Prompt self-monitoring /review/community mobilisation
	Ad-hoc women or men meeting held separately	- Demonstrate glow germ on participants. - Explain 2 stories (Doctor's & Funtu's) on flipchart. - Play silent animation video 'Choose	Neighbour-hoods	30 min	- Engender disgust through glow-germ: dirt on hands - Engender all

	EVENT	ACTIVITY	WHERE	TIME	PURPOSE
2		soap' on iPad/laptop.			motivational drives – particularly nurture and affiliation through stories - Engage men & women to support mothers of young children - Prompt specific goal setting
Day 3	Meeting Alkalo	As Day 2	Alkalo's residence	20 min	As Day 2
	Announce to village presence of team	As Day 1	As Day 1	2 hrs	As Day 1
	House-to-house visit with MaaSupervisors	As Day 2 – additionally: During household visits, video mothers who succeeded to became a MaaChampion to show at meetings	Residence of mothers	3 hrs	As Day 2 – additionally with videoing to provide contingent reward
	Afternoon event	As Day 1 & including the below: - Show animation video from India handwashing SuperAmma project with translation.[14] - Show videos from mothers who succeeded to become MaaChampion - Take photo of new pledged mothers with their plastic sheets and of MaaChampions & displayed on honour boards.	As Day 1	4 hrs	As Day 1
Day 4	Meeting Alkalo	As Day 2	Alkalo's residence	20 min	As Day 2
	Announce to village presence of team	As Day 1	As Day 1	2 hrs	As Day 1
	House-to-house visit with MaaSupervisors	As Day 3	Residence of mothers	3 hrs	As Day 3
	Afternoon Event	As Day 1 including below: - Present Medal for MaaChampions / MaaSupervisors with drumming - Group picture with all MaaChampions, MaaSawarr and MaaFamboos for the honour board. - During village wide ceremony, erect a weaning-food hygiene board at village entrance with drumming/campaign songs & present certificate to the Alkalo - Give motivational advice on sustainability by Alkalo, MaaSupervisors	As Day 1	4 hrs	As Day 1 including below: - Create ownership of the project and self-monitoring to enable sustainability - A community sense of commitment by MaaChampions - Inculcated motivational drives - Encourage

	EVENT	ACTIVITY	WHERE	TIME	PURPOSE
		& PHOs - Closing remark (emphasis on sustainability)			achievement of goals
Day 5	Meeting Alkalo	As Day 2	Alkalo's residence	20 min	As Day 2
	Announce to village presence of team	As Day 1	As Day 1	2 hrs	As Day 1
	House-to-house visit with MaaSupervisors	As Day 3	Residence of mothers	3 hrs	As Day 3
	Afternoon event	As Day 4 but not including erection of the village board	As Day 4	4 hrs	As Day 4

Table 3 (below): Intervention tools & their application during the intervention

Concept/tool	Details	Purpose
Competitions for mothers & MaaSupervisors		
Competitions for mothers	From mothers who pledged who learnt the 6 messages (MaaFamboo) to mothers who sustained their improved 6 practices (MaaSawaar), to the role 'model mothers' who also supported 2 other mother mothers to sustain activities (MaaChampion).	To set graded tasks, provide general encouragement for improved behaviour, prompt identification with a role model & to encourage a change of social norms.
MaaSupervisors (MaaSupervisors) competitions	Must supervise 5 – 10 mothers, of which 50% must achieve role model status.	
Performing arts for all village members		
Songs (at times combined with communal dancing)	*Campaign song*: Information about the 6 key messages & benefits of practices. Explained the benefits of care & love for one's child. *Pledged song*: Focused on nurture, disgust & purity to encourage mothers to pledge to carry out the practices. *Welcome song:* A cultural greeting song to welcome and honour, with elements of messages added.	To engage communities particularly mothers & to make it easy for mothers to learn messages form the songs.
Stories	*Story 1:* Story of MaaChampion heard from her grown up child who is now a successful doctor, telling the story to her family. *Story 2:* Story of Funtu about how villagers rejected her & how her child suffered, while meeting the MaaChampion & following her advice made her popular & a good mother.	To stimulate the motivational drives help mothers understand & remember messages easily. To communicate the messages in a memorable way. To prompt identification with the role model & consequences of not following the 6 key messages.
Drama	*One Drama:* describing a day in the life of MaaChampion and Funtu	
Environmental cues for mothers	Posters, danglers, & plastic sheet as reminders & to facilitated mothers in adopting the 6 key practices (the plastic was to facilitate putting pots on a clean surface).	To remind & facilitate the mothers to perform the 6 key practices.
Other Tools for team members or villagers		
Flipcharts	2 stories & key messages were described in 3 different flipcharts.	For telling the stories in men & women's discussion groups & to stimulate the motivational drives & MaaSupervisors to use during their work
T-shirts for the intervention team	Bearing project logo & title of MaaChampion	To identify & formalise the intervention members.
Project Banners	A piece of polythene presenting 6 key messages & a photo of the MaaChampion on it. Was displayed in each village before the afternoon events.	To make people aware of intervention events & remind people of the 6 key messages.
Glow-germ	2 mothers volunteered: One washed hands with soap & water, the other with only water. Mothers then put hands under UV lamp to show 'glowing germs' on the hands that did not use soap.	To use during the men & women's group discussions to engender the motivational drive for disgust & consequences of not using soap.

Table 4: Thirty village/cluster baseline characteristics by study arms. (n=30)

Variables	Control n=15	Intervention n=15
Village population n	**5088**	**5219**
Village population median (IQR)	**351 (297 - 400)**	**354 (282 - 406)**
Households per village median (IQR)	**40 (30 - 60)**	**33 (26 - 49)**
Children aged < 5 years median (IQR)	**86 (71 - 111)**	**86 (77 - 99)**
Children aged 6-24 months median (IQR)	**39 (34 - 57)**	**43 (33 - 55)**
Major ethnic group in village n (%)		
Mandingo	3 (20)	5 (33.3)
Wolof	5 (33)	5 (33.3)
Fula	7 (47)	5 (33.3)
Main income of villages n (%)		
Farming	13 (87)	12 (80)
Farming & Business	2 (13)	3 (20)
Distance to nearest health facility*		
< 5 km	6 (40)	7 (56)
≥ 5 ≤ 10 km	5 (33)	4 (27)
> 10 km	4 (27)	4 (27)
Availability of school in the village n (%)		
No school	9 (60)	10 (67)
Primary	4 (27)	5 (33)
Primary/middle school	2 (13)	0 (0)
Availability of village/community groups n (%)		
Village Development Committee	15 (100)	15 (100)
Water Sub-committee	11 (73)	7 (47)
Women's Group	13 (87)	15 (100)
Location of village		
North of river	7	7
South of river	8	8
Quartile of population size of villages		
1	3	3
2	4	4

3	4	4
4	4	4

*- this is the actual travel distance by mothers on food or transport and not the scaled map distance.

Table 5: Twenty mothers per village/cluster baseline characteristics by study arm. (n=600)

Variable	Control N=300	Intervention N=300
Number of children alive for index mother	1059	1084
Mother's education n (%)		
Not gone to any school/illiterate	186(62)	176(59)
Primary	90 (30)	80(27)
Other (Arabic or Islamic, senior secondary, college)	24 (8)	44 (14)
Mother's ethnicity n (%)		
Mandingo	60(20)	80(27)
Fula	140(47)	120(40)
Wolof	100(33)	100(33)
Mother's Occupation n (%)**		
Farmer	280 (93)	275 (92)
Other (trading, animal husbandry, civil servant)	20 (7)	25 (8)
Index child's gender		
Male	138 (46)	146 (49)
Female	162 (54)	154 (51)
Index child's health reports for the last 7 days		
Reported diarrhoea by mother n (%)#		
Child had diarrhoea in last 7 days (3 watery stool in 24hrs)	86 (29)	61 (20)
Reported cases of RTI by mother n (%)#		
Child had RTI in last 7 days (cough with difficulty breathing)	30 (10)	30 (10)
Husband's ethnicity n (%)		
Mandingo	50(17)	60(20)
Fula	150(50)	140(47)
Wolof	100(33)	100(33)
Structure of house n (%)		
Mud wall corrugated roof	124 (41)	126 (42)
Cement wall corrugated roof	43 (15)	30 (10)
Mud wall thatched roof	133 (44)	144 (48)

Belongings

Land n (%)	285 (95)	281 (94)
Cattle n (%)	174 (58)	178 (59)
Goat n (%)	217 (72)	216 (72)
Mobile n (%)	254 (85)	270 (90)
Radio n (%)	191 (64)	204 (68)
Tap n (%)	4 (1)	9 (3)
Fridge n (%)	3 (1)	8 (3)

- December survey was during the dry season

** - all mothers were housewives, but had additional regular other work

Table 6 *[this table can be shortened or put in on-line appendix]*: Themes and quotes from focus group discussion with the intervention team (Project lead, 2 Public Health Officers, male Traditional Communicator, driver)

Themes	Sub-themes	quotes
Respect to the village authorities and their involvement	Paying respect to (visit) and obtaining permission of the head of village at the very start and at the start of each visit to the village essential for full cooperation of all village. The involvement of the Alkalo and his wife (their photos or videos performing or endorsing practices) is a role model for the villagers. Printing photos is an effort with available rural resouces (Challenge)	"This is Africa. We do things with respect….the way the programme started, we go to Alkalo to get his permission with respect…get consent…that is the way to go…even politicians do this…that is why throughout the programme wherever we went, they told us you are here to help us…" TC "Videoing or taking pictures of Alkalo or his wife and printing in colour was very useful…though we struggled with the printer" PM "useful to show the head of community and his wife are involved in the project…we showed the villagers that look these people are appreciating the programme and what are you waiting for." PHO2
House-to-house visits are important	Important for community participation in the meetings Important for mother's engagement as they were monitored and involved House visits took effort and time. (Challenge)	"…because you meet them and tell them about the meeting at 3 o'clock, then by 3 you see them all coming" PM "House-to-house visit was so effective where we collect direct information on what is happening in the ground" PHO2
Songs and drama were liked	Villagers and especially children learnt the concepts through songs and stories/drama Children sang the songs when team was not there	"for me, the part that I think triggered these people was the cultural drama…Fontou's role, people could relate to it…you see community elders nodding, women giggling, and everyone becoming absorbed" PM

	Important for sustainability	"in the drama,…during food preparation her (Fontou's) hands get contaminated, that is when it triggers the mothers and all community" PHO2 "when you go to the villages you see the little children singing [our songs]. Even if we are not in the village, the kids are singing next to their mothers and so all are aware" PHO1 "When MaaChampion played her role, they [mothers] have the will and courage to see how to do hygienic food and how to prevent the child from eating contaminated food…her role was very important" PHO2 "later we [TCs] could continue the songs during wedding and birthing ceremonies…I told them even any woman who can sing in the village can continue singing like we do [to encourage the mothers]."
Glow germ demonstration	Glow germ demonstrations in meetings were effective	"Glow Germ show everyone, man, woman, child and elderly about germ on their hands…they saw it light up…" PHO2
Women and competitions	Women liked their videos or photos taken and shown to the other villagers if they achieved milestones Giving them the plastic sheet at the start was a cue for their involvement Women wanted to be a part of the competitions and to be a MaaChampion Even some women who had no child or a deceased child participated!!	"Giving MaaFambo who pledge something to get them going…its like a starting point…to start the whole thing." PM "mothers not involved or if they don't have a child, they certainly feel it…one child passed away before, the mother still put out all project things and learnt the steps and wanted to be a part of the programme…" PHO2 "…another one has a doll. She had a doll and she prepared the food like our messages for the doll…every time I went to the village and did house visits, I look for her like other mothers…she boiled the water and

		everything like others." PHO2
Indian and Nepal stories/animations worked well	The Indian animation in English was translated verbally, and the concepts, settings were similar and could be related to by Gambian mothers The Napal stories needed little adaptation to print with Gambian adaptations	"we explained that this is India…and I translated the words in local language…but they understood very well…African women have the same problems..." TC
Team work and membership of PHO	Representing the local Public Health Department was an important introduction for the team	"B was so humble…team work was so important" TC "They all knew us, and we said we are from Regional Public Health Team…it gave us respect with the Alkalo and community health volunteer and TBAs."
Involvement of policy makers, managers and funders vital	Local Advisory Committee at the central level prevented potential bureaucratic or other threats Involvement of local government/Public Health Directorate and their staff assisted in introduction to village authorities, long term support of the programme	"The Advisory Committee gave us all permissions and was good for us…" "Some of the villages knew these lads…they all respected the regional public health directorate…" PM
Male and female member of the team	Female team members attracted the women villagers Male team members gained respect of village head, elders and men who influenced mothers	"When we go (to villages) TBA and MaaChamions and MaaSupervisors go to her [female TC]…they called her MaaChampion [she played this role in the drama]….she became a part of the village more than our team" TC "men in our team were important… to get the attention of men and Alkaloo and everyone" PHO2
Local female volunteers and TBAs	Local female volunteers and TBAs spread the messages and encouraged women during and between team visits This created a social norm/expectation from the mothers	"…everywhere we went they [TBAs and MaaSupervisors] go ahead of us…when we were there they became a part of us" TC "TBAs assessed others [mothers] and help us do our

		mother's assessments too" PHO "J made sure TBAs and supervisors do the right thing…we examined them each day of the training…gave them big posters to help remind them." TC

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Promoting hygienic weaning-food handling practices through a community based programme: intervention implementation and baseline characteristics for a cluster-randomized controlled trial in rural Gambia.

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Promoting hygienic weaning-food handling practices through a community based programme: intervention implementation and baseline characteristics for a cluster-randomized controlled trial in rural Gambia.

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Abstract

Objective: Contamination of weaning-food leads to diarrhoea in under-5s. Public health interventions to improve practices in low and middle-income countries are rare and often not evaluated using a randomised method. We describe an intervention implementation and provide baseline data for such a trial.

Design: clustered randomised controlled trial

Setting: Rural Gambia

Participants: 15 villages/clusters each of 20 randomly selected mothers with 6-24 months old children per arm

Intervention: To develop the public health intervention, we utilised (a) formative research findings to determine theoretically-based critical control point corrective measures and motivational drives for behaviour change of mothers; (b) lessons from a community based weaning-food hygiene programme in Nepal and a handwashing intervention programme in India; (c) culturally-based performing arts, competitions and environmental clues. Four intensive intervention days per village involved the existing health systems and village/cultural structures that enabled per-protocol implementation and engagement of whole villager communities.

Results: Baseline village and mother's characteristics were balanced between the arms after randomisation. Most villages were farming villages accessing health centres within 10 miles, with no schools but numerous village committees and representing all Gambia's three main ethnic groups. Mothers were mainly illiterate (61%), farmers (92%); 24% and 10% of children under-5 were reported to have diarrhoea and respiratory symptoms respectively in the last seven days (dry-season). Intervention

process engaged whole village members, and provided lessons for future implementation; culturally-adapted performing arts were an important element.

Conclusion: This research has potential as a new low-cost and broadly available public health programme to reduce infection through weaning-food. The theory-based intervention was widely consulted in the Gambia and with experts, and was well accepted by the communities. Baseline analysis provides socioeconomic data and confirmation of MICS data on the prevalence of diarrhoea and respiratory symptoms in the dry season in the poorest region of Gambia.

[Abstract 298 words]

Article Summary - Bullet point of strengths and weaknesses:

Strengths:

- Strongly theory based community intervention
- Pragmatic public health intervention involving existing public health workforce, village and country leaders in rural Gambia (low cost and easy to replicate)
- Use of traditional Gambian performers/performing arts in the intervention (attractive to villagers and target mothers)

Weaknesses:

- For the trial, it is impossible to fully blind communities
- Villages selected from Primary Care Villages in the poorest region of the Gambia may pose a generalisability constraint

Trial registration: The trial was registered on the 17th October 2014 with the Pan African Clinical Trial Registry in South Africa with numberPACTR201410000859336.

Keywords: behaviour change, weaning-food, hygiene, food preparation, community intervention, performing arts, motivational drivers, scalability, Africa.

Background

It is estimated that two billion episodes of diarrhoea annually occur among children under-5 years resulting in over 1.2 million deaths globally.[1]The highest prevalence are in low and middle-income countries (LMIC) clustered around those aged 6–24 months[2]: the weaning age. Contaminated weaning-food[3] is an obvious source of infection but to-date the emphasis for research and interventions have focussed on water hygiene.

In general, handwashing with soap by mothers can reduce infant diarrhoea by 47%.[4] A central element of safe food preparation is handwashing, but this is not the only component requiring improvement for weaning-food hygiene.[5,6] Two small individually randomised proof-of-concept efficacy trials with individual training and follow-up of mothers for a weaning-food hygiene intervention (in Mali[6] and Bangladesh[7]), and a community intervention evaluated in a small before-and-after cluster study in Nepal,[8] explored potential alternatives. The former was too intensive to be scalable, while the latter needs to be evaluated in a larger trial and could be simplified further to become a model for a population-level intervention package.

Fundamentally, community-level interventions should be short, simple, culturally acceptable, low-cost and involve existing structures. In this article we describe the intervention implementation and provide baseline data to evaluate such an intervention in the Gambia, W. Africa. The Gambia has a high rate of childhood diarrhoea but to our knowledge, there have been no recent studies or interventions of weaning-food in the Gambia. Moreover, our formative research[9] indicates that the practices and rates of contamination have not changed significantly since 1978.[10] Significantly, we found that weaning-food samples collected immediately after preparation before feeding to the child, were significantly contaminated with faecal coliform and that this contamination increased after ≥ five hours' storage.[9]

The evaluation for our intervention was designed as a cluster-randomized control trial (cRCT). We describe here the intervention implementation phase of the complex public health community intervention, and the baseline survey data for our the cRCT. We draw lessons from our intervention implementation for future expansion. The primary objective of the main cRCT trial is to investigate the effects of ae complex public health community intervention that sought to improve mothers' weaning-food hygiene practices. We further sought to investigate the effect of the intervention on the level of microbiological contamination in food and water prepared for the child's consumption; and to establish the prevalence of diarrhoea and respiratory symptoms, and diarrhoea admission, as reported by mothers.

Methods/Design

Design

The unit of randomization for this parallel cRCT. The 4-day community intervention was followed by a reminder visit after five months. Two cross-sectional samples were taken to measure baseline characteristics and outcomes: one before randomisation and the other six months post-intervention roll-out. There were no changes to the protocol after commencement.

Setting and population

The cRCT was conducted in the Central River Region (CRR), one of Gambia's administrative regions. CRR is 48000 km^2 in area, organised into 11 districts with 659 villages, and a population of 201,506 of which 41,334 (20%) are under-5 years of age.[11] CRR was selected for the intervention as it has the highest incidence diarrhoea in the Gambia, particularly in children aged 6–24 months (26.5% of children under-5 had diarrhoea in the two weeks preceding the UNICEF Multiple Indicator

Cluster Survey (MICS) in 2010, verses 17% nationally.[12] The rates for Acute Respiratory Infection (ARI) of children under-5 were 14.2% in CRR compared to 6% nationally). CRR is rural, with low literacy, and is economically the poorest region in the Gambia. Villages in the region differ in their access to water supply and health care. A typical village has a head and a religious leader, but the size of settlements registered on the national population census (in 2013) ranges from as few as 27 to 1,800 population per village, giving mean village size for CRR of 357(SD±59).[11] As with the other regions in the Gambia, UNICEF and the Gambian Ministry of Health and Social Welfare (MOH) have selected a number of villages (158 in CRR) to become Primary Health Care (PHC) villages where they have trained (for four weeks) a Village Health Worker (VHW) and a Traditional Birth Attendant (TBA) to provide health promotion and basic health support to the villagers.[13]

Inclusion criteria for study villages for the Intervention were PHC villages in CRR with a population of 200–450. It was felt that such villages, with lay health workers, would be best able to support the programme given the available resources. The 200–450 population criteria per village was decided on three grounds: the requirement for a minimum of 20 families with children aged 6-24 months, a population close to the mean village size in CRR (357), and the need to avoid villages that were too large given the size of the team implementing the intervention. Exclusions for the villages were those that were within 5km of already selected villages.

Inclusion criteria for households within the villages for the baseline were mothers with children aged 6-24 months; exclusions were those expecting not to be resident in the village for the following six months. There were no other exclusions.

Recruitment

The villages were randomly selected by a UK epidemiologist, aware of the biases fraught with a non-random village sampling, from a list of all villages in CRR after applying the selection criteria. We provided written and oral information and sought informed consent from the village heads for the villagers' participation in the programme.

For the baseline, a list of all mothers with children aged between 6-24 months living in the village at the time was obtained from the maternal-child health register, and households were chosen randomly based on the study criteria. Mothers gave written informed consent. In case of illiteracy, the information was read out (and a written copy left behind), and a thumb print obtained in the presence of a family witness and the fieldworker.

Baseline measurement

During the initial recruitment visit (December 2014; dry season), after consent, we characterized all 30 villages and 20[1] randomly chosen mothers within them before randomisation, and collecting data about socioeconomic background of the families and diarrhoea and respiratory illnesses of the index child over the last 7 days.

Randomisation

[1] **On-line annex: Trial Sample size:** Observations during the formative research indicated that the proportion of events in which correct behaviour was displayed (i.e. practices of heating stored food, hand washing with soap before food preparation, during food preparation if contaminated, and before feeding the baby (measured the first time activity occurred)) was 17/150 (11.3%). As this was to be a cluster RCT, we assumed an intracluster correlation coefficient (ICC) of 0.04[14] between villages and a coefficient variation of cluster size 0.22. With a significance level of 5%, we aimed to detect a minimum of 25% absolute increase in behaviour in the intervention compared to the control arms with 95% power. As we were able to recruit 15 clusters per arm, a minimum of 12 mothers per cluster was required.[15] We aimed to recruit 20 mothers within each village at outcome evaluation to guard against loss of mothers during the eight hour observation by female fieldworkers during evaluation home visits. In a sensitivity analysis, assuming a larger ICC of 0.1, the power (84%) remained reasonable.

Randomisation took place after all village heads provided consent and the baseline data collection had been completed. Randomisation was conducted by a statistician in the UK. The villages were grouped and randomised within strata (north or south of the river, and by quartiles of the village population) into 15 control and 15 intervention villages.

Blinding

While it was not possible to blind of the implementers of the intervention programme nor the families who received the intervention. The families exposed to the intervention were unaware of the comparative nature of the intervention with a control village.

Data analysis

This article presents the data for the baseline which are analysed using descriptive summaries.

Control villages

After consent by the head of village, and randomisation, the control villages received a one day visit by a PHO who using a flip chart during a village gathering talked about using water in household gardening. No further visits were made to the control villages.

Intervention

The intervention components and delivery package were theoretically-based, and informed by the local context from our formative research, and by the lessons/tools from community interventions in handwashing studies in India[14]and weaning-food hygiene in Nepal.[8] The latter employed the same theoretical models in similar study questions. The intervention comprised a community-mobilisation campaign delivered to all the villages and focussed on mothers of weaning babies and those with children under-5 years in whole village. The intervention team

visited each village on days 1, 2, 17 and 25 and was delivered between 16th February and 28th April 2015 (the dry season). A set of activities were conducted that involved mothers and other village members in village-wide events, neighbourhood meetings, home visits, with the wider involvement of the village authorities and volunteers. We included a 5th visit after six months as it was envisaged that were such a programme to be implemented at scale, then for the behaviour change to be sustained, villages would require a reminder visit before or early in the diarrhoea high-risk rainy season. [16] Mothers and their families are busy at this time and hence more likely to forget weaning-food hygiene behaviour. The programme's daily schedule and tools and including their links with the motivational theory, are summarised in Tables 1 and 2.

We used two theoretical frameworks in designing the intervention: Firstly, Hazard Analysis and Critical Control Points (HACCP),[17,18] which are conventionally used in the food processing industry to reduce microbiological contamination. The WHO/FAO Expert Committee on Food Safety has recommended the use of HACCPs in homes in LMICs to provide insight into food preparation hazards and remedial preventive measures.[18,19] There is also evidence from efficacy and a small population trial that weaning-food hygiene activities following the HACCP approach can help identify measures to improve weaning-food safety.[18] Table 3 summarises the corrective measures that were prioritised following our formative research.[9]

Secondly, we used an applied motivational behaviour change model[20] that facilitated the application of identified corrective measures in a way that would add to mother's knowledge and attitude and would motivate a change in mothers' behaviour. The model draws upon psychology research that proposes ways of classifying various drivers of human behaviour. Our formative research found that Nurture, Disgust, Affiliation, Status and Purity were the strongest motivational drives for our village mothers.[9]

As with the India and Nepal programmes,[8,14] we focussed on the use of performing arts (using culturally ingrained styles of drama and songs),[21] competitions and environmental cues[22] to deliver the HACCP corrective measures and motivational drives. Details of our community weaning-food hygiene programme, which was designed by the research team at the University of Birmingham (which included a Gambian Public Health officer from MOH) were widely consulted with expert health promotion agencies who were represented on a Local Scientific Advisory Committee in the Gambia (MOH, UNICEF, WHO, University of the Gambia, National Nutrition Agency (NANA), and the MRC Gambia).

Subsequently, the material was translated into the three local languages (Mandinka, Wolof and Fula), field-tested and piloted iteratively by the intervention team in the CRR. This team, which also delivered the programme, comprised one literate male and one illiterate female traditional communicators (TC) with health promotion experience, three Public Health Officers (PHO) from the local Regional Public Health Department (2 with Higher National Diploma from the Gambian College School of Public Health with an additional Masters in Public Health) and an illiterate driver (for 24 days of the 60 days of the village visit, there were two PHOs in the team for the remainder there were three PHOs). TCs are performing artists who use traditional African drumming, singing and acting to communicate messages. The team were deliberately selected from the within existing structures in rural Gambia to demonstrate replicability and scaling. The team was assisted by a female volunteer (usually a TBA) from each village who received two weeks training assisted the work programme during, and in-between, the team visits. The TBAs were encouraged to find one or more assistant volunteers by day one of the team's visit (3 visits in smaller villages ended with no assistants, 11 had one assistant, and one had three assistants).The assistants were called "MaaSupervisors" and visited the families between team

visits to recruit more mothers of young children, reinforce the target practices, and hence help ingrain the practices with the cultural norms of the wider community.

The intervention focussed on a central role model character the "MaaChampion", a mother who practised the key behaviours used in the messages (Table 3) and encouraged other mothers to do the same. Village mothers could achieve "MaaChampion" status if they successfully demonstrate the practices and knowledge, and encouraged two other mothers to do so. 'Funtu' (a derogatory noun for a discarded useless thing) was another character: a mother who failed to practise any of the target behaviours and reaped the consequences with her family and other villagers. These two characters were described using story drama and songs in the context of an average village, Together they demonstrated all the key messages and motivational drives, and engendered a wish for behaviour change in village mothers as they identified with the characters' lifestyles and behaviours.

Other components such as competitions (for mothers of children <5 years), environmental cues (for mothers engaged in the competitions), and demonstrations, had an important role in embedding behaviour change. The programme's daily schedule and tools, including their link with the motivational theory, are summarised in Tables 1 and 2.

Overall, the aim was to apply theory, and apply successful elements of two previous studies[8,14] while ensuring the intervention was as simple and cost-effective as possible. It also needed to be understandable and replicable by existing local health system/staff in the Gambia.

Implementation was staggered over two months. During implementation of the intervention, there were no diversions from the protocol. The intervention team logged significant events, comments and the overall participation of villagers/mothers in the programme to enable full

evaluation of the intervention implementation. At the end of the intervention implementation, the intervention team were interviewed in a focus group discussion to explore the experience of the team during village visits and implementation, and identify successful elements and learning points. These will be reported in a qualitative publication.

Results

Recruitment and baseline characteristics:

The trial flow chart (Figure 1) outlines how 15 clusters were recruited per arm with a total of 300 mothers in the intervention and 300 in control villages at baseline. No village or family refused to participate. The median village size was 351 (IQR 297-400) in intervention and 354 (IQR 282-406) in control villages. The background characteristics of villages and baseline families were well-balanced between the arms (Tables 4 and 5). The majority of villages had no school and no health facility within 5km; the main source of income for all villages was farming with only the three major Gambian ethnic groups represented. All villages had Development Groups and most had Women's Groups or Water Sub-groups indicating some village level organisation.

The majority of the mothers were farmers and illiterate. The structure of the houses and belongings provided a good indication of economic status and indicated that nearly half could be categorised as poor by rural Gambian standards with no cattle, and houses with thatched roof and mud walls.

Intervention development and implementation

Stories, songs, posters and animations from previous relevant programmes in India and Nepal were transferable from Asia to our African setting and the tools were easy to adapt within six weeks (including staff training, refining of the material, field testing and piloting). Material

production (banners, posters, flip charts etc.) took a further four weeks. Animations from South Asia were used unadapted and seemed to fully engage our target audience (live translation of spoken words was provided during the showing).

For replicating the program in other settings, particular lessons were learnt for low-cost adaptation and replication of the material that are important for scaling such programmes. First, it was initially intended that the story booklets/flipcharts would have professionally drawn artist graphics (as per Nepal study), but the team found that printed photographs of consented local women/actors performing the stories in a local home was more effective for the story flipcharts and other printed material. They could be done by the team members themselves rather than professionally produced, thus lowering the cost.

Second, unlike the Nepal programme where each village visit detailed one theme/message, all messages/practices were discussed in all visits. This simplified the intervention and meant that the same tools, stories and songs could be used more than once during village visits. Moreover, as there were only four core visits and one reminder visit, we found that villagers continued to be interested in the material: repetition brought familiarity which helped participants to understand the messages in more depth, and to relate the stories and songs to their lives. From the 571 mothers of 6-24 month old children in the 15 intervention villages, during the 4 visits there were 392 (69%) MaaFamboos (pledged) to 291 (51%) MaaChampions. All villages reached the status of 'Weaning-food Hygiene Village' with a third of mothers of children under-5 years as MaaChampions. All levels of the community, including men, women of all ages and children were involved in the programme as they attended meetings, encouraged each other to participate and sang the songs.

Discussion

We summarise an intervention implementation and provide baseline data of the first African community-level weaning-food hygiene intervention programme. The baseline characteristics revealed satisfactory randomisation with villages and families that were representative of Gambia's CRR.[12] Reported diarrhoea and ARI rates in our dry season (best conditions for villagers), agreed with a2010 MICS survey for CRR (26.5% and 14.2%, respectively).[12]

The intervention strengths include a strong theoretical base and application of appropriate, replicable and transferable tools from two Asian programmes (in Nepal and India). The communities welcomed the use of culturally embedded performing arts, while the involvement of regional PHOs, rather than research staff, provided a pragmatic and potentially scalable intervention.

A possible limitation affecting the generalisability of our intervention implementation is that non-Primary Health Care villages were not sampled. However as the MaaSupervisors were from any background and we trained them for two weeks, the intervention did not rely on the training of TBAs and Village Health Workers. Thus we anticipate that this intervention could have been implemented in non-Primary Health Care villages. A further limitation is that a formal qualitative evaluation process was not conducted, although documented observations from the programme implementation and a focus group with the project team shortly after the implementation will provide evidence for success elements. The involvement of policy makers, public health managers and funders from the start, as well as local implementing agencies (as part of the Local Scientific Advisory Committee) helped avoid potential bureaucratic or other threats to the programme. As the delivery method is low-cost, replicable and utilises existing

systems (PHOs, village organisations and TCs), the programme could be scaled-up even with relatively limited resources. If combined with related programmes on child nutrition or Community-led Total Sanitation ran by UNICEF, NANA or MOH our intervention, if proven effective, could further strengthen existing health systems with the training and use of non-specialised staff in rural settings.

Performing arts, although used in health promotion campaigns, are rarely evaluated as instruments in themselves for community behaviour change. Although formal evaluation of their work was beyond our resources it was found that the wider community engagement (men and women; young and old) was primarily due to the initial attraction provided by the traditional communicators. During team visits they engendered a joyous atmosphere, and their songs and stories became ingrained in daily village life with their repetition by children and villagers learnt and repeated them. Qualitative data from team members (Publication draft), who were experienced public health officers delivering government or UNICEF health promotion programmes, reveals that drama, animation, songs, stories, and handwashing demonstrations using GlowGerm[23] were much more effective than the traditional communication of messages with talks and flipcharts/posters which the team members had used in previous projects. The villagers seemed to adopt the stories and songs, calling/singing them out loud as the team walked around the village and between visits. On the whole the villagers welcomed the team and all components of the programme, including the competitions that increased peer-support, and which encouraged mothers of young children to achieve MaaChampion status.

A controversial issue relating to the use of performing arts is the need to adapt the tools to different cultural settings. Significantly, for expansion of this, or similar hygiene programmes, we found the tools from Asia (India and Nepal) to be easy to adapt to the style of communication

used by African TCs and performing artists. There is a dearth of literature describing formal evaluations of the use of such TCs in song and drama during campaigns and we hope to contribute to this after reporting the trial data.

Conclusion

We describe a theoretically-based community intervention in a low socioeconomic population region of the Gambia with high child morbidity. We found that weaning-food hygiene intervention programmes based upon HACCP and motivational theory, and using culturally engendered performing arts, may be transferable across LMICs. At the implementation stage, the study was successful in the active involvement of policy makers and public health service providers (Public Health Officers) and traditional performing artists and village authorities. This engagement was successful in developing and implementing tools, leading to a low-cost intervention that was easy to deliver within existing public health structures and which was well-received by villagers in the lowest resourced region of the Gambia.

[Manuscript 3390 words without headings]

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Authors Contributorship Statement: All authors contributed to design of the study/study protocol and helped with drafting the manuscript (Dr Ensink contributed to draft of protocol and early versions of manuscript before his murder). The following specific contributions apply:

Buba Manjang – Trial Manager, contributed to design and development of the intervention and evaluation, implementation of the study in the field, data collection and data analysis, Co-PI;

Karla Hemming – Senior Trial Statistician and RCT design Co-I;

James T. Martin – Junior Trial Statistician contributing to analysis plan and analysis;

Sandy Cairncross and Jeroen Ensink – WASH experts contributed to design of the intervention and evaluation in the RCT;

Chris Bradley - water scientist contributed to the design of study in general pertaining to safe waters and testing;

Jama Sowe and Abdou Jarju - both Public Health officers, contributed to the development of the intervention and its implementation and study design;

Semira Manaseki-Holland – Trial Director, contributed to design and development of the intervention, evaluation, and the trial as a whole, implementation of the intervention, and completion of the data collection: Co-PI.

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Registration: The protocol was registered on the 17th October 2014 with Pan African Clinical Trial Registry with number; PACTR201410000859336 at South Africa.

Ethical approval: This study had full ethical approval from Gambia Government / MRC Joint Ethics committee (SCC 1385v2) and the University of Birmingham (ERN_14-0574). A written informed consent form was obtained from caregivers of children aged 6-24 months. All the information collected was kept strictly confidential.

Data sharing statement: This paper only documents the baseline data for a cluster randomised controlled trial. The remaining analysis is still not completed and will be done by our research team. Once this is complete the database is available for other researchers from the corresponding author after five years to allow for all required use by the primary research team.

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Figure 1: The trial flow chart.

Table 1: Details of intervention activities and during visits to the intervention villages. The idea of a four day programme was adapted from the India SuperAmma study.[14] However, the details of events were adapted mainly from the Weaning-food Hygiene Nepal study,[14] itself drawing on aspects from the SuperAmma India study (see footnote to Table 3 for source of adapted tools)

	EVENT	ACTIVITY	WHERE	TIME	PURPOSE
Day 1	Meeting the Alkalo (village head)	- TCs play a song in praise of the Alkalo. - The team greet the Alkalo - Explain purpose/project - Meet VHW & TBA and MaaSupervisor	Alkalo's residence	20 min	- Alkalo is the entry point to the village; must receive a visit before start of work - Alkalo & wife have social status & their support motivates mothers
	Announce to the villagers	-TCs invite villagers to afternoon meeting by drumming & campaign song with the use of a loud speaker	Within whole village	2 hrs	- Create alert - Mobilise the community - Memorisation assisted by repetition of song & messages
	House-to-house visit with MaaSupervisors	- House-to-house visit (invite household members to afternoon meeting) with TBA & VHW	Residence of every household especially with young children	3 hrs	- Social mobilisation to involve the whole community
	Record a short video	- Video the Alkalo & wife handwashing & reheating weaning-food to show at the village meeting later	Alkalo's residence	15 min	- Alkalo & wife have social status & their support motivates mothers -Engender a social norm
	Afternoon event	-TC's Drum/sing the six messages & pledging song while villagers arrive at meeting site - Opening prayers by the Imam (religious leader) lead prayers for the gathering (Gambian cultural norm) - Opening remark by the Alkalo. - Introduction of project by PHO - 2 Drama (MaaChampion & Funtu) by TCs - Summary of six messages from the drama by PHO. - Question & answer from village audience led by PHO - Pledge song by TCs - Play 'Choose soap' silent animation video. [14] - Show video of Alkalo (washing hands with soap) & his wife (reheated weaning-food) translated live in local language - Announce MaaChampion competition by PHO.	Village "Bantaba" (a central place where villagers meets – usually under a large tree)	4 hrs	-Inform the community/provide instructions - Model or demonstrate behaviour - Engender all motivational drivers, particularly nurture and affiliation - Prompt identification with a role model - Prompt action through pledging - Set graded tasks through competitions - Target mothers for their pledge - Prompt intention formation - Memorisation assisted by repetition of song & messages - Display of photos of pledged mothers for contingent reward

		- Invite mothers of children 6-24m to pledge to practise behaviours - Give pledged mother's plastic sheets for covering surfaces to enable hygienic drying of utensils/pots on a clean surface - Take a group photo of pledged mothers for the honour board. - Closing remark by PHO. - More drumming & songs (motivational). - Print & display pledged mothers & Alkalo's photos on honour board at the Bantaba			
	Community volunteers training	- Train new assistant MaaSupervisors by village volunteers/trained MaaSupervisors, supervised by PHO	Village Bantaba	2 hrs	- Enable encouragement of mothers and competition success - Involve more community members to engender development of social norms
Day 2	Meeting the Alkalo	- Greet Alkalo as Day 1	Alkalo's residence	10 min	As Day 1
	Announce to the villagers	As Day 1	As Day 1	2 hrs	As Day 1
	House-to-house visit with Maa-Supervisors	- Engage MaaSupervisors with household visits & boost their confidence - Assess/encourage pledged mothers for progress to next stage	Residence of each pledged mother	3 hrs	- Prompt practice of key behaviours - Provide feedback - Prompt self-monitoring /review/community mobilisation
	Ad-hoc women or men meetings held separately in neighbour-hoods	- Glow germ demonstration - Explain 2 stories (MaaChampion & Funtu) on flipchart - Play silent animation video 'Choose soap' on iPad/laptop - Visit home of mothers with the MaaSupervisors to assess them for MaaChampion status	Neighbour-hoods	30 min	- Engender disgust through glow-germ: dirt on hands - Engender all motivational drivers – particularly nurture and affiliation through stories - Engage men & women to support mothers of young children - Prompt specific goal setting
Day	Meeting Alkalo	As Day 2	As Day 2	20 min	As Day 2
	Announce to the villagers	As Day 1	As Day 1	2 hrs	As Day 1
	House-to-house visit with MaaSupervisors	As Day 2 – additionally: - During household visits, video mothers who succeeded to became a MaaChampion to show at meetings	As Day 2	3 hrs	As Day 2 – additionally videoing to provide contingent reward
	Afternoon event	As Dayone & including the below: - Show animation video from India handwashing "SuperAmma"	As Day 1	4 hrs	As Day 1

3		project with spontaneous translation.[14] - Show videos from mothers who succeeded to become MaaChampions - Take photo of new pledged mothers with their plastic sheets and of MaaChampion's with medals & displayed on honour boards (pledging and certification ceremonies)			
Day 4	Meeting Alkalo	As Day 2	As Day 2	20 min	As Day 2
	Announce to village	As Day 1	As Day 1	2 hrs	As Day 1
	House-to-house visit with MaaSupervisors	As Day 3	As Day 3	3 hrs	As Day 3
	Afternoon Event	As Day 1 including below: - Certification ceremony: Present medals for MaaChampions / MaaSupervisors with drumming - Group picture with all MaaChampions, MaaSawarr and MaaFamboos for the honour board - During village wide ceremony, erect a weaning-food hygiene board at the village entrance establishing the village as a "weaning-food hygiene" village with drumming/campaign songs & present village certificate to the Alkalo (Certification ceremony) - Give motivational advice on sustainability by Alkalo, MaaSupervisors,PHOs - Closing remark (emphasis on sustainability)	As Day 1	4 hrs	As Day One including below: - Create ownership of the project and self-monitoring to enable sustainability - A community sense of achievement , and pride commitment by MaaChampions - Inculcated motivational drivers - Encourage achievement of goals through the board as a reminder
Day 5	Meeting Alkalo	As Day 2	As Day 2	20 min	As Day 2
	Announce to the villagers	As Day 1	As Day 1	2 hrs	As Day 1
	House-to-house visit with MaaSupervisors	As Day 3	As Day 3	3 hrs	As Day 3
	Afternoon event	As Day 4 but not including erection of the village board or certification	As Day 4	4 hrs	As Day 4

Table 2 (below): Intervention tools & their application during the intervention

Concepts/Tool	Target population	Details	Purpose
Competitions for mothers & MaaSupervisors			
Mother's Competitions #	Mother and children <5 yrs, but specifically 6-24m of age	3 stages: 1) mothers who learnt the six messages and pledged to practice the behaviours (MaaFamboo); 2) mothers who demonstrated a sustained practice of six messages (MaaSawaar); 3) mothers who did all the above and supported two other mother to become a MaaFamboo (MaaChampion)	To set graded tasks, provide general encouragement (contingent reward) for improved behaviour, prompt identification with a role model & to encourage a change of social norms
MaaSupervisors competitions #	MaaSupervisors	Older respected woman who must encourage mothers, (focus on a minimum of 10) of which 50% must achieve the MaaChampion status.	
Performing arts for all village members			
Songs (at times combined with communal dancing) #	Mother of young children and all villagers attending meetings	*Campaign song*: Information about the six key messages & benefits of practices. Explain the benefits of care & love in terms of a grateful child with a successful future. *Pledged song*: Focused on nurture, disgust & purity to encourage mothers to pledge to carry out the practices. *Welcome song:* A cultural greeting song to welcome and honour the Head of the Village and those present, with elements of messages added.	To engage communities particularly mothers & to make it easy for mothers to learn messages form the songs
Stories (portrayed in drama, animation and flip charts) #		*Story 1:* Story of MaaChampion heard from her grown up child who is now a successful doctor, proudly telling the story to her family *Story 2:* Story of Funtu about how villagers rejected her & how her child suffered, while meeting the MaaChampion & following her advice made her popular & a good mother	To stimulate the motivational drivers help mothers understand & remember messages easily. To communicate the messages in a graphically memorable and entertaining way To prompt identification with the role model (MaaChampion) & consequences of not following the six key messages
Drama #		*One Drama:* describing a day in the life of MaaChampion and Funtu	
Animations $		*Animation 1:* Choose soap.[14] Shows a hand touching faeces and then eating with and without washing with soap first. *Animation 1:* SuperAmma.[14] Shows a similar story to MaaChampion, but in an Indian village, with reference to handwashing with soap in general rather than references to food hygiene.	
Environmental cues for mothers			
Posters, danglers,	Mother of young	All had 6-key intervention practices graphically written on them.	To provide non-monetary incentives (contingent

and medals #	children in the competition	The mothers posters, dangler and medals were all displayed around the house and kitchen	reward) for mothers To provide visual reminders of the six key messages in the kitchen, household
Plastic sheet		A 1.5x1.5 locally available sheet of plastic	To provide a visual reminders of the message about drying pots and utensils on a clean surface To facilitate this practice at the start of the programme when villagers do not have easy access to plastic sheets
Other Tools for team members or villagers			
Posters #	All village members	Had 6-key intervention practices graphically written on them	To remind & facilitate the mothers to perform the six key practices.
Flipcharts #	Mother of young children and all villagers attending meetings	The two stories & key messages were described in three different flipcharts	Visual aids for telling the stories in men & women's discussion groups & to stimulate the motivational drivers For MaaSupervisors to use during their work
T-shirts for the intervention team	All village members	Bearing project logo & title of MaaChampion	To identify & formalise the intervention members
Project Banners	All village members	A piece of polythene presenting six key messages & a photo of the MaaChampion on it. Displayed temporarily in each village before the afternoon events	To make villages aware of intervention events & villages people of the 6 key messages
Glow-germ #	Mother of young children and all villagers attending meetings	2 adults volunteer: Both rub the glow germ cream on their hands. One washes hands with soap & water, the other with only water. Mothers then put hands under UV lamp to show 'glowing germs' on the hands that did not use soap	To use during the men & women's group discussions to engender the motivational drive for disgust & consequences of not using soap

$ tool adapted from SuperAmma India Handwashing study[14]

tool adapted from Weaning-food Hygiene Nepal study[8]

Table 3: Critical control points and corrective measures (practices) and handwashing motivational drivers that were targeted by our weaning-food hygiene intervention

Critical Control Points	**Corrective measures – behaviours the intervention aimed to improve**
Before food preparation	***1. Handwashing with water and soap before food preparation***
	2. Washing of pots and utensils before food preparation and drying on a clean (and cleanable) surface
During Cooking when hand becomes contaminated	***3. Handwashing with clean water and soap when contaminated during cooking***
Stored Food storage before feeding to the child	4. ***Reheating of pre-made food after storage before feeding***
Before feeding the child	***5. Handwashing with clean water and soap before feeding child (mother) or eating (child)***
Water ready for drinking by the child	***6. Boiling and cooling of water ready for drinking by child***
Evo-Eco model motivational drivers for handwashing behaviour change	**Definitions of motivational drivers**
Nurture	- ***the desire for a happy, thriving child***
Disgust	- ***the desire to avoid and remove contamination***
Affiliation	- ***the desire to fit in with what others in a reference group are doing***
Status	- ***the desire to have greater access to resources than others in the group***
Purity	- ***the desire to be favoured by God and to be holy***

Table 4: Thirty village/cluster baseline characteristics by study arms. (n=30)

Variables	Control n=15	Intervention n=15
Village population n	**5088**	**5219**
Village population median (IQR)	**351 (297 - 400)**	**354 (282 - 406)**
Households per village median (IQR)	**40 (30 - 60)**	**33 (26 - 49)**
Children aged < 5 years median (IQR)	**86 (71 - 111)**	**86 (77 - 99)**
Children aged 6-24 months median (IQR)	**39 (34 - 57)**	**43 (33 - 55)**
Major ethnic group in village n (%)		
Mandingo	3 (20)	5 (33.3)
Wolof	5 (33)	5 (33.3)
Fula	7 (47)	5 (33.3)
Main income of villages n (%)		
Farming	13 (87)	12 (80)
Farming & Business	2 (13)	3 (20)
Distance to nearest health facility*		
< 5 km	6 (40)	7 (56)
≥ 5 ≤ 10 km	5 (33)	4 (27)
> 10 km	4 (27)	4 (27)
Availability of school in the village n (%)		
No school	9 (60)	10 (67)
Primary	4 (27)	5 (33)
Primary/middle school	2 (13)	0 (0)
Availability of village/community groups n (%)		
Village Development Committee	15 (100)	15 (100)
Water Sub-committee	11 (73)	7 (47)
Women's Group	13 (87)	15 (100)
Location of village		
North of river	7	7
South of river	8	8
Quartile of population size of villages		
1	3	3
2	4	4
3	4	4
4	4	4

*- this is the actual travel distance by mothers on food or transport and not the scaled map distance.

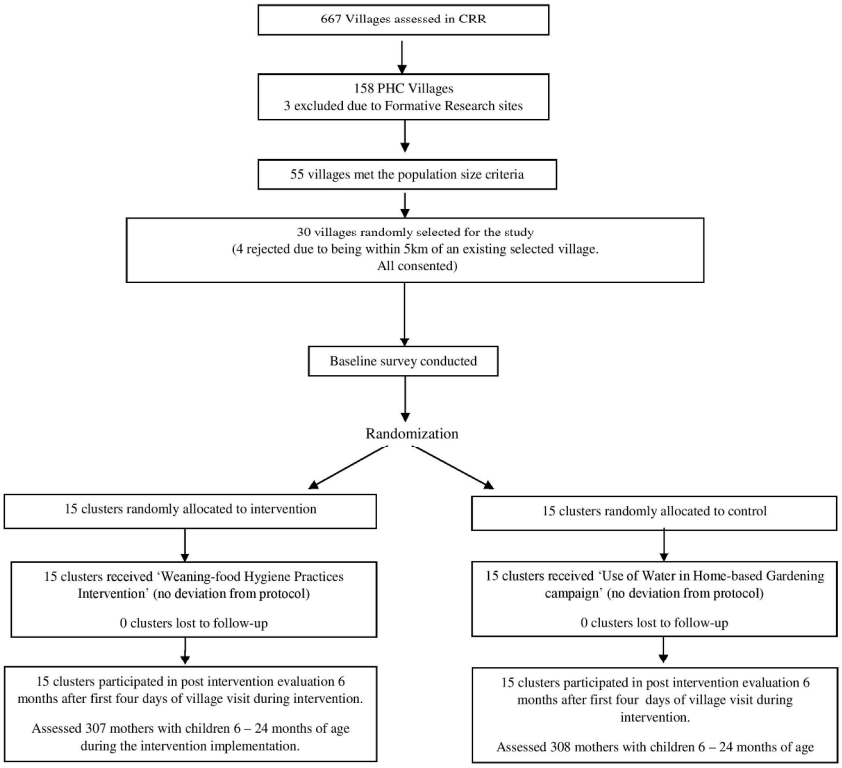
Table 5: Characteristics of mothers in the evaluation survey by intervention allocation.

Variables	Control n=300	Intervention n=300
Number of children alive for index mother (SD)	5.1(6.1)	6.0 (6.1)
Age group of mother		
<20 years	31 (10%)	27 (9%)
20-30 years	177 (59%)	185 (62%)
>30 years	92 (31%)	88 (29%)
Education level of mother		
None/illiterate	183 (61%)	179 (60%)
Other (Islamic, home etc)	48 (16%)	44 (15%)
Primary	29 (10%)	31 (10%)
Secondary or higher*	40 (13%)	46 (15%)
Ethnicity of mother		
Mandingo	60 (20%)	80 (27%)
Wolof	100 (33%)	100 (33%)
Fula	140 (47%)	120 (40%)
Occupation of mother†		
Farmer	280 (93%)	275 (92%)
Other‡	20 (7%)	25 (8%)
Sex of index child		
Male	138 (46%)	146 (49%)
Female	162 (54%)	154 (51%)
Ethnicity of husband		
Mandingo	50 (17%)	60 (20%)
Wolof	100 (33%)	100 (33%)
Fula	150 (50%)	140 (47%)
Structure of house		
Mud wall, corrugated roof	124 (41%)	126 (42%)
Cement wall, corrugated roof	43 (15%)	30 (10%)
Mud wall, thatched roof	133 (44%)	144 (48%)
Belongings		
Land	285 (95%)	281 (94%)
Cattle	174 (58%)	178 (59%)
Goat	217 (72%)	216 (72%)
Mobile	254 (85%)	270 (90%)

Radio		191 (64%)	204 (68%)
Tap		4 (1%)	9 (3%)
Fridge		3 (1%)	8 (3%)
Source of water			
Covered well		184 (61%)	172 (57%)
Open well		116 (39%)	128 (43%)
Sex of Index Child	**Male**	156 (52%)	151 (50%)
Mean age (mths) of child (SD)		18 (7.9)	19 (7.6)
Reported diarrhoea by mother in past 7 days§		86 (29%)	61 (20%)
Reported ARI by mother in past 7 days¶		30 (10%)	30 (10%)

Values for the individual variables are numbers (%). ARI=acute respiratory infection. * Arabic/Islamic, senior secondary or college. †All mothers were housewives, but had additional regular other work. ‡Trading, animal husbandry or civil servant. §Defined as ≥ 3 watery stools in previous 24 h. ¶Defined as cough with difficulty breathing.

Figure 1: The trial flow chart.



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Promoting hygienic weaning-food handling practices through a community based programme: intervention implementation and baseline characteristics for a cluster-randomized controlled trial in rural Gambia.

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Promoting hygienic weaning-food handling practices through a community based programme: intervention implementation and baseline characteristics for a cluster-randomized controlled trial in rural Gambia.

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Abstract

Objective: Contamination of weaning-food leads to diarrhoea in under-5s. Public health interventions to improve practices in low and middle-income countries are rare and often not evaluated using a randomised method. We describe an intervention implementation and provide baseline data for such a trial.

Design: clustered randomised controlled trial

Setting: Rural Gambia

Participants: 15 villages/clusters each with 20 randomly selected mothers with 6-24 months old children per arm.

Intervention: To develop the public health intervention, we utilised (a) formative research findings to determine theoretically-based critical control point corrective measures and motivational drives for behaviour change of mothers; (b) lessons from a community based weaning-food hygiene programme in Nepal and a handwashing intervention programme in India; (c) culturally-based performing arts, competitions and environmental clues. Four intensive intervention days per village involved the existing health systems and village/cultural structures that enabled per-protocol implementation and engagement of whole villager communities.

Results: Baseline village and mother's characteristics were balanced between the arms after randomisation. Most villages were farming villages accessing health centres within 10 miles, with no schools but numerous village committees and representing all Gambia's three main ethnic groups. Mothers were mainly illiterate (60%), farmers (92%); 24% and 10% of children under-5 were reported to have diarrhoea and respiratory symptoms respectively in the last seven days (dry-season). Intervention

process engaged whole village members, and provided lessons for future implementation; culturally-adapted performing arts were an important element.

Conclusion: This research has potential as a new low-cost and broadly available public health programme to reduce infection through weaning-food. The theory-based intervention was widely consulted in the Gambia and with experts, and was well accepted by the communities. Baseline analysis provides socioeconomic data and confirmation of MICS data on the prevalence of diarrhoea and respiratory symptoms in the dry season in the poorest region of Gambia.

[Abstract 299 words]

Article Summary - Bullet point of strengths and weaknesses:

Strengths:

- Strongly theory based community intervention
- Pragmatic public health intervention involving existing public health workforce, village and country leaders in rural Gambia (low cost and easy to replicate)
- Use of traditional Gambian performers/performing arts in the intervention (attractive to villagers and target mothers)

Weaknesses:

- For the trial, it is impossible to fully blind communities
- Villages selected from Primary Care Villages in the poorest region of the Gambia may pose a generalisability constraint

Trial registration: The trial was registered on the 22ndth July 2014 with the Pan African Clinical Trial Registry in South Africa with number PACTR201410000859336.

Keywords: behaviour change, weaning-food, hygiene, food preparation, community intervention, performing arts, motivational drivers, scalability, Africa.

Background

It is estimated that two billion episodes of diarrhoea annually occur among children under-5 years resulting in over 1.2 million deaths globally.[1]The highest prevalence are in low and middle-income countries (LMIC) clustered around those aged 6–24 months[2]: the weaning age. Contaminated weaning-food[3] is an obvious source of infection but to-date the emphasis for research and interventions have focussed on water hygiene.

In general, handwashing with soap by mothers can reduce infant diarrhoea by 47%.[4] A central element of safe food preparation is handwashing, but this is not the only component requiring improvement for weaning-food hygiene.[5,6] Two small individually randomised proof-of-concept efficacy trials with individual training and follow-up of mothers for a weaning-food hygiene intervention (in Mali[6] and Bangladesh[7]), and a community intervention evaluated in a small before-and-after cluster study in Nepal,[8] explored potential alternatives. The former was too intensive to be scalable, while the latter needs to be evaluated in a larger trial and could be simplified further to become a model for a population-level intervention package.

Fundamentally, community-level interventions should be short, simple, culturally acceptable, low-cost and involve existing structures. In this article we describe the intervention implementation and provide baseline data to evaluate such an intervention in The Gambia, West Africa. The Gambia has a high rate of childhood diarrhoea but to our knowledge, there have been no recent studies or interventions of weaning-food in the Gambia. Moreover, our formative research[9] indicates that the practices and rates of contamination have not changed significantly since 1978.[10] Significantly, we found that weaning-food samples collected immediately after preparation before feeding to the child, were significantly contaminated with faecal coliform and that this contamination increased after more than five hours' storage.[9]

The evaluation for our intervention was designed as a cluster-randomized control trial (cRCT) as the intervention would be delivered at the village level. We describe here the intervention implementation phase of the complex public health community intervention, and the baseline survey data for our the cRCT. We draw lessons from our intervention implementation for future expansion. The primary objective of the main cRCT trial is to investigate the effects of a complex public health community intervention that sought to improve mothers' weaning-food hygiene practices. We further sought to investigate the effect of the intervention on the level of microbiological contamination in food and water prepared for the child's consumption; and to establish the prevalence of diarrhoea and respiratory symptoms, and diarrhoea admission, as reported by mothers.

Methods/Design

Design

Villages were the unit of randomization for this parallel cRCT. The 4-day community intervention was followed by a reminder visit after five months. Two cross-sectional samples were taken to measure baseline characteristics and outcomes: one before randomisation and the other six months post-intervention roll-out. There were no changes to the protocol after commencement.

Setting and population

The cRCT was conducted in the Central River Region (CRR), one of The Gambia's administrative regions. CRR is 48000 km^2 in area, organised into 11 districts with 659 villages,

and a population of 201,506 of which 41,334 (20%) are under-5 years of age.[11] CRR was selected for the intervention as it has the highest incidence diarrhoea in The Gambia, particularly in children aged 6–24 months (26.5% of children under-5 had diarrhoea in the two weeks preceding the UNICEF Multiple Indicator Cluster Survey (MICS) in 2010, verses 17% nationally.[12] The rates for Acute Respiratory Infection (ARI) of children under-5 were 14.2% in CRR compared to 6% nationally). CRR is rural, with low literacy, and is economically the poorest region in the Gambia. Villages in the region differ in their access to water supply and health care. A typical village has a head and a religious leader, but the size of settlements registered on the national population census (in 2013) ranges from as few as 27 to 1,800 population per village, giving mean village size for CRR of 357(SD±59).[11] As with the other regions in The Gambia, UNICEF and the Gambian Ministry of Health and Social Welfare (MOH) have selected a number of villages (158 in CRR) to become Primary Health Care (PHC) villages where they have trained (for four weeks) a Village Health Worker (VHW) and a Traditional Birth Attendant (TBA) to provide health promotion and basic health support to the villagers.[13]

Inclusion criteria for study villages for the Intervention were PHC villages in CRR with a population of 200–450. It was felt that such villages, with lay health workers, would be best able to support the programme given the available resources. The 200–450 population criteria per village was decided on three grounds: the requirement for a minimum of 20 families with children aged 6-24 months, a population close to the mean village size in CRR (357), and the need to avoid villages that were too large given the size of the team implementing the intervention. Exclusions for the villages were those that were within 5km of already selected villages.

Inclusion criteria for households within the villages for the baseline were mothers with children aged 6-24 months; exclusions were those expecting not to be resident in the village for the following six months. There were no other exclusions. Sample size calculation (supplementary file 1) was based upon data from formative research investigating behaviours and testing food and water samples for faecal coliforms.

Recruitment

The villages were randomly selected by an epidemiologist in the UK, aware of the biases fraught with a non-random village sampling, from a list of all villages in CRR after applying the selection criteria. We provided written and oral information and sought informed consent from the village heads for the villagers' participation in the programme.

For the baseline, a list of all mothers with children aged between 6-24 months living in the village at the time was obtained from the maternal-child health register, and households were chosen randomly based on the study criteria. Mothers gave written informed consent. In case of illiteracy, the information was read out (and a written copy left behind), and a thumb print obtained in the presence of a family witness and the fieldworker.

Baseline measurement

During the initial recruitment visit (December 2014; dry season), after consent, we characterized all 30 villages and 20[1] randomly chosen mothers within them before randomisation, and collecting data about socioeconomic background of the families and diarrhoea and respiratory illnesses of the index child over the last 7 days.

Randomisation

Randomisation took place after all village heads provided consent and the baseline data collection had been completed. Randomisation was conducted by a statistician in the UK using a computerised random number generator. The villages were grouped and randomised within strata (north or south of the river, and by quartiles of the village population) into 15 control and 15 intervention villages. Allocation concealment was not possible because the intervention team had to know which village would receive the intervention before it was implemented.

Blinding

While it was not possible to blind the implementers of the intervention programme or the families who received the intervention, the families exposed to the intervention were unaware of the comparative nature of the intervention with a control village.

Data analysis

This article presents the data for the baseline which are analysed using descriptive summaries.

Control villages

After consent by the head of village, and randomisation, the control villages received a one day visit by a PHO who using a flip chart during a village gathering talked about using water in household gardening. No further visits were made to the control villages.

Intervention

The intervention components and delivery package were theoretically-based, and informed by the local context from our formative research, and by the lessons/tools from community interventions in handwashing studies in India[14]and weaning-food hygiene in Nepal.[8] The latter

employed the same theoretical models in similar study questions. The intervention comprised a community-mobilisation campaign delivered to all the villages and focussed on mothers of weaning babies and those with children under-5 years in whole village. The intervention team visited each village on days 1, 2, 17 and 25 and was delivered between 16th February and 28th April 2015 (the dry season). A set of activities were conducted that involved mothers and other village members in village-wide events, neighbourhood meetings, home visits, with the wider involvement of the village authorities and volunteers.[15] We included a 5th visit after six months as it was envisaged that were such a programme to be implemented at scale, then for the behaviour change to be sustained, villages would require a reminder visit before or early in the diarrhoea high-risk rainy season.[16] Mothers and their families are busy at this time and hence more likely to forget weaning-food hygiene behaviour. The programme's daily schedule and tools and including their links with the motivational theory, are summarised in Tables 1 and 2.

We used two theoretical frameworks in designing the intervention: Firstly, Hazard Analysis and Critical Control Points (HACCP),[17,18] which are conventionally used in the food processing industry to reduce microbiological contamination. The WHO/FAO Expert Committee on Food Safety has recommended the use of HACCPs in homes in LMICs to provide insight into food preparation hazards and remedial preventive measures.[18,19] There is also evidence from efficacy and a small population trial that weaning-food hygiene activities following the HACCP approach can help identify measures to improve weaning-food safety.[18] Table 3 summarises the corrective measures that were prioritised following our formative research.[9]

Secondly, we used an applied motivational behaviour change model[20] that facilitated the application of identified corrective measures in a way that would add to mother's knowledge and attitude and would motivate a change in mother's behaviour. The model draws upon psychology

research that proposes ways of classifying various drivers of human behaviour. Our formative research found that Nurture, Disgust, Affiliation, Status and Purity were the strongest motivational drives for our village mothers.[9]

As with the India and Nepal programmes,[8,14] we focussed on the use of performing arts (using culturally ingrained styles of drama and songs),[21] competitions and environmental cues[22] to deliver the HACCP corrective measures and motivational drives. Details of our community weaning-food hygiene programme, which was designed by the research team at the University of Birmingham (which included a Gambian Public Health officer from MOH) were widely consulted with expert health promotion agencies who were represented on a Local Scientific Advisory Committee in the Gambia (MOH, UNICEF, WHO, University of the Gambia, National Nutrition Agency (NANA), and the MRC Gambia).

Subsequently, the material was translated into the three local languages (Mandinka, Wolof and Fula), field-tested and piloted iteratively by the intervention team in the CRR. This team, which also delivered the programme, comprised one literate male and one illiterate female traditional communicators (TC) with health promotion experience, three Public Health Officers (PHO) from the local Regional Public Health Department (two with Higher National Diploma from the Gambian College School of Public Health with an additional Masters in Public Health) and an illiterate driver (for 24 days of the 60 days of the village visit, there were two PHOs in the team for the remainder there were three PHOs). TCs are performing artists who use traditional African drumming, singing and acting to communicate messages. The team were deliberately selected from the within existing structures in rural Gambia to demonstrate replicability and scaling. The team was assisted by a female volunteer (usually a TBA) from each village who received two weeks training assisted the work programme during, and in-between, the team visits. The TBAs

were encouraged to find one or more assistant volunteers by day one of the team's visit (3 visits in smaller villages ended with no assistants, 11 had one assistant, and one had three assistants).The assistants were called "MaaSupervisors" and visited the families between team visits to recruit more mothers of young children, reinforce the target practices, and hence help ingrain the practices with the cultural norms of the wider community.

The intervention focussed on a central role model character the 'MaaChampion', a mother who practised the key behaviours used in the messages (Table 3) and encouraged other mothers to do the same. Village mothers could achieve 'MaaChampion' status if they successfully demonstrate the practices and knowledge, and encouraged two other mothers to do so. 'Funtu' (a derogatory noun for a discarded useless thing) was another character: a mother who failed to practise any of the target behaviours and reaped the consequences with her family and other villagers. These two characters were described using story drama and songs in the context of an average village. Together they demonstrated all the key messages and motivational drives, and engendered a wish for behaviour change in village mothers as they identified with the characters' lifestyles and behaviours.

Other components such as competitions (for mothers of children younger than 5 years), environmental cues (for mothers engaged in the competitions), and demonstrations had an important role in embedding behaviour change. The programme's daily schedule and tools, including their link with the motivational theory, are summarised in Tables 1 and 2.

Overall, the aim was to apply theory, and apply successful elements of two previous studies[8,14] while ensuring the intervention was as simple and cost-effective as possible. It also needed to be understandable and replicable by existing local health system/staff in The Gambia.

Implementation was staggered over two months. During implementation of the intervention, there were no diversions from the protocol. The intervention team logged significant events, comments and the overall participation of villagers/mothers in the programme to enable full evaluation of the intervention implementation. At the end of the intervention implementation, the intervention team were interviewed in a focus group discussion to explore the experience of the team during village visits and implementation, and identify successful elements and learning points. These will be reported in a qualitative publication.

Patient and Public Involvement: Patients: The details of the intervention were developed in consultation with mothers and villagers during an extensive piloting phase. There were no particular patient advisors. The results will be communicated after the follow-up is complete through the Public Health Officers who visit the villages. There was no other involvement of patients.

Results

Recruitment and baseline characteristics:

The trial flow chart (Figure 1) outlines how 15 clusters were recruited per arm with a total of 300 mothers in the intervention and 300 in control villages at baseline. No village or family refused to participate. The median village size was 351 (IQR 297-400) in intervention and 354 (IQR 282-406) in control villages. The background characteristics of villages and baseline families were well-balanced between the arms (Tables 4 and 5). The majority of villages had no school and no health facility within 5km; the main source of income for all villages was farming with only the

three major Gambian ethnic groups represented. All villages had Development Groups and most had Women's Groups or Water Sub-groups indicating some village level organisation.
The majority of the mothers were farmers (555, 92%) and illiterate (363, 60%). The structure of the houses and belongings provided a good indication of economic status and indicated that nearly half could be categorised as poor by rural Gambian standards with no cattle, and houses with thatched roof and mud walls.

Intervention development and implementation

Stories, songs, posters and animations from previous relevant programmes in India and Nepal were transferable from Asia to our African setting and the tools were easy to adapt within six weeks (including staff training, refining of the material, field testing and piloting). Material production (banners, posters, flip charts etc.) took a further four weeks. Animations from South Asia (available on public domain) were used unchanged and seemed to fully engage our target audience (live translation of spoken words was provided during the showing).

For replicating the program in other settings, particular lessons were learnt for low-cost adaptation and replication of the material that are important for scaling such programmes. First, it was initially intended that the story booklets/flipcharts would have graphics drawn by a professionally artist (as per Nepal study), but the team found that printed photographs of consented local women/actors performing the stories in a local home was more effective for the story flipcharts and other printed material. They could be done by the team members themselves rather than professionally produced, thus lowering the cost.

Second, unlike the Nepal programme where each village visit detailed one theme/message, all messages/practices were discussed in all visits. This simplified the intervention and meant that

the same tools, stories and songs could be used more than once during village visits. Moreover, as there were only four core visits and one reminder visit, we found that villagers continued to be interested in the material: repetition brought familiarity which helped participants to understand the messages in more depth, and to relate the stories and songs to their lives. From the 571 mothers of 6-24 month old children in the 15 intervention villages, during the four visits there were 392 (69%) MaaFamboos (pledged) to 291 (51%) MaaChampions. All villages reached the status of 'Weaning-food Hygiene Village' with a third of mothers of children under-5 years as MaaChampions. All levels of the community, including men, women of all ages and children were involved in the programme as they attended meetings, encouraged each other to participate and sang the songs.

Discussion

We summarise an intervention implementation and provide baseline data of the first African community-level weaning-food hygiene intervention programme. The baseline characteristics revealed satisfactory randomisation with villages and families that were representative of The Gambia's CRR.[12] Reported diarrhoea and ARI rates in our dry season (best conditions for villagers), agreed with a 2010 MICS survey for CRR (26.5% and 14.2%, respectively).[12]

The intervention strengths include a strong theoretical base and application of appropriate, replicable and transferable tools from two Asian programmes (in Nepal and India). The communities welcomed the use of culturally embedded performing arts, while the involvement of regional PHOs, rather than research staff, provided a pragmatic and potentially scalable intervention.

A possible limitation affecting the generalisability of our intervention implementation is that non-Primary Health Care villages were not sampled. However as the MaaSupervisors were from any background and we trained them for two weeks, the intervention did not rely on the training of TBAs and Village Health Workers. Thus we anticipate that this intervention could have been implemented in non-Primary Health Care villages. A further limitation is that a formal qualitative evaluation process was not conducted, although documented observations from the programme implementation and a focus group with the project team shortly after the implementation will provide evidence of success elements. The involvement of policy makers, public health managers and funders from the start, as well as local implementing agencies (as part of the Local Scientific Advisory Committee) helped avoid potential bureaucratic or other threats to the programme. As the delivery method is low-cost, replicable and utilises existing

systems (PHOs, village organisations and TCs), the programme could be scaled-up even with relatively limited resources. If combined with related programmes on child nutrition or Community-led Total Sanitation ran by UNICEF, NANA or MOH our intervention, if proven effective, could further strengthen existing health systems with the training and use of non-specialised staff in rural settings.

Performing arts, although used in health promotion campaigns, are rarely evaluated as instruments in themselves for community behaviour change. Although formal evaluation of their work was beyond our resources it was found that the wider community engagement (men and women; young and old) was primarily due to the initial attraction provided by the traditional communicators. During team visits they engendered a joyous atmosphere, and their songs and stories became ingrained in daily village life with their repetition by children and villagers learnt and repeated them. Qualitative data from team members (Publication draft), who were experienced public health officers delivering government or UNICEF health promotion programmes, revealed that drama, animation, songs, stories, and handwashing demonstrations using GlowGerm[23] were much more effective than the traditional communication of messages with talks and flipcharts/posters which the team members had used in previous projects. The villagers seemed to adopt the stories and songs, calling/singing them out loud as the team walked around the village and between visits. On the whole the villagers welcomed the team and all components of the programme, including the competitions that increased peer-support, and which encouraged mothers of young children to achieve MaaChampion status.

A controversial issue relating to the use of performing arts is the need to adapt the tools to different cultural settings. Significantly, for expansion of this, or similar hygiene programmes, we found the tools from Asia (India and Nepal) were easy to adapt to the style of communication

used by African TCs and performing artists. There is a dearth of literature describing formal evaluations of the use of such TCs in song and drama during campaigns and we hope to contribute to this after reporting the trial data.

Conclusion

We describe a theoretically-based community intervention in a low socioeconomic population region of the Gambia with high child morbidity. We found that weaning-food hygiene intervention programmes based upon HACCP and motivational theory, and using culturally engendered performing arts, may be transferable across LMICs. At the implementation stage, the study was successful in the active involvement of policy makers and public health service providers (Public Health Officers) and traditional performing artists and village authorities. This engagement was successful in developing and implementing tools, leading to a low-cost intervention that was easy to deliver within existing public health structures and was well-received by villagers in the lowest resourced region of The Gambia.

[Manuscript 3390 words without headings]

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Authors Contributorship Statement: All authors contributed to design of the study/study protocol and helped with drafting the manuscript (Dr Ensink contributed to draft of protocol and early versions of manuscript before his murder). The following specific contributions apply:

Buba Manjang – Trial Manager, contributed to design and development of the intervention and evaluation, implementation of the study in the field, data collection and data analysis, Co-PI;

Karla Hemming – Senior Trial Statistician and RCT design Co-I;

James T. Martin – Junior Trial Statistician contributing to analysis plan and analysis;

Sandy Cairncross and Jeroen Ensink – WASH experts contributed to design of the intervention and evaluation in the RCT;

Chris Bradley - water scientist contributed to the design of study in general pertaining to safe waters and testing;

Jama Sowe and Abdou Jarju - both Public Health officers, contributed to the development of the intervention and its implementation and study design;

Semira Manaseki-Holland – Trial Director, contributed to design and development of the intervention, evaluation, and the trial as a whole, implementation of the intervention, and completion of the data collection: Co-PI.

Conflict of interest: Authors declare no conflict of interest.

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Registration: The protocol was registered on the 22ndth July 2014 with Pan African Clinical Trial Registry with number; PACTR201410000859336 in South Africa.

Ethical approval: This study had full ethical approval from Gambia Government / MRC Joint Ethics committee (SCC 1385v2) and the University of Birmingham (ERN_14-0574). A written informed consent form was obtained from caregivers of children aged 6-24 months. All the information collected was kept strictly confidential.

Data sharing statement: This paper only documents the baseline data for a cluster randomised controlled trial. The remaining analysis is still not completed and will be done by our research team. Once this is complete the database is available for other researchers from the corresponding author after five years to allow for all required use by the primary research team.

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Figure 1: The trial flow chart.

Table 1: Details of intervention activities and during visits to the intervention villages. The idea of a four day programme was adapted from the India SuperAmma study.14 However, the details of events were adapted mainly from the Weaning-food Hygiene Nepal study,14 itself drawing on aspects from the SuperAmma India study (see footnote to Table 3 for source of adapted tools)

	EVENT	ACTIVITY	WHERE	TIME	PURPOSE
Day 1	Meeting the Alkalo (village head)	- TCs play a song in praise of the Alkalo - The team greet the Alkalo - Explain purpose/project - Meet VHW & TBA & MaaSupervisor	Alkalo's residence	20 min	- Alkalo is the entry point to the village; must receive a visit before start of work - Alkalo & wife have social status & their support motivates mothers
	Announce to the villagers	-TCs invite villagers to afternoon meeting by drumming & campaign song with the use of a loud speaker	Within whole village	2 hrs	- Create alert - Mobilise the community - Assist memorisation by repetition of song & messages
	House-to-house visit with MaaSupervisors	- House-to-house visit (invite household members to afternoon meeting) with TBA & VHW	Residence of every household especially with young children	3 hrs	- Social mobilisation to involve the whole community
	Record a short video	- Video the Alkalo & wife handwashing & reheating weaning-food to show at the village meeting later	Alkalo's residence	15 min	- Alkalo & wife have social status & their support motivates mothers -Engender a social norm
	Afternoon event	-TC's Drum/sing the six messages & pledging song while villagers arrive at meeting site - Opening prayers by the Imam (religious leader) lead prayers for the gathering (Gambian cultural norm) - Opening remark by the Alkalo - Introduction of project by PHO - 2 Drama (MaaChampion & Funtu) by TCs - Summary of six messages from the drama by PHO - Question & answer from village audience led by PHO - Pledge song by TCs - Play 'Choose soap' silent animation video [14] - Show video of Alkalo (washing hands with soap) & his wife (reheated weaning-food) translated live in local language - Announce MaaChampion competition by PHO - Invite mothers of children 6-24m to pledge to practise behaviours	Village "Bantaba" (a central place where villagers meets – usually under a large tree)	4 hrs	-Inform the community/provide instructions - Model or demonstrate behaviour - Engender all motivational drivers, particularly nurture & affiliation - Prompt identification with a role model - Prompt action through pledging - Set graded tasks through competitions - Target mothers for their pledge - Prompt intention formation - Assist memorisation by repetition of song & messages - Display of photos of pledged mothers for contingent reward

		- Give pledged mother's plastic sheets for covering surfaces to enable hygienic drying of utensils/pots on a clean surface - Take a group photo of pledged mothers for the honour board - Closing remark by PHO - More drumming & songs (motivational) - Print & display pledged mothers & Alkalo's photos on honour board at the Bantaba			
	Community volunteers training	- Train new assistant MaaSupervisors by village volunteers/trained MaaSupervisors, supervised by PHO	Village Bantaba	2 hrs	- Enable encouragement of mothers & competition success - Involve more community members to engender development of social norms
Day 2	Meeting the Alkalo	- Greet Alkalo as Day 1	Alkalo's residence	10 min	As Day 1
	Announce to the villagers	As Day 1	As Day 1	2 hrs	As Day 1
	House-to-house visit with Maa-Supervisors	- Engage MaaSupervisors with household visits & boost their confidence - Assess/encourage pledged mothers for progress to next stage	Residence of each pledged mother	3 hrs	- Prompt practice of key behaviours - Provide feedback - Prompt self-monitoring /review/community mobilisation
	Ad-hoc women or men meetings held separately in neighbour-hoods	- Glow germ demonstration - Explain 2 stories (MaaChampion & Funtu) on flipchart - Play silent animation video 'Choose soap' on iPad/laptop - Visit home of mothers with the MaaSupervisors to assess them for MaaChampion status	Neighbour-hoods	30 min	- Engender disgust through glow-germ: dirt on hands - Engender all motivational drivers – particularly nurture & affiliation through stories - Engage men & women to support mothers of young children - Prompt specific goal setting
Day	Meeting Alkalo	As Day 2	As Day 2	20 min	As Day 2
	Announce to the villagers	As Day 1	As Day 1	2 hrs	As Day 1
	House-to-house visit with MaaSupervisors	As Day 2 – additionally: - During household visits, video mothers who succeeded to became a MaaChampion to show at meetings	As Day 2	3 hrs	As Day 2 – additionally videoing to provide contingent reward
	Afternoon event	As Dayone & including the below: - Show animation video from India handwashing "SuperAmma" project with spontaneous translation[14]	As Day 1	4 hrs	As Day 1

3		- Show videos from mothers who succeeded to become MaaChampions - Take photo of new pledged mothers with their plastic sheets & of MaaChampion's with medals & displayed on honour boards (pledging & certification ceremonies)			
Day 4	Meeting Alkalo	As Day 2	As Day 2	20 min	As Day 2
	Announce to village	As Day 1	As Day 1	2 hrs	As Day 1
	House-to-house visit with MaaSupervisors	As Day 3	As Day 3	3 hrs	As Day 3
	Afternoon Event	As Day 1 including below: - Certification ceremony: Present medals for MaaChampions / MaaSupervisors with drumming - Group picture with all MaaChampions, MaaSawarr & MaaFamboos for the honour board - During village wide ceremony, erect a weaning-food hygiene board at the village entrance establishing the village as a "weaning-food hygiene" village with drumming/campaign songs & present village certificate to the Alkalo (Certification ceremony) - Give motivational advice on sustainability by Alkalo, MaaSupervisors,PHOs - Closing remark (emphasis on sustainability)	As Day 1	4 hrs	As Day One including below: - Create ownership of the project & self-monitoring to enable sustainability - A community sense of achievement, & pride commitment by MaaChampions - Inculcated motivational drivers - Encourage achievement of goals through the board as a reminder
Day 5	Meeting Alkalo	As Day 2	As Day 2	20 min	As Day 2
	Announce to the villagers	As Day 1	As Day 1	2 hrs	As Day 1
	House-to-house visit with MaaSupervisors	As Day 3	As Day 3	3 hrs	As Day 3
	Afternoon event	As Day 4 but not including erection of the village board or certification	As Day 4	4 hrs	As Day 4

TC= Traditional Communicator; PHO= Public Health Officer; VHW=Village Health Volunteer; TBA=Traditional Birth Attendant; UV= ultraviolet

Concepts/Tool	Target population	Details	Purpose
Competitions for mothers & MaaSupervisors			
Mother's Competitions #	Mother & children <5 yrs, but specifically 6-24m of age	3 stages: 1) mothers who learnt the 6 messages & pledged to practice the behaviours (MaaFamboo); 2) mothers who demonstrated a sustained practice of 6 messages (MaaSawaar); 3) mothers who did all the above & supported 2 other mother to become a MaaFamboo (MaaChampion)	To set graded tasks, provide general encouragement (contingent reward) for improved behaviour, prompt identification with a role model & by engaging community action to encourage a change of social norms
MaaSupervisors competitions #	MaaSupervisors	Older respected woman who must encourage mothers, (focus on a minimum of 10) of which 50% must achieve the MaaChampion status	
Performing arts for all village members			
Songs (at times combined with communal dancing) #	Mother of young children & all villagers attending meetings	*Campaign song*: Information about the 6-key messages & benefits of practices & specially explain the benefits of care & love in terms of a grateful child with a successful future *Pledged song*: Focused on nurture, disgust & purity to encourage mothers to pledge to carry out the practices *Welcome song:* A cultural greeting song to welcome & honour the Head of the Village & those present, with elements of messages added	To engage communities particularly mothers & to make it easy for mothers to learn messages form the songs
Stories (portrayed in drama, animation & flip charts) #		*Story 1:* Story of MaaChampion heard from her grown up child who is now a successful doctor, proudly telling the story to her family *Story 2:* Story of Funtu about how villagers rejected her & how her child suffered, while meeting the MaaChampion & following her advice made her popular & a good mother	To stimulate the motivational drivers help mothers understand & remember messages easily To communicate the messages in a graphically memorable & entertaining way To prompt identification with the role model (MaaChampion) & consequences of not following the 6-key messages
Drama #		*One Drama:* describing a day in the life of MaaChampion & Funtu	
Animations $		*Animation 1:* Choose soap.[14] Shows a hand touching faeces & then eating with & without washing with soap first *Animation 2:* SuperAmma.[14] Shows a similar story to MaaChampion, but in an Indian village, with reference to handwashing with soap in general rather than references to food hygiene	

Environmental cues for mothers			
Posters, danglers, & medals #	Mother of young children in the competition	All had 6-key intervention practices graphically written on them The mothers posters, dangler & medals were all displayed around the house & kitchen	To provide non-monetary incentives (contingent reward) for mothers To provide visual reminders of the 6-key messages in the kitchen, household
Plastic sheet		A 1.5x1.5 locally available sheet of plastic	To provide a visual reminders of the message about drying pots & utensils on a clean surface To facilitate this practice at the start of the programme when villagers do not have easy access to plastic sheets
Other Tools for team members or villagers			
Posters #	All village members	Had 6-key intervention practices graphically written on them	To remind & facilitate the mothers to perform the 6-key practices
Flipcharts #	Mother of young children & all villagers attending meetings	The 2 stories & key messages were described in three different flipcharts	Visual aids for telling the stories in men & women's discussion groups & to stimulate the motivational drivers For MaaSupervisors to use during their work
T-shirts for the intervention team	All village members	Bearing project logo & title of MaaChampion	To identify & formalise the intervention members
Project Banners	All village members	A piece of polythene presenting 6-key messages & a photo of the MaaChampion on it, displayed temporarily in each village before the afternoon events	To make villages aware of intervention events & villages people of the 6-key messages
Glow-germ #	Mother of young children & all villagers attending meetings	2 adults volunteer: Both rub the glow germ cream on their hands, one washes hands with soap & water, the other with only water; then they put hands under UV lamp to show 'glowing germs' on the hands that did not use soap	To use during the men & women's group discussions to engender the motivational drive for disgust & consequences of not using soap

TC= Traditional Communicator; PHO= Public Health Officer; VHW=Village Health Volunteer; TBA=Traditional Birth Attendant; UV= ultraviolet
$ tool adapted from SuperAmma India Handwashing study[14]
# tool adapted from Weaning-food Hygiene Nepal study[8]

Table 2 (above): Intervention tools & their application during the intervention

Table 3: Critical control points and corrective measures (practices) and handwashing motivational drivers that were targeted by our weaning-food hygiene intervention

Critical Control Points	**Corrective measures – behaviours the intervention aimed to improve**
Before food preparation	***1. Handwashing with water and soap before food preparation***
	2. Washing of pots and utensils before food preparation and drying on a clean (and cleanable) surface
During Cooking when hand becomes contaminated	***3. Handwashing with clean water and soap when contaminated during cooking***
Stored Food storage before feeding to the child	4. ***Reheating of pre-made food after storage before feeding***
Before feeding the child	***5. Handwashing with clean water and soap before feeding child (mother) or eating (child)***
Water ready for drinking by the child	***6. Boiling and cooling of water ready for drinking by child***
Evo-Eco model motivational drivers for handwashing behaviour change	**Definitions of motivational drivers**
Nurture	- ***the desire for a happy, thriving child***
Disgust	- ***the desire to avoid and remove contamination***
Affiliation	- ***the desire to fit in with what others in a reference group are doing***
Status	- ***the desire to have greater access to resources than others in the group***
Purity	- ***the desire to be favoured by God and to be holy***

Table 4: Thirty village/cluster baseline characteristics by study arms. (n=30)

Variables	Control n=15	Intervention n=15
Village population n	**5088**	**5219**
Village population median (IQR)	**255 [297-400]**	**306 [244 – 352]**
Households per village median (IQR)	**40 (30 - 60)**	**33 (26 - 49)**
Children aged < 5 years median (IQR)	**86 (71 - 111)**	**86 (77 - 99)**
Children aged 6-24 months median (IQR)	**39 (34 - 57)**	**43 (33 - 55)**
Major ethnic group in village n (%)		
Mandingo	3 (20)	5 (33.3)
Wolof	5 (33)	5 (33.3)
Fula	7 (47)	5 (33.3)
Main income of villages n (%)		
Farming	12 (80)	13 (87)
Farming & Business	3 (20)	2 (13)
Distance to nearest health facility*		
< 5 km	6 (40)	7 (56)
≥ 5 ≤ 10 km	5 (33)	4 (27)
> 10 km	4 (27)	4 (27)
Availability of school in the village n (%)		
No school	8 (53)	10 (67)
Primary	5 (33)	5 (33)
Primary & middle	2 (13)	0 (0)
Availability of village/community groups n (%)		
Village Development Committee	15 (100)	15 (100)
Water Sub-committee	11 (73)	7 (47)
Women's Group	13 (87)	15 (100)
Location of village		
North of river	7	7
South of river	8	8
Quartile of population size of villages		
1	3	3
2	4	4
3	4	4
4	4	4

*- this is the actual travel distance by mothers on food or transport and not the scaled map distance.

Table 5: Characteristics of mothers in the evaluation survey by intervention allocation.

Variables	Control n=300	Intervention n=300
Number of children alive for index mother (SD)	5.1(6.1)	6.0 (6.1)
Age group of mother		
<20 years	31 (10%)	27 (9%)
20-30 years	171 (57%)	186 (62%)
>30 years	97 (32%)	88 (29%)
Education level of mother		
None/illiterate	186 (62%)	177 (59%)
Other (Islamic, home etc)	51 (17%)	45 (15%)
Primary	30 (10%)	39 (13%)
Secondary or higher*	33 (11%)	39 (13%)
Ethnicity of mother		
Mandingo	46 (15%)	78 (26%)
Wolof	120 (41%)	96 (32%)
Fula	127 (43%)	118 (39%)
Other	3 (2%)	8 (3%)
Occupation of mother†		
Farmer	280 (93%)	275 (92%)
Other‡	20 (7%)	25 (8%)
Sex of index child		
Male	138 (46%)	146 (49%)
Female	162 (54%)	154 (51%)
Ethnicity of husband		
Mandingo	47 (16%)	82 (28%)
Wolof	119 (40%)	96 (33%)
Fula	126 (43%)	115 (39%)
Other	2 (1%)	0 (0%)
Structure of house		
Mud wall, corrugated roof	124 (43%)	121 (41%)
Cement wall, corrugated roof	32 (11%)	43 (15%)
Mud wall, thatched roof	134 (46%)	129 (44%)

Other	0 (0)	2 (1)
Belongings		
Land	282 (95%)	280 (94%)
Cattle	173 (58%)	178 (59%)
Goat	216 (73%)	216 (72%)
Mobile	253 (85%)	269 (90%)
Radio	191 (64%)	203 (68%)
Tap	4 (1%)	9 (3%)
Fridge	3 (1%)	8 (3%)
Source of water		
Covered well or tap	119 (40)	141 (48)
Open well or other open water sources	181 (60)	152 (52)
Sex of Index Child **Male**	156 (52%)	151 (50%)
Mean age (mths) of child (SD)	18 (7.9)	19 (7.6)
Reported diarrhoea by mother in past 7 days§	60 (20%)	82 (28%)
Reported ARI by mother in past 7 days¶	30 (10%)	30 (10%)

Values for the individual variables are numbers (%) unless otherwise stated. ARI=acute respiratory infection.

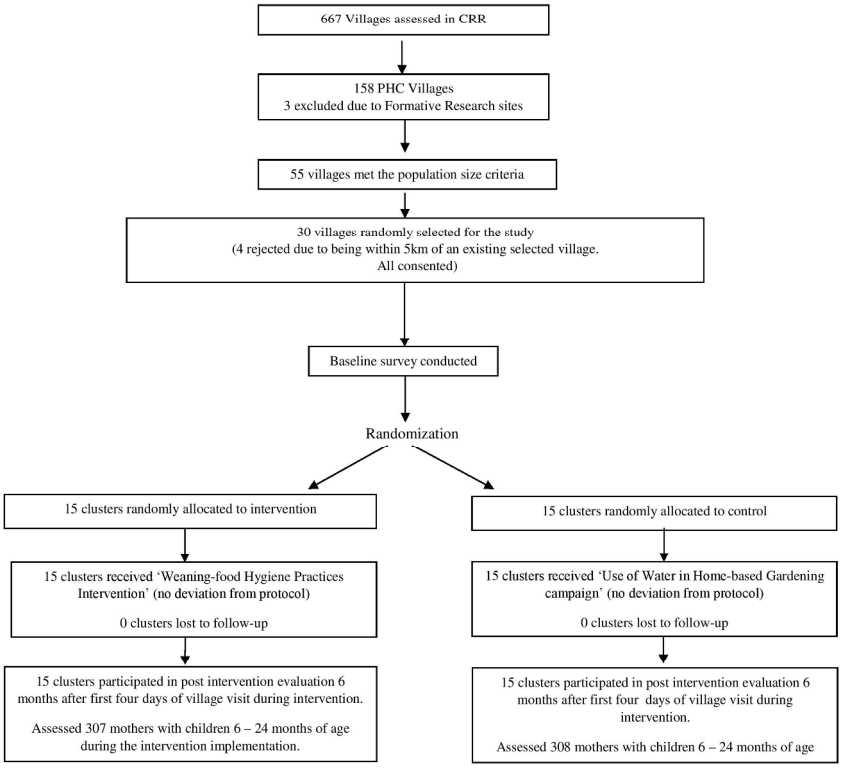
* Arabic/Islamic, senior secondary or college.

†All mothers were housewives, but had additional regular other work.

‡Trading, animal husbandry or civil servant.

§Defined as ≥ 3 watery stools in previous 24 h.

¶Defined as cough with difficulty breathing.



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On-line annex Supplementary file 1:

Trial Sample size: Observations during the formative research indicated that the proportion of events in which correct behaviour was displayed (i.e. practices of heating stored food, hand washing with soap before food preparation, during food preparation if contaminated, and before feeding the baby (measured the first time activity occurred)) was 17/150 (11.3%). As this was to be a cluster RCT, we assumed an intracluster correlation coefficient (ICC) of 0.04[14] between villages and a coefficient variation of cluster size 0.22. With a significance level of 5%, we aimed to detect a minimum of 25% absolute increase in behaviour in the intervention compared to the control arms with 95% power. As we were able to recruit 15 clusters per arm, a minimum of 12 mothers per cluster was required.[15] We aimed to recruit 20 mothers within each village at outcome evaluation to guard against loss of mothers during the eight hour observation by female fieldworkers during evaluation home visits. In a sensitivity analysis, assuming a larger ICC of 0.1, the power (84%) remained reasonable.

Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	3-4
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	6-7
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	7
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	7, 9, 10
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		**7**
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	8
	4b	Settings and locations where the data were collected		**7-8**
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	10-13
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	7

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		**7**
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	On-line annex
	7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		**10**
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	10
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	9

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		**10**
	11b	If relevant, description of the similarity of interventions		
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	NA
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		**NA**
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	14
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	14
Recruitment	14a	Dates defining the periods of recruitment and follow-up		**11**
	14b	Why the trial ended or was stopped		**NA**
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	31-32, 33-34

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	14
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	NA
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		**NA**
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		**NA**
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		**NA**
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		**17**
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	17
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		**NA**
Other information				
Registration	23	Registration number and		**21**

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	**Is the protocol**
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	**21**

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

REFERENCES

1 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

2 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.