Scaling Up Nurturing care, a Radio Intervention to Stimulate Early child development in Burkina Faso:

SUNRISE Cluster Randomised Control Trial (CRT)

V2.1 November 2021

General Information

Title	SUNRISE cluster randomised trial: Scaling Up Nurturing care, a Radio Intervention to Stimulate Early child development in Burkina Faso
Acronym	SUNRISE
Trial ID	ISRCTN ID: Pending
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Sponsor	LSHTM
Lead applicant	Prof Betty Kirkwood. London School of Hygiene & Tropical Medicine, betty.kirkwood@lshtm.ac.uk
Applicants (name, institution, contract information)	Mr Roy Head, Development Media International (DMI), roy@developmentmedia.net Dr Zelee Hill, University College London (UCL), z.hill@ucl.ac.uk Professor Pasco Fearon, UCL, p.fearon@ucl.ac.uk Dr Jolene Skordis-Worrall, UCL, j.skordis-worrall@ucl.ac.uk Mr Bassirou Kagone, DMI, Bassirou.Kagone@developmentmedia.net
Collaborators	Dr Bernadette Daelmans, Coordinator, Policy, Planning and Programmes, Department of Maternal, Newborn, Child and Adolescent Health (MCA), WHO Geneva. Dr Tarun Dua, Program Manager, Neurological Diseases and Neuroscience, Department of Mental Health and Substance Abuse, WHO Geneva.
Data collection Agency	Innovations for Poverty Action (IPA), Ouagadougou, Burkina Faso
Institutions	London School of Hygiene & Tropical Medicine (LSHTM), Development Media International (DMI), University College London (UCL) & Innovations for Poverty Action (IPA)
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Protocol version control

OLD VERSION	NEW VERSION	DATE (DD/MM/YY)	AMENDMENT	AMENDED BY
	V1	27/02/2021	NA	NA
	V2	05/11/2021	Listed below	Betty Kirkwood
	V2.1	23/11/2021	Listed below	Betty Kirkwood

Amendments incorporated in version 2:

1. Additional information/clarifications included in response to comments from sponsor.

2. Only changes to design: Home-IT score changed from primary to secondary outcome & FCI measures changed from 3-monthly to 6-monthly on advice of TSC/DMEC meeting in Sep 2021.
3. Section 3.3.2 on “Planned Formative Research” replaced by “New evidence from additional formative research” as this has now been completed.
4. Some editorial changes to improve clarity.

Amendments in version 2.1:

1. Added a new section (4.6.3) on informed consent.
2. Section 4.4: Added the stata command that will be used.
3. A few editorial changes.

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Scaling **U**p **N**urturing care, a **R**adio **I**ntervention to **S**timulate **E**arly child development in Burkina Faso: SUNRISE Cluster Randomised Trial (CRT)

ABSTRACT

SUNRISE aims to develop and evaluate a radio campaign to promote nurturing care behaviours in the first 3 years of life, particularly responsive parenting and providing opportunities for early learning. The campaign will run for 3 years and comprise: 60-second radio 'spots' including scripted dramas and modelling of responsive parent-child interactions broadcast 10 times a day in 6 languages in weekly cycles; plus long format programs 2-3 times a week, incorporating longer dramas, real life testimonials and practical 'how to' advice, with space for listeners to call in, express opinions and ask questions. The campaign will run for 3 years with its impact on early child development (ECD) evaluated using a cluster RCT design.

BACKGROUND

Almost 250 million children under the age of five years in low and middle income countries are at high risk of not reaching their developmental potential (1). Many are likely to do poorly in school and subsequently as adults will have low incomes, high fertility, and provide poor health care, nutrition, and stimulation to their own children, thus contributing to the intergenerational transmission of disadvantage (2). The loss of human potential that the above statistics represent is associated with more than a 20% deficit in adult income, with implications for national development (3,4). Risk factors are particularly high in Sub-Saharan Africa with 66% of children under 5 years of age at risk of not developing to their full potential (2); and 44% failing to meet basic cognitive or socio-emotional milestones by 3-4 years of age (5).

Early child development has risen exponentially in policy importance over the last 10 years (6). It is embedded in the Sustainable Development Goals (7), and is explicit in the new vision of the UN Secretary-General's Global Strategy for Women's, Children's and Adolescents' Health 2016–2030 with the objectives of Survive, Thrive and Transform (8). Several global institutions, including UNICEF, the World Bank, UNESCO and the World Health Organization have prioritized ECD in their work programmes (9). This commitment culminated in the launch of the Nurturing Care Framework (NCF) during the 71st World Health Assembly in 2018 (10). The NCF focuses on the critical period from pregnancy to age three, when neuroplasticity is at its peak and large numbers of synaptic connections are made in response to interactions with the environment, particularly with caregivers, which modify how genes are expressed (11,12). Brain development in this period provides the foundation for learning and for physical and mental health throughout the life course (11,13–15)

Current intervention approaches have focused on community health workers (CHWs) or para-professionals promoting responsive care and early learning by providing information, performance (demonstration or coaching) and materials such as low cost toys and picture books to families (16). There is strong evidence from proof of principle trials that these interventions can improve child development outcomes, and can compensate for developmental delays due to risks such as poverty and malnutrition (16,17). Despite the existence of proven interventions, and growing momentum and funding for action there is little rigorous evaluation of interventions beyond proof of principle trials (2,6), and few programs have gone to scale (4). Most of the proof of principle trials tested labour-intensive interventions (16), and the potential challenges of delivering these models at scale is well recognized (13,16,18–20). Determining who can effectively deliver ECD interventions, and whether interventions can be taken to scale with sufficient integrity and fidelity are key research priorities (21).

Given the feasibility issues with current approaches, testing a more feasible delivery model has the potential to make a major contribution to the field at a time that is pivotal for policy makers. To date there has been little focus on trials beyond face to face parenting approaches focusing on the mother-child dyad, despite calls to engage the wider family (16,22) and to utilize mass media (10). Mass media is a promising approach for nurturing care interventions and can have a cost effective impact at scale as demonstrated by a recent cluster RCT of a radio campaign targeting child survival in rural Burkina Faso, (23–25). Unlike face-to-face interventions mass media can deliver messages directly to millions of people, at a standardized quality, several times a day. Furthermore, radio campaigns can reach all

caregivers and stakeholders in the community and so have the potential to shift social norms and create an enabling environment for behaviour change.

SUNRISE aims to develop and evaluate a similar radio campaign promoting nurturing care behaviours, in order to explore whether mass media campaigns can accelerate progress towards achieving the ECD targets of the sustainable development goals.
This will be carried out in Burkina Faso, as it has a uniquely localised, radio-dominated media environment, with very low national radio or TV penetration outside urban centres. This makes it an ideal setting to use a cluster randomised trial design to evaluate the impact; the SUNRISE radio campaign will be broadcast through randomly-selected local FM radio stations without the risk of this 'leaking' into areas covered by the local radio stations selected as controls, and without losing the aggregate power of the media. Working in Burkina Faso will also add to the small number of ECD studies conducted in Sub-Saharan Africa (26–29) .

METHODS

1. Aims & Objectives

More specifically, SUNRISE aims to develop and evaluate a radio campaign to promote nurturing care behaviours in the first 3 years of life, particularly responsive parenting and providing opportunities for early learning. These are the two components of the nurturing care roadmap which promote physical, social, emotional and cognitive development by ensuring: 1) Children have secure emotional attachments with caregivers; 2) Caregivers are sensitive and responsive to the child's cues; 3) Caregiver-child interactions are enjoyable and stimulating; 4) Communication is bi-directional; 5) Communication is language rich and 6) There are opportunities for play and early learning (10).

The specific objectives are:

1. To design and implement a nurturing care radio campaign in Burkina Faso.
2. To evaluate the impact on ECD outcomes using a cluster randomised trial (CRT) design.
3. To carry out a detailed process evaluation.
4. To cost the delivery of the campaign and estimate the cost-effectiveness when delivered at scale, compared to other approaches.
5. To create ECD communications capacity in Burkina Faso, enabling a national scale-up.
6. To develop a roadmap to advise governments in low and middle-income countries on media campaigns for ECD.

2. Overview of SUNRISE CRT

The SUNRISE campaign will comprise: 60-second radio 'spots' including scripted dramas and modelling of responsive parent-child interactions broadcast 10 times a day in 6 languages in weekly cycles; plus long format programs 2-3 times a week, incorporating longer dramas, real life testimonials and practical 'how to' advice, with space for listeners to call in, express opinions and ask questions. The campaign will run for 3 years with its impact on early child

development (ECD) evaluated using a cluster RCT design; the clusters will be defined by the broadcast reach of local radio stations.

Fifteen clusters have been identified from across Burkina Faso which satisfy the following conditions: there are at most two dominant radio stations and no discernible broadcast from stations in neighbouring clusters; they are not based in the large cities of Ouagadougou or Bobo-Dioulassou; and they are not subject to any security risk. Eight will be randomised to broadcast the SUNRISE campaign and 7 to act as controls. One hundred and twenty-five babies from each cluster who are born after the campaign has been running for 3 months will be enrolled into the trial and have six-monthly ECD assessments conducted throughout the campaign. All trial procedures will be carried out in full compliance with Good Clinical Practice (GCP) guidelines.

3. The SUNRISE Radio Campaign

The SUNRISE campaign builds on the saturation+ approach successfully used in DMI's previous child survival campaign in Burkina Faso promoting family health behaviour and care seeking for sick children. This approach is based on:

1. Saturation: Broadcasting approximately 10 times per day
2. Science-informed content: Using a variety of evidence-based methods and behaviour change theories to inform campaign design
3. Stories: Using innovative creative techniques within both spots and interactive programming to maximise audience engagement

The SUNRISE campaign will follow DMI's established intervention approach & implementation schedule with:

1. 60-second radio spots, tailored to increase awareness, knowledge, motivation, skills and opportunity regarding the target behaviours. These spots are highly cost-effective as they are short, entertaining and can be repeated multiple times. Over 100 different spots will be produced. We will achieve population saturation of messaging within cluster sites by broadcasting these 60 second spots 10 times every day in each of 6 languages for a week. This weekly cycle will continue for three years. 60-second radio 'spots' broadcast in weekly cycles, 10 times a day, and in 6 languages (i.e. one or two spots plays intensely for a week and then replaced with new spots for the following week and so on). These will include scripted dramas and modelling of responsive parent-child interactions.
2. Long format 60-minute programmes broadcast 2-3 times a week, incorporating longer dramas, real life testimonials and practical 'how to' advice, with space for listeners to call in, express opinions and uncertainties and ask questions. The call-in component enables listeners to recognise voices on air as representative of their own.

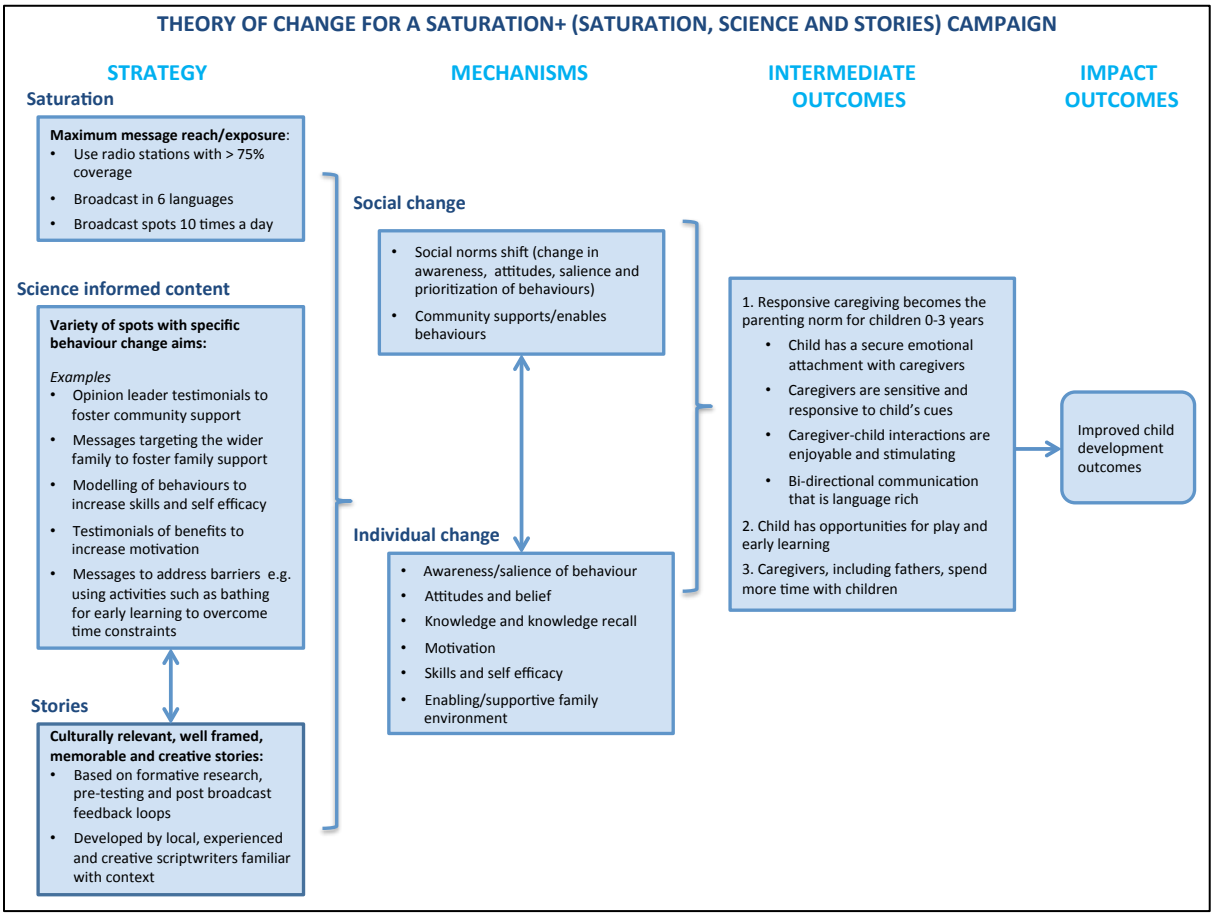
The ECD content and approach will be informed by:

- The SUNRISE theory of change (Section 3.1): Which highlights the mechanisms through which SUNRISE will work with 'spots' focusing on raising awareness of the behaviours, shifting attitudes/social norms, providing families with the skills and motivation required to adopt behaviours, and garnering community and family support for behaviours.

- The SUNRISE curriculum (Section 3.2): This will determine the specific behaviours we would like caregivers to adopt, how we will approach age specific messages and the message schedule.
- Formative research (Section 3.3): This aims to understand current practices and the potential for behaviour change, key barriers to adopting behaviours and how these could be mitigated against, and how we can best communicate responsivity over the radio.
- Lessons learned from: developing parenting videos tested as part of an effectiveness RCT in Jamaica (30) and the child survival radio campaign RCT in Burkina Faso (24)

3.1 Theory of change

Figure 1: Theory of Change for the SUNRISE Radio Campaign



The theory of change for the campaign is shown in Figure 1 with the Saturation+ approach triggering social and individual change through mechanisms including: Shifting social norms, fostering a supportive community and family environment, increasing awareness, and changing attitudes, beliefs, knowledge, motivation, and skills. We hypothesize that these changes will lead to improved responsive caregiving, greater opportunities for play and early learning and caregivers (including fathers) spending more time with their young children. These, in turn, are expected to improve child development outcomes.

3.2 SUNRISE Curriculum Development: A systematic common elements approach

There is currently no agreed upon curriculum for ECD interventions and numerous programmes exist that have both similarities and differences from each other in terms of their content. As part of our preparatory work to translate ECD intervention principles into radio campaign content we therefore undertook a systematic review of reviews to identify ECD programmes with good evidence of impact on developmental outcomes in low/middle income countries and conducted detailed systematic coding of the intervention manuals of all effective programmes, using an approach developed by Chorpita, Daleiden & Weisz (31). The intervention elements identified by this process that were common to the majority of effective interventions consisted of the following targets and their respective activities, materials and messages:

1. Responsiveness (including two-way interaction, scaffolding)
2. Opportunities for early learning (e.g., making, providing toys, building responsive interactions into routines)
3. Play, exploration (including provision of toys, puzzles, singing, games, shared book reading)
4. Love, comfort and attachment
5. Communication (including pointing, naming, speaking to, and with, the child, stimulating linguistic environment)
6. Praise [including broader parenting and harsh discipline]
7. Noticing, observing, empathy, mentalising
8. Family and community engagement

We have developed a curriculum matrix based on these elements that will provide a structure for ensuring the radio campaign has appropriate coverage of the primary evidence-based intervention foci, cross-referenced by *child age*, intended *audience*, and the *behaviour change principles* contained in our theory of change (increasing motivation, knowledge/skills and opportunity). As well as supporting the work of the creative team in developing programme contents, we are also developing monitoring tools based on this structure that will allow us to systematically capture how the intervention was delivered during the campaign.

3.3 Formative research

Knowledge of radio listening patterns, station reach, what languages to broadcast in, and approaches that can be effectively used on the radio will be complemented by formative research to develop messages and approaches that are feasible, well targeted, and appropriate for the environmental and cultural context. This will be informed by the COM-B behaviour change model to ensure we develop an understanding of the behaviours in relation to capabilities, opportunities and motivation (32).

3.3.1 Existing evidence on nurturing care behaviours in Burkina Faso

In 2018 we completed mixed method research to inform the development of the SUNRISE proposal. We conducted a household survey with 962 mothers of children 0-3 years of age residing in 130 rural villages (33). We used an adapted MICS instrument to collect data on current caregiving practices. We found that:

1. Mothers are the main caretakers of young children and engaged most in ECD-related activities at all ages.
2. Few families engaged in ECD activities with children 0-5 months. Singing had the highest coverage with 35% of families engaging in this with children 0-5 months in the last 3 days.
3. Engagement in singing and playing increased to moderate levels among older children, with around 70% of families engaging in these activities in the last 3 days with children 2 years of age.
4. Engagement in other ECD activities remained low among older children, for example engaging in reading/looking at pictures with the child in the last 3 days was 6% for 3 year olds, counting or drawing activities 19%, showing/naming objects 24% and chatting with the child 33%.
5. Reasons for not engaging in these activities included lack of literacy, lack of books and toys or playthings and a belief that the child was too young.

We also conducted qualitative formative research with the prominent ethnic group, the Mossi, in two rural villages (33). This consisted of 12 focus-group-discussions (FGDs) with mothers, fathers and grandmothers with children or grandchildren aged 0-3 years of age. We explored child development expectations, caregiving practices, and the acceptability, motivators and obstacles to responsive caregiving and learning. During the FGDs we played radio spots on talking, playing and praising, and asked participants to try the behaviours at home. We held repeat focus groups a week later to discuss their experiences. We found that:

1. Behaviours and beliefs need to change as interactions are mainly didactic and instructive, with few opportunities for learning. Small children are not felt to be able to learn through interaction, but rather through instruction and repetition with toys given to keep children happy and occupied.
2. The promoted behaviours were acceptable and enjoyable and all participants tried them. Many participants reported positive changes in their children and found the engagement personally motivating and rewarding.
3. Targeting the broader family is acceptable, e.g. fathers play a limited role in childcare as they are seen as providers rather than carers, but were excited to interact with their children, reporting tangible changes in their relationship with their children after trying the behaviours.
4. The potential to improve school attainment and make the child happy was particularly motivating. Families also wanted children to be socialized to become upstanding members of the community ('good citizens')
5. The main obstacles were:
    a. Time constraints particularly during the agricultural season
    b. Lack of knowledge of the importance of caregiver behaviours
    c. A belief that the child's character is fixed and 'emerges' as they grow
    d. Moving caregivers beyond didactic interactions that teach a child a 'skill'
    e. A fear of spoiling the child through praise and promoting 'individualism' which is inconsistent with community values

3.3.2 New evidence from additional formative research

Our pre-existing formative research data came from only one ethnic group. To get a clearer idea of the diversity of experiences and perspectives the formative research team at UCL conducted additional formative research in early 2021 in two other ethnicities, following ethical approval from both UCL and the Burkina Faso Ministry of Health.

The objectives were to determine:

1. How caregivers currently interact with young children and how young children currently spend their day
2. The cultural norms around early child development and parenting
3. Parents' common aspirations for children and for their future
4. The acceptability of responsive caregiving activities to caregivers of young children
5. What motivates caregivers to engage in responsive caregiving and early learning activities, and what obstacles do they face?
6. The language used by caregivers to describe their interactions with their young children, including young children's early learning

Data were collected in four villages total, two each in Balé Province in the south of the country and Boulgou Province in the east, where ethnic groups other than the Mossi are dominant, that were typical of the area and safe. In-depth interviews (IDIs), focus group discussions (FGDs) and video observations with caregivers of children aged 0-3 years were carried out in each village. Table 1 details the number of participants per research activity. Respondents were purposively selected to ensure a range of children's ages but ensuring that caregivers of children less than 1 year were adequately represented.

Table 1. Participants per formative research activity, 2021 data collection

Research Activity	Participant group	Total number of participants or focus groups
1. Individual in-depth interviews	Mothers	n=16
	Fathers	n=16
2. Focus Group Discussions*	Mothers	n=8
	Fathers	n=8
	Grandmothers	n=8
3. Video observations of caregiver/child interactions	Mothers	n=8
	Fathers	n=8
4. Video observation follow up interviews	Mothers	n=8
	Fathers	n=8

*Total number of FGDs includes two rounds of discussions with each of 4 groups of participants

In-depth interviews focused on understanding current caregiver behaviors in relation to interactions with children, how children currently spend their day, and caregivers' perceptions of how young children learn.

Focus group discussions were carried out with mothers, fathers and grandmothers in two rounds. The first FGD explored social norms around early child learning and caregivers' daily engagement with children aged 0-3 years. Participants then listened to four pre-recorded radio spots (in local languages) explaining the benefits of ECD interactions and encouraging caregivers to engage with their children through different activities that emphasized communication, play or praise. Participants were asked to react to the content of the radio spots and to try at least one of the activities mentioned in the spots at home with their child or grandchild over the following days. After about a week, the same participants were reconvened to share and discuss their experiences implementing the suggested ECD activities with their young child. Participants were encouraged to attend the follow up discussion even if they were not able to engage in any ECD activities with their child as the second FGDs focused on challenges or barriers participants faced in trying to integrate ECD activities into their daily routines.

Video observations: A number of mothers and fathers who participated in IDIs were also invited to participate in video observations of their interactions with their young children. Video observations gave insight into the types and quality of parent interactions with their young children. Caregivers were filmed performing a set of age-appropriate activities with their children such as eating, playing, reading a book or helping with a household chore. Video recordings were reviewed by a child psychologist who identified key segments of the recordings and formulated structured interview guides for data collectors. A few days after the initial observation, these selected segments of the recordings were played back to parents and data collectors posed questions from the structured guide. For example, parents were asked to describe what they intended in the interaction, their reflections on the child's behaviour and response, and their wider understanding of the meaning and associated norms related to the child's and their behaviour.

Analysis was completed using NVivo qualitative analysis software (released March 2020). Initial code books were developed for each research activity by a French-speaking researcher based on the semi-structured guides and research aims. A selection of transcripts were double coded at the beginning of analysis to further develop code books. The team held regular meetings to discuss and refine code books, clarify questions and translations, and ensure continuity in approach to coding. Codes were modified and added by all team members as themes emerged throughout analysis. The non- Francophone team member translated French transcripts into English using Google Translate for analysis.

Main findings from this research are:

1. Caregivers already subscribe to and are implementing a number of beliefs and practices conducive to increasing the quality and frequency of responsive caregiver-child interactions.
2. No differences in practices or perceptions were observed between ethnicities.
3. Caregivers were receptive to the benefits of practising ECD behaviours with their young children.
4. Participants who implemented ECD behaviours in their homes responded positively to engaging in new behaviours and felt that their children also enjoyed these interactions.
5. Children's almost immediate reactions to engaged interactions demonstrated their receptivity to the behaviours and greatly motivated caregivers.
6. Overall, suggested behaviours did not go against socio-cultural norms.

7. Participants were joyful while playing with their children, which could be a significant motivator for caregivers to increase, improve or continue responsive interactions and play.
8. After integrating behaviors into their daily routines, a number of caregivers found that many activities did not take that much time and could be done in parallel with already existing daily routines.
9. Some caregivers believed that young children could not learn or understand language which might discourage caregivers from engaging in responsive interactions, especially with babies.
10. Some participants received negative comments from others for engaging with their young children but no one was deterred.

3.4 ECD workshops for scriptwriters

We have run three ECD workshops with DMI scriptwriters in Burkina Faso to develop a team ethos around our shared objectives and values regarding ECD, to consider issues of equity, culture and tradition as they pertain to ECD concepts, and to build a shared language and common understanding of how ECD practice can be translated into radio for the SUNRISE project. Central topics have included reviewing the fundamental concepts underpinning ECD and the nurturing care framework, in-depth discussion of the more subtle and potentially challenging concepts to convey on radio, particularly responsive caregiving, and cultural barriers to acceptance of some ECD practices (praise, discipline, and individualist versus collectivist notions of childcare). These workshops will continue in parallel with the formative research so that this learning is incorporated in the team's thinking about content development for the radio campaign.

3.5 Message briefs

For each key behaviour in the curriculum, we will synthesize findings from the strands described above into a 1-page message brief. These briefs make the research more accessible to the script writing team and bridges the gap between research and creativity. Our team of scriptwriters will use these message briefs to write approx. 60 dramatic scripts and long format content, which will go through a validation process involving creative staff in both Burkina Faso and London. The best scripts are then produced and pretested in multiple languages using FGDs to test for clarity, popularity, and understanding. The final spots and long format content will then be selected and distributed for broadcast.

Post broadcast feedback will be obtained through periodic focus group discussions (FGDs) to find out whether people have heard and understood the campaign messages, their reaction to them and whether there are any remaining obstacles to behaviour change. Spots and long format content are then revised based on these findings.

4. SUNRISE Cluster Randomised Trial (CRT)

4.1 Trial clusters

The trial clusters are defined by the broadcast reach of local radio stations. Eligible clusters for the trial were identified as follows. First 23 potential clusters in areas of Burkina Faso where there is no security risk were identified by modelling the reach and signal strength of local radio stations based on tower location, antenna characteristics, and terrain features. A

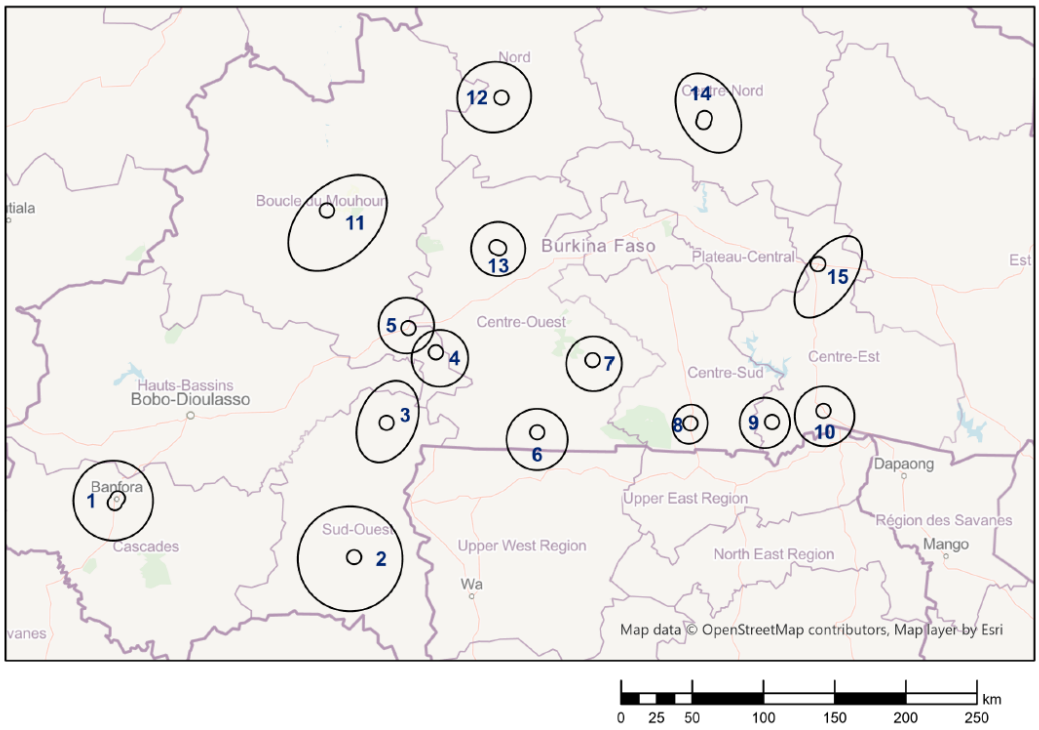
media survey was then carried out to check the radio stations listened to in each of these clusters.

This resulted in 15 clusters which satisfy the following conditions: there are at most two dominant radio stations within the cluster; there is no discernible broadcast from stations in neighbouring clusters; they are not based in the large cities of Ouagadougou or Bobo-Dioulassou; and they are not subject to any security risk. The clusters and their radio station(s) are detailed in Table 2 and their locations are shown in Figure 2.

Table 2: Clusters with their Main Town & Local Radio Stations

Cluster	Town	Local Radio Station(s)
1	Banfora	Radio Munyu
2	Gaoua	Radio RTB2 Sud-Ouest
3	Dano	Radio Manivelle de Dano
4	Poura	Radio Poura
5	Boromo	Radio La Voix des Bales
6	Leo	Radio Tampani
7	Sapouy	Radio Loudon
8	Po	Radio Goulou
9	Zabre	Radio Paglayiri
10	Bittou	Radio Zekoula
11	Dedougou	Radio Salaki
12	Gourcy	Radio Savane FM Nord; Radio Unite, Gourcy
13	Koudougou	Radio Palabre; La Voix du Sanguier
14	Kaya	Kaya FM; Radio Manegda
15	Pouytenga	Radio Pognere

Figure 2: Location of clusters



4.2 Mapping evaluation areas & Mobilising communities

Trial participants will be recruited from an evaluation area within each cluster that is close to the radio station(s), has a high signal strength confirmed by a motorbike survey and likely to have a high listenership based on the media survey. The following will be excluded from the area: towns, villages within 5 Km of towns, villages already on the national electricity grid and villages with populations of 5000 or more as they are likely to be a priority for the national electrification programme. These exclusions have been chosen to maximise the local radio station(s) as the main communication channel, with minimal audiences lost to television. The boundaries of the evaluation area will be defined such that they cover populations of 10-15,000 after these exclusions.

All households will be mapped using GPS coordinates, and household numbers allocated. This will be carried out by a team of 15 fieldworkers (FWs; 1/cluster), supported by 5 field supervisors. Before starting they will arrange meetings with the village elders, explain the purposes of the study and seek permission to proceed.

4.3 Baseline survey

4.3.1 Inclusion criteria

All mothers with a child/children aged less than 3 years will be eligible to be included in the baseline survey.

4.3.2 Exclusion criteria

Mothers who are visiting or are only temporary residents in the village ie. mothers who do not expect to be resident for the next 6 months.

4.3.3 Data collection

A baseline survey will be carried out before the start of the campaign. Fieldworkers will explain the study using information sheets in the relevant local languages and ask for consent to collect data from all eligible mothers with a child/children aged less than 3 years. Data will be collected on tablets and will comprise socio-demographic and socio-economic factors; parental education levels and literacy; and radio ownership and listening patterns. In addition, the FWs will administer the following to mothers of children aged 2 years:

- the short form of the Caregiver Reported Early Development Instruments (CREDI (34)) which is designed to serve as a population-level measure of ECD for children from birth to age three, and which has 20 questions primarily focused on milestones and behaviours that are easy for caregivers to understand, observe, and describe.
- The Family Care Indicators (FCI, (35)) survey developed by UNICEF to assess key caregiving/family home environment variables considered critical for early child development. This has been used very extensively, including in the global MICS surveys (36).

Data from the baseline will be used to:

1. Inform the content of the SUNRISE radio campaign through: Understanding gaps in responsive parenting, provision of early learning opportunities and overall ECD status; Provision of detailed radio listenership data including the stations families listen to, the duration and timing during the day when they listen to radio, and exposure to specific radio programs.
2. Provide a sampling frame for the surveillance system of 3-monthly household visits that will be used to recruit trial participants and conduct ECD assessments with GIS maps of households of households within the EAs. These maps will be used to develop detailed field visit schedules for field workers; create day and week work groups based on optimal workload distribution and geographical proximity of households to ensure that all eligible families are visited on schedule at regular intervals.
3. Carry out the restricted randomization (see section 4.4 below).

4.4 Randomisation of clusters

The SUNRISE campaign will be broadcast by the local radio stations in eight of the clusters chosen at random to be in the intervention group; the other 7 clusters will be in the control group and their radio stations will continue to broadcast as normal. This will be carried out using restricted randomization to ensure that the intervention and control clusters are balanced at baseline with respect to radio exposure and predictors of ECD outcomes as follows:

- Mean CREDI z-score; difference between intervention and control groups to be a maximum of 0.1.
- Mean % key FCI behaviours followed by mothers; difference between intervention and control groups to be a maximum of 10%.
- % mothers listening to the radio in the last week; difference between intervention and control groups to be a maximum of 10%.
- % mothers who are literate; difference between intervention and control groups to be a maximum of 10%.

The restricted randomization will be carried out by the independent trial statistician using the cvcrand command[1] in Stata. This performs covariate-constrained randomisation which is suitable for cluster randomised trials with a small number of clusters. The 20% most balanced allocation schemes using the four variables described above will be generated. This subset will then be checked to ensure that it is not a biased selection by checking for anomalies in the frequencies of co-allocations of pairs of clusters. If bias happens, the restricted randomisation will be repeated using the CREDI criteria plus 2 of the other three. One allocation scheme will then be selected at random from the final restricted randomisation results and shared with the campaign team but not with the trial evaluation team.

4.5 Interventions

4.5.1 SUNRISE clusters

All caregivers and the children they care for will have the potential to benefit from the SUNRISE radio campaign broadcast on their local radio stations which will be promoting responsive caregiving and providing opportunities for early learning to support child development during the first three years of life. They may also benefit from any other programmes broadcast concerning maternal, newborn and child health and wellbeing as well as from the routine maternal and child health services currently available.

4.5.2 Control clusters

Radio stations in the control clusters will continue to broadcast as normal. Caregivers and the children they care for may benefit from any programmes broadcast concerning maternal, newborn and child health and wellbeing as well as from the routine maternal and child health services currently available.

4.6 Trial Participants

The first 125 eligible children born in each cluster after the campaign has been running for three months will be enrolled together with their families. They will be identified through 3-monthly surveillance visits to all compounds identified at baseline; it is expected that recruitment will be achieved within a 6-month period. They will form the **trial cohort** and be followed 3-monthly until the end of the radio campaign. Its impact on ECD nurturing care behaviours and ECD outcomes in the first 3 years of life will be evaluated.

Everyone with access to a radio in the intervention clusters can potentially hear the campaign messages and long programmes. The selection of mothers for the trial cohort to evaluate the impact of the campaign has been specifically chosen to ensure their maximum potential exposure to the SUNRISE radio campaign in the intervention clusters as this will be broadcast during their last trimester of pregnancy until the final ECD outcome assessment of their children.

4.6.1 Inclusion criteria

Live newborns with a birth date at least 3months following the launch of the SUNRISE radio campaign will be eligible to be enrolled into the trial.

[1] https://journals.sagepub.com/doi/10.1177/1536867X1801800204

4.6.2 Exclusion criteria

Children with major infant congenital defects, children not living with their mother, and children with mothers who are not capable of participating in assessments.

4.6.3 Informed consent

Participants will be approached and recruited from their homes by the trained fieldworkers, who will explain the study by reading an information sheet translated into the local languages of the 15 clusters in the trial. Where a local language does not have a commonly used written format, the information sheet will be written in French and translated orally into the local language by the interviewers, as practised during the training sessions. All translations will be validated using back translation plus pilot testing.

The information sheets include guidance on how information will be kept secure and confidential and the limits of confidentiality during home visits. Participants will be made aware that their decision to participate will not in any way impact their access to existing health services that they may already be accessing. After sharing this information, participants will have the opportunity to ask questions and their understanding will be verified before consent is requested.

If they are happy with the answers they have received and agree to take part, participants will complete a consent form, with their agreement to participate indicated by YES responses to all key aspects of the study followed by a signature on the consent forms, which the fieldworker will also need to sign. Consent will cover recruitment and the 11 follow-up 3-monthly visits. Separate, additional consent processes will be undertaken at the 18-20 month visit in order to obtain consent for video recording of parent-child interactions and at the 30-32 month (final) visit, when mothers will be asked to consent for their child to take part in a developmental assessment.

Signed consent forms will be kept by the mothers; the fieldworkers will take photos of these on their tablets.

4.6.4 Voluntary participation and right to refuse or withdraw

FWs will explain to mothers that their participation in this research is entirely voluntary. They do not have to take part if they do not wish to do so. They may also stop participating at any time they choose. They do not need to explain their reasons for not taking part but it would be helpful if they were able to give us some information about your decision. Whether they choose to participate or not, the mother and her baby will still receive the same care and attention from health centres in their area.

4.7 Schedule of assessments

The trial will be supported by a ***surveillance system*** with regular 3-monthly visits by the cluster fieldworker (FW) to all households. These visits will be used to recruit the trial participants, maximize their follow-up during the trial and collect a variety of data on ECD behaviours and outcomes as well as process evaluation data on radio listening patterns, according to the schedule shown in Table 3.

Table 3: Schedule of visits and assessments, by age

Visit	1	2	3	4	5	6	7	8	9	10	11
Age (m)	0-2	3-5	6-8	9-11	12-14	15-17	18-20	21-23	24-26	27-29	30-32
Recruitment	X										
Radio Coverage	X	X	X	X	X	X	X	X	X	X	X
ECD Knowledge	X						X				X
ECD Behaviour Assessments											
FCI			X		X		X		X		X
HOME-IT							X				
Observed responsiveness (NICHD)							X				
ECD Outcome Assessments											
CREDI-LF			X		X		X		X		X
CDI			X		X		X		X		X
MDAT (or GSED-LF)											X

Key:	Primary Outcome	X
	Secondary Outcome	X

The assessments include:

- **Radio coverage:** Data will be collected at every 3 monthly visit with questions related to listenership in the past week and child health advice heard on the radio.
- **ECD Knowledge** will be assessed using a subset of questions from the Knowledge of Infant Development Inventory (KIDI, 37) which measures factual knowledge of parental practices, child development processes and norms of behaviour for children 0-3 years of age. It is appropriate for use with persons of limited education and is considered to be culturally neutral. It will be administered at recruitment and again when the child is age 18029m and 30-32m..
- The **Family Care Indicators** (FCI, 35) survey was developed by UNICEF to assess key caregiving/family home environment variables considered critical for early child development. This has been used very extensively, including in the global MICS surveys. It will be administered 6-monthly starting when the child is age 6-8m.
- The **HOME-IT inventory** (Home Observation for Measurement of the Environment, Infants & Toddler version) provides a comprehensive assessment of the family environment, including the provision and variety of stimulating play materials, the organization of the physical environment, and levels of parental involvement, responsivity and acceptance of the child's behavior. It will be administered when the child is age 18-20m.

- **Responsiveness** will be directly observed when the child is age 18-20m. Mothers will be video recorded carrying out a set of interactive tasks in which the child is introduced to a series of novel toys; this will last about 15 minutes. The videos will be independently coded, blind to whether the mother is in an intervention or control cluster, using the **National Institute of Child Health and Human Development (NICHD)** sensitivity scales, which assess "a parent's accuracy in perceiving and interpreting their infant's cues and their ability to react in a timely and appropriate manner".
- The long form (LF, 45 items) of the **Caregiver Reported Early Development Index** (CREDI, 34) will be administered 6-monthly starting when the child is age 6-8m. It is a developmental screening instrument designed specifically for large-scale surveys and evaluations for children aged zero to three years. It relies only on parental reporting and assesses 5 domains of early developmental milestones and behaviours, namely Motor, Language, Cognitive, Socio-Emotional and Mental Health, tailored to the child's age.
- The **Communicative Development Inventories** (**CDI)** will be administered 6-monthly starting when the child is age 6-8m. It is one of the most widely used and well-validated tools for assessing early language development and is available in many languages. The Words and Gestures short form (Level I) will be used for assessments up to including age 18-20m. This is a parent-reported checklist of early communication and receptive language, comprised of an 89-word vocabulary checklist with separate columns for comprehension and production. The Words and Sentences short form (Level II) of the CDI will be used at later ages. These measures contain a 100-word productive vocabulary checklist and a question about combining words.
- The **Malawi Developmental Assessment Tool** (MDAT, 38) will be administered at the final visit when the child is age 30-32m. This is a well validated in-person developmental assessment conducted by trained fieldworkers, that has been specifically designed and adapted to be appropriate in low resource settings and for a wide range of cultures and contexts. It was based on pre-existing well established developmental assessments, including the Denver Developmental Screening Test and the Griffiths Test, supplemented by new items designed to be relatively culture- and context-free indicators of early child development. It consists of 136 test items, with 34 items covering each of the 4 developmental domains of gross and fine motor development, language and social development. A total norm-referenced z-score can be computed as an overall index of child development. The tool shows excellent inter-rater reliability and good sensitivity and specificity for identifying children with developmental disability/delays. The MDAT has been validated in several sub-Saharan African counties including Burkina Faso.
- The **Global Scales of Early Development – Long Form (GSED-LF)** is a recently devised standardised developmental assessment, drawing on evidence and existing tools (including the MDAT), for use in the programme evaluation of ECD interventions. It consists of 158 test items covering motor, cognitive, language, social, and socio-emotional development. It has been field tested in 6 countries including Cote D'Ivoire. The nature of the assessment and the training requiring is highly similar to the MDAT. Validation of the GSED is being undertaken at the moment and we await the results of those evaluations. During the early phases of this trial, we will evaluate the evidence as it becomes available regarding this possible alternative assessment of child development and consider whether there are advantages to the use of the GSED relative to the MDAT. If a decision is taken to use the GSED-LF this will be ratified by the Trial Steering Committee and notified and approved by the ethics committee via an amendment.

4.8 Trial Outcomes

4.8.1 Primary Outcomes

The primary **impact** outcome, assessed at age 30-32m, will be:

- The total MDAT score measured at the final follow-up visit when children will be aged 30-32 months. Parents in the intervention clusters will have benefited from maximum exposure to the SUNRISE campaign from the third trimester of pregnancy throughout their children's lives.

The primary **intermediate** outcome, assessed when the child is age 18-20m, will be:

- The z-standardized sum score for observed responsiveness from the National Institute of Child Health and Human Development (NICHD) sensitivity scales.

4.8.2 Secondary outcomes

Secondary **impact** outcomes will be:

- The 4 MDAT developmental domain scores for gross and fine motor development, language and social development, assessed at age30-32m.
- The 5 CREDI-LF scores measured 6-monthly from 6-8 months of age until 30-32 months of age.
- The 5 Communicative Development Inventories (CDI) scores measured 6-monthly from 6-8 months of age until 30-32 months of age.

Secondary **intermediate** outcomes will be:

- The HOME-IT inventory (Home Observation for Measurement of the Environment, Infants & Toddler version) score assessed when the child is age 18-20m.
- The 5 Family Care Indicators (FCI) scores measured 6-monthly starting when the child is 6-8 months of age until they are 30-32 months of age.

4.8.3 Tertiary outcomes

- The two Knowledge of Infant Development Inventory (KIDI) scores measured when the child is 18-20 months of age and when they are 30-32 months of age.

4.9 Cultural adaptation

We will use the following systematic process of cultural adaptation for all instruments:

a) Translation of the assessment instruments into the 6 local languages spoken by residents in the trial clusters, and adaptation of the testing materials for the local context;
b) Ensuring technical equivalences;
c) Cognitive interviews with respondents and project staff (field research);
d) Modifications of translated versions, based on the field research;
e) Pretesting, including further modification;

f) training of assessors, establishing inter-rater reliability; and

g) Pilot-testing, including testing of standard operating procedures.

4.10 Sample size

We anticipate assessing at least 100 children per cluster, after allowing for a maximum 20% loss to follow-up from recruitment. This will give 90% power to detect an effect size of 0.25, assuming an intra-class correlation of 0.01 (personal communication, from the Save the Children ECD trial in Rwanda) and 80% power to detect an effect size of 0.21. It will also give 90% power to detect an effect size of 0.4 in other ECD outcomes, the level achieved in several successful ECD interventions, assuming an intra-class correlation of 0.04, which is informed by unpublished results from the SPRING trial, and 80% power to detect an effect size of 0.33.

4.11 Statistical Methods

Findings will be reported according to the CONSORT guidelines for cluster randomized trials. Analyses will be intention to treat and include all data from trial children and their families, regardless of their exposure to the radio campaign. Random-effects linear regression models using individual-level data will be used to adjust for the clustered design and any imbalances between intervention and control arms. Effect sizes will be presented as standardized mean differences with 95% confidence intervals (CI). The data analysis plan will be published prior to the end of recruitment.

Analyses will initially be carried out blind with clusters randomly allocated randomly to groups X & Y. Results will be presented to the TSC /DMEC and all data procedures and statistical methods agreed. This is in order to ensure that any decisions made concerning methods, choice of indicators, outliers etc cannot be influenced by the trial results. Partially unblinded analyses will then be presented with the two trial groups labelled by letters rather than as intervention and control. The findings will be discussed, and the interpretation of any differences agreed, ignorant to the knowledge of which group is intervention and which control. The code will then be broken. Interpretation of findings cannot be changed at this stage.

4.12 Blinding

Although the nature of the intervention precludes formal masking of fieldworkers during data collection, we believe that this is unlikely to lead to bias for the following reasons: the data collection will be carried out completely independently of the campaign team; emphasis throughout training will be on understanding early child development, rather than on evaluating the radio campaign; the assessments will follow standardized data collection protocols; and the coders of the responsive parenting videos will be blind to their allocation status. In addition, the strict “blinding” procedures for data analysis described in Section 4.11 have been designed to avoid any bias in methodological decisions or interpretation of findings all analyses will first be conducted blind to intervention allocation as. Finally, the randomisation will be carried out and the code held by the independent trial statistician; it will only be shared with campaign team.

4.13 Methods for protecting against bias

Methods for protecting against bias include:

1. Selecting FM radio stations for the trial with geographically distinct catchment areas, minimising the risk of contamination between clusters. Regular process data collection will also monitor this.
2. Using restricted randomisation to maximise comparability between intervention and control clusters at baseline with respect to radio exposure and key predictors of ECD.
3. Recruiting all eligible infants living in trial clusters to avoid selection bias and increase generalisability.
4. Range of quality control procedures to ensure data accuracy: cultural adaptation of instruments, pre-testing, establishing inter-rater reliability, range and consistency checks etc.
5. Regular visits to trial families to minimize loss to follow-up.

5. Process evaluation

5.1 Tracking and post-broadcast feedback

Independent radio trackers will determine if spots were broadcast as planned. Post-broadcast feedback on the campaign will be obtained through periodic focus group discussions (FGDs) and semi-structured key informant interviews. These data will be collected from at least two different communities every quarter, throughout the campaign duration. The objective is to find out whether the target audience have heard and understood the campaign messages, their reactions to them and whether there are any remaining barriers to behavioural change. Message briefs and creative content can then be revised based on these findings, allowing continual iteration and adaptation of the campaign. These procedures are part of the standard DMI campaign methodology.

5.2 Surveillance monitoring data

Monitoring data on radio coverage will be collected every 3 months from trial mothers including listenership in the past week and questions concerning child health advice heard on the radio. These data will also be collected from a separate **monitoring cohort** of mothers who participated in the baseline survey together with 6-monthly questions on key behaviours & knowledge targeted by the campaign (to be designed in early 2022). These mothers will be followed for the first 18 months of the campaign. As they participated in the baseline survey, they will have older children; data collected from them will therefore allow the trial monitoring committees to make an early assessment of whether the campaign appears to be changing parental caring behaviours across the whole target age range of the first 3 years of life, as well as providing valuable feedback to the campaign.

5.3 Qualitative research

Acceptability will be measured through 25-30 qualitative interviews with caregivers, who will be asked about their experience and views on the intervention approach and content. Data from the post-production feedback research will also be utilized. The mechanisms and

barriers to behavioural uptake will be explored through qualitative interviews with a further sample of 25-30 families. Approximately five intervention communities will be selected to reflect the diversity within the study areas. Within communities' respondents will be selected to give diversity in key characteristics such as parity and socio-economic status. The sample sizes have been estimated for planning purposes, but the actual sample size will be based on the concept of saturation sampling, that is, we will continue investigating until no new information is elucidated.

The qualitative data around acceptability and mechanisms will be collected by trained interviewers who will use semi-structured guides. We will include non-direct questioning where caregivers narrate how they interact with their child followed by direct questions on exposure to the spots, their impact and an exploration of the potential intervention mechanisms. Guides will be translated into local languages and pretested through role plays and pilot interviews with respondents. Interviewers will take field notes during the interviews, which will then be written up, as well as tape-recording the interviews. Interviewers will meet regularly to discuss their findings and supervisors will read transcripts and give feedback on interviewer technique and content. Analysis will begin through the identification of themes during daily debriefing sessions. Key analytical categories will then be identified, and the interviews systematically indexed into the categories and interpreted and written up. Data quality will be ensured by in depth training of interviewers, pre-testing guides, encouraging reflexivity during data collection and the provision of feedback by supervisors on each interview transcript. During analysis consensus coding methods will be used for initial interviews.

6. Economic evaluation

The cost and affordability of programmes to stimulate nurturing care are crucial elements of the pathway to successful scale-up (18). However, the multi-sectoral nature of ECD programming has challenged the measurement of program costs and benefits, particularly in low-and middle-income country settings (39). In the absence of primary data, modelling techniques have been used to estimate the economic benefits of intervening in the first years of life (3) including long term effects (40). However, few studies in low-income settings have generated primary cost effectiveness and cost benefit ratios to aid national priority setting and improve program uptake (39).

SUNRISE offers the opportunity to fully cost, from the provider perspective, a large-scale intervention to promote ECD. These provider costs will be used to calculate a range of incremental cost effectiveness ratios including cost per beneficiary and cost per unit of cognitive gain. The full provider costing will then form the basis for affordability estimates calculated as a percentage of national gross domestic product. The cost of a fully-scaled programme will also be compared with current health and education spending in context. Simple modelling of the gains from improved early childhood stimulation, using estimates from the Lancet Series in Early Child Development (4), would then be used to conduct a fiscal space analysis to explore the expansion in national income likely to arise from the effects of the program, and what percentage of that growth in income the program cost constitutes. Finally, the equity impact of this intervention will be measured, as early child development interventions are known to attenuate the effects of poverty (2,41).

7. Data Management – Protection & Confidentiality

Data protection and confidentiality procedures will be specified and followed, in keeping with Good Clinical Practice (GCP) and the General Data Protection Regulation 2018. We plan to use REDCap for data collection which is a secure web application for building and managing online surveys and databases; REDCap is 21 CFR Part 11, FISMA, HIPAA, and GDPR compliant. All data (including video observations) will be collected on secure, password protected handheld tablets within an encrypted database, with the data transferred daily to a secure password protected cloud server, managed by IPA in Ouagadougou. All electronic data will be backed up locally on a weekly basis on encrypted external hard drives and stored off-site in Ouagadougou. Encrypted transfer of pseudonymized quantitative data to LSHTM will take place monthly via secure internet connection to a GCP-compliant LSHTM database, which allows full auditing of all data input and edits. Qualitative interviews will be audio-recorded on digital audio recorders.

As video and audio data cannot be de-identified, transfer of this material to the UK will be done through UCL's Data Safe Haven, which is a dedicated highly secure system for storing and handling sensitive data. The Data Safe Haven has been certified to the ISO27001 information security standard and conforms to the NHS Information Governance Toolkit. The Data Safe Haven is built using a walled garden approach, where the data is stored, processed and managed within the security of the system, avoiding the complexity of assured end point encryption. Video recordings will be viewed only by members of the SUNRISE team and for the purposes of the research, unless further explicit written consent is obtained.

Data concerning cluster allocation will not be stored in the local or LSHTM research databases, but held separately by the trial statistician in a secure password protected file.

8. Post-trial Data Access and Sharing

A final data sharing plan will be agreed between the study team, sponsor, Research Ethics Committee and funder and published before data collection is complete. The study's data sharing policy will be made accessible on the study website at LSHTM, on LSHTM's data repository, on the study's ClinicalTrials.gov record and on the Figshare repository (see below). All accessible data sources will be anonymised at the individual participant, family and cluster level. No identifiable data will be made publicly available. All data will be stored in accordance with GDPR regulations for research and in line with recognised data security standards (MRC, Wellcome, LSHTM and UCL policies).

The fully anonymised study dataset (with newly generated IDs, and appropriate consents in place), alongside codebooks and a detailed dataset guide, will be made available after 3 years of study completion and placed on LSHTM's Data Compass repository, a curated repository of research data and other reusable outputs produced by LSHTM and its collaborators. The data will also be mirrored on Figshare (http://www.figshare.com), a widely used online repository where users can make research outputs available in a shareable and discoverable manner.

All published papers will include links to the repository, with access to the relevant analytic data sets and analysis scripts, to ensure transparency and reproducibility. The datasets will be assigned unique DataCite DOIs. Video data and qualitative interviews, where anonymization is either not possible or there is a high risk of individuals being identified, will not be made

available in the repository. However, suitably qualified researchers will be able to access these data under strict collaboration agreements. Data access will be overseen by a committee composed of the PIs and at least one independent member. Access requests will be reviewed by the committee and recorded, with individual data sharing agreements signed by the data requester and his/her institution prior to data release. All variables will be labelled using a pre-defined naming convention and data and metadata catalogues will be produced to support data sharing. The catalogues and metadata will be listed on the LSHTM repository, the clinicaltrials.gov record and the Figshare entry. Personally-identifying data will be held for 10 years after the study is complete and then securely destroyed. Anonymized data will be curated and made available for public access 3 years after the study is complete.

Broadcast content sharing: DMI will make all the SUNRISE radio spots available for broadcast free of charge when intended to be used for public health purposes and not for commercial gain.

9. Trial monitoring

9.1 Trial Steering Committee (TSC)

The role of the TSC is to contribute to independent oversight of the trial. Its specific roles are as follows:

1. Approve the trial protocol - All TSC members should have opportunity to comment on the protocol.
2. Approve any amendments to the protocol, where appropriate.
3. Approve any proposals by the project management team (PMT) concerning any substantive change to the design of the trial, including additional sub- studies.
4. Approve / comment on the trial analysis plan.
5. Review annual reports submitted by the PMT which would allow them to monitor recruitment rates, intervention completions, outcome assessment completion rates, dropout rates, follow-up rates and review strategies from the PMT to deal with any problems.
6. Review outcome analyses for interpretation and ensure the timely reporting of trial results
7. Ensure that mechanisms to safeguard the rights, safety and well-being of the participants are in place and being adhered to.
8. Make final decisions as to the future continuation (or otherwise) of the trial after input from the data monitoring and ethics committee (DMEC).
9. Consider and act on any new information when presented by the PMT

TSC members should be constructively critical of the ongoing trial, but also supportive of aims and methods of the trial.

Name	**Designation and organizational affiliation**	**Role in TSC**
Linda Richter	Director, DST-NRF Centre of Excellence in Human Development, University of the Witwatersrand. Developmental Psychologist & Distinguished Research Fellow, Human Sciences Research Council, South Africa.	Chair

Jose Martines	Research Coordinator, Centre for Implementation Science in Maternal & Child Health, Bergen, Norway.	Member
Thérèse Stukel	Senior Scientist, Institute for Clinical Evaluative Sciences & Professor, Institute of Health Policy, Management and Evaluation, University of Toronto, Canada.	Member
Ali Sie	Director, Le Centre de Recherche en Santé de Nouna (CRSN) (Nouna Health Research Center), Burkina Faso.	Member

9.2 Data Monitoring and Ethics Committee (DMEC)

The role of the DMEC is to safeguard the interests of trial participants, assess the safety and efficacy of the interventions during the trial, to ensure continued trial integrity, scientific value, and ethical treatment of study subjects and monitor the overall conduct of the clinical trial. The DMEC is independent from the trial team. The DMEC should receive and review the information on progress and accruing data of this trial and provide advice on the conduct of the trial to the Trial Steering Committee (TSC).

Name	**Designation and organizational affiliation**	**Role in TSC**
Rajiv Bahl	Coordinator, Maternal, Newborn, Child and Adolescent Health Research and Development, World Health Organization, Geneva, Switzerland	Chair
Thierry Mertens	Professor of International Health, New University of Lisbon, Portugal	Member
Charlotte Tawiah-Agyemang	Community research & communication specialist, Kintampo Health Research Centre, Ghana Health Service, Ghana	Member
Susan Walker	Professor of Nutrition, Tropical Medicine Research Institute, Faculty of Medical Sciences University of the West Indies, Jamaica	Member
Helen Weiss	Professor of Epidemiology, Associate Dean of Research for EPH, and Director of the MRC International Statistics & Epidemiology group, London School of Hygiene & Tropical Medicine, London, United Kingdom	Independent statistician

The specific roles of the DMEC include ongoing reviews of trial progress including updated figures on recruitment, data quality, and main outcomes and safety data. The DMEC will fulfil the following roles, as appropriate for the stage of the trial and/or in response to other information made available to the DMEC:

1. assess data quality, including completeness (and by so doing encourage collection of high quality data)
2. monitor recruitment figures and losses to follow-up
3. monitor compliance with the protocol by participants and investigators

4. monitoring evidence for treatment differences in the main outcome measures
5. monitor evidence for treatment harm (e.g. unexpected and related Severe Adverse Events, deaths)
6. decide whether to recommend that the trial continues to recruit participants or whether recruitment should be terminated either for everyone or for some treatment groups and/or some participant subgroups
7. suggest additional data analyses
8. advise on protocol modifications suggested by investigators or Sponsor (e.g, to inclusion criteria, trial endpoints, or sample size)
9. monitor planned sample size assumptions
10. monitor continuing appropriateness of patient information
11. monitor compliance with previous DMEC recommendations
12. considering the ethical implications of any recommendations made by the DMEC
13. assess the impact and relevance of external evidence

9.3 Trial auditing

The study may be subject to audit by the London School of Hygiene & Tropical Medicine under their remit as trial sponsor, the Study Coordination Centre and other regulatory bodies to ensure adherence to GCP.

10. Ethical approval

As a non-CTIMP, no regulatory approvals for medicinal products will be required. The study will be reviewed by the ethics committees of the Ministry of Health, Burkina Faso, UCL and LSHTM. LSHTM will be the study sponsor. The trial will be registered with ClinicalTrials.gov prior to initiation.

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