Preventing Infant Diarrhoea in The Gambia using Household play spaces and education

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Section 1: Aims and objectives

Globally, in 2017, over half-a-million children under-5 died from diarrhoea, with the highest rates in Sub-Saharan Africa (SSA) (Reiner Jr, 2020), particularly in children aged 6-24 months, when children tend to mouth objects (Bauza et al., 2017). Despite various interventions, diarrhoea rates in SSA and low and middle-income countries (LMIC) remain high. In addition, recent evidence suggests that the dirt and animal faeces ingested (geophagy) by toddlers is contaminated with diarrhoea-causing pathogens (Budge et al., 2021). Unfortunately, clean play areas are not always available in LMICs, and mothers do not take adequate steps to prevent their children from ingesting these harmful substances. This highlights the need for better strategies to promote safe play and hygiene practices in LMICs.

Therefore, we propose a research framework that aims to test the effectiveness of a culturally acceptable household play-space to address geophagy as a critical, common cause of childhood diarrhoea in a SSA country, The Gambia.

More specifically, for our objectives, we aim to answer the following research questions:

1.Does using play-spaces reduce the incidence of diarrhoea in 6-24-month-old children (toddlers) in The Gambia?

2.Will providing complementary education and peer-support interventions to mothers with play-spaces additionally lower the incidence of diarrhoea in toddlers?

3.What is the cost-effectiveness of introducing play-spaces and added education regarding improved health outcomes for toddlers?

4.Will using playpens result in externalities, e.g., decrease childhood injuries, lessen mothers' domestic workload, or harm short-term child development?

The Gambia is an appropriate study site due to its high burden of diarrhoeal disease. Its shared ethnic/tribal populations and cultural/geographic similarities with neighbouring countries in West Africa, where diarrhoea is also a significant public health concern, enhance the potential for our intervention to be widely applicable and scalable in the region. Overall, The Gambia represents a valuable opportunity to address and test solutions to a pressing public health issue in SSA.

To address these research questions, we will first establish a precise analytical framework embedded in existing published evidence and pilot studies (explained in Section 2). We will then test this framework in the field by conducting a randomised controlled trial (RCT), enabling us to evaluate the cost-effectiveness of play-spaces and education for mothers in improving health outcomes for children, particularly concerning diarrhoea. In addition, we will assess the externalities/unexpected consequences of play-spaces, such as reducing childhood injuries (Budge et al., 2021).

Section 2: Academic Relevance

When livestock live near households, child-mouthing behaviour presents a significant transmission risk for intestinal pathogens (Budge et.al., 2019; Reid et al., 2018). Perin et al. (2015) observed in rural Bangladesh that 28% of 6–30-month-old children with observed geophagy had significantly higher rates of intestinal inflammation and were twice as likely to be stunted 9-months post-observation compared to children with no observed geophagy. In rural Bangladesh, the presence of animal faeces in the yard increased diarrheal risk by 25% and was negatively associated with child height-forage scores (Headey et al., 2017). Similarly, in rural Gambia, for every hour a child was observed playing on the ground, they were 12.4% more likely to experience diarrhoea (Harris-Snell, 2019).

Mitigating this ground-to-mouth transmission pathway with a walled play-space presents several possible economic benefits: reducing illness and death from diarrhoea, reducing the cost of diarrhoea treatment for families, less time/earnings lost to caring for the child, and freeing health service time for managing other conditions. Further external benefits are available through reduced childhood injury and a lower domestic workload from less child-supervision, freeing up mothers' time.

Evidence suggests that geophagy occurs not simply because of a maternal hygiene informational failure. For example, Ngure et al. (2019), who provided Water Sanitation and Hygiene (WASH) information to mothers in rural Burkina Faso, found that post-information provision, only a quarter of WASH triggering events resulted in hand washing, and rarely with soap. Similarly, for more educated carers in rural Zimbabwe (78% with secondary education), observed hand washing rarely occurred after human or animal faecal contact (Ngure et al., 2013). Furthermore, they found that in-laws or village elders advised geophagy to build the intestinal resilience of children (Ngure et al., 2013). Hence, the behaviour is deeper rooted in culture rather than a problem of information constraints. The former is more responsive to peereducation facilitating technology use and behavioural change (Merzel and D'Afflitti, 2003). The complex relationship between knowledge, social norms, technology, and behavioural change is why WASH information provision failed to change behaviour.

A household play-space is a walled enclosure that can stand as a material intervention to prevent toddlers' ingestion of soil and faeces. The WHO has described it as a critical intervention component of WASH for improving infant health (WHO/UNICEF, 2019). In Ghana, playmats were given as a part of a larger WASH program, which significantly decreased child stunting post-intervention (SPRING, 2018). However, data on the research design and uptake were not recorded, and playmats were used alongside other WASH and agricultural interventions, so their isolated effect could not be identified.

In a recent feasibility study for play-spaces in rural Ethiopia (Budge et al., 2021), households preferred walled play-spaces with removable padded-floors to facilitate cleaning (important since preferences for continual-use factors are key for longstanding benefits from this intervention). While the treatment group was 43% less likely to experience diarrhoea (a secondary outcome), the small sample size left the study underpowered to detect the definitive health effects of the play-spaces. The authors highlight the importance of a 'transformative' WASH approach, combining education and peer support with material interventions to block pathogen exposure. They recommend a larger well-powered trial and economic analysis for such interventions to reduce diarrhoea.

Overall, the effectiveness of a play-space in reducing diarrhoea has not been investigated and the lack of economic evaluations of play-spaces presents a barrier to policy-makers, funding agencies, and manufacturers for making play-spaces widely available in LMICs. Our study builds on the Ethiopian pilot to inform donor investment in low-cost play-spaces which could be sold or given to new mothers, with or without further peer-education. We also investigate whether continual-use and outcomes can be enhanced through additional education, peer-support, and information provision.

Section 3: Design

Context

The Gambia's under-five mortality rate is currently 47.9/1000 live births (UNICEF, 2020), with diarrhoea being the second highest cause of death (Wutor et al., 2022). Therefore, it fails to meet the UN's Sustainable Development Goal for health(SDG3): to "decrease mortality rate of under-5's to at least 25/1,000 live births" (WHO, 2022).

In particular, in rural Gambia, Saha et al.(2013) found a diarrhoea point prevalence of 7.7% (95%CI=6.1–9.9) in 0-59-month olds, with 12-23-months having the highest rate for point prevalence(11.9%). Our study takes place in the Central River Region (CRR), chosen as it is The Gambia's poorest region with the highest diarrhoea rates (G.B.S, 2010), with evidence that children play in the dirt and exhibit geophagy (Harris-Snell et al., 2019).

Furthermore, The Gambia has high poverty levels, with a poverty headcount ratio of 48.6% in 2015 (at national poverty lines (World Bank, 2017)). Low-income families often invest less in preventive care (due to credit-constraints, lack of information and social-norm barriers). Therefore, providing a low-cost preventative measure, with or without peer-support, is critical for families and health systems to overcome overreliance on curative measures, which are often costly and dependent on the efficiency of local healthcare centres.

Additionally, Saha et al. found a lack of information about diarrhoea prevention among caregivers: in 2013, around half of primary caregivers were aware of preventative methods for watery diarrhoea in under-5-year-old children. Without proper education and support, caregivers cannot adapt their behaviours to prevent diarrhoea (Saha et al., 2013).

In this study, we propose a research framework to address the high diarrhoea rates in toddlers in the CRR of The Gambia through a material intervention (play-spaces) combined with additional education and peer support to enhance the use of the intervention.

Hypothesis

We hypothesise that the introduction of play-spaces will reduce cases of diarrhoea and injuries due to less geophagy and since the child is playing in a safe enclosure. Furthermore, we expect to find a reduction in child development due to loss of exploration, freedom of play and social interaction with peers and siblings. Including the addition of education for Mothers should enhance the beneficial results due to the education promoting the use of the play-spaces.

Experimental Design

We propose a 3-arm parallel RCT to estimate the causal effect of introducing playspaces and the additional benefit of education and peer-support on diarrhoea incidence in toddlers in The Gambia. We further investigate externalities such as childhood injuries and development and conduct a cost-effectiveness analysis evaluating the feasibility of the intervention.

Sampling

We will consider individuals from a list of all the CRR villages with population <10,000 (using the last national census of The Gambia).

Procedures for recruiting villages and families, including a census for obtaining a sampling frame and the mother's consent, are explained in appendix 1. We will use a random number generator to select and allocate eligible villages and individuals into experimental groups.

Based on the results of the Budge et al. (2021) study, we estimate that there would be around a 30% reduction in diarrhoea incidence from the introduction of playspaces with education and peer support, while we expect half that for the isolated effect of the play-space. Following a 90% power and 5% significance (recommended by (Duflo et.al, 2006)) we used a statistical package (Raudenbush et al., (2011)) to estimate a sample size of 1600 children per group/arm (total of 4800 children). Considering attrition rates, protocol violations, and how larger samples allow us to evaluate more significant scaled cost-assessments, we intend to recruit 5700 children.

Eligibility criteria

See appendix 2 for inclusion/exclusion criteria rationale.

Inclusion criteria:

1. Mother-child pairs with the child aged 6-18 months.
2. Living in one of the selected rural villages and not intending to move before the 12-month follow-up survey.

Exclusion criteria:

1.No domestic animals

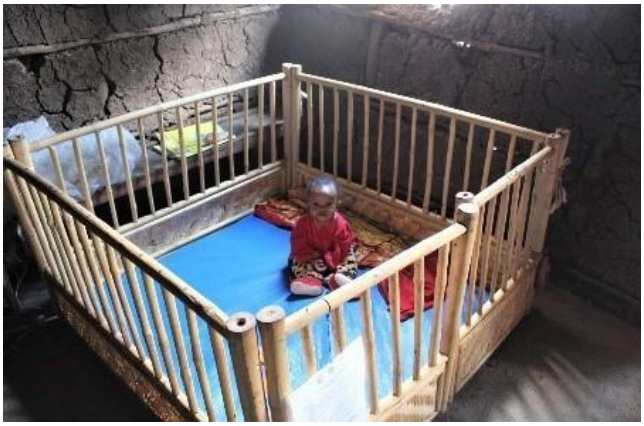
2.No consent to participate in the study.

Experimental group allocation

We will randomly allocate our sample into three equally sized groups:

Group-1: This group will receive a play-space. The play-space design and materials will be locally-sourced, using methods utilised by Budge et al. (2021) in Ethiopia (Figure.1). The play-space is given to the mother with an introductory instruction leaflet as one would get on purchase in a shop (see appendix 3 for details). There will be no further visits to the mothers except for the two follow-up surveys.

Figure.1: (Budge et.al., 2021)



Group-2: In addition to receiving a play-space, mothers in this group will receive a weekly hour-long home-visit session for 4-weeks, and monthly after that until the 12month survey is complete. The session will be peer-taught/supported by trained older mothers, since education/peer-support has benefits of social norm change (discussed in Section.2). The sessions will centre around how best to use the playspace for child safety and happiness: the importance of cleaning the plastic mat on the playspace floor, and using the play-space instead of the child being outside on dirt to reduce diarrhoea and injuries.

Group-3: Control group, who will receive no intervention.

Comparing results from groups-1 and 3 will allow us to distinguish the effects of playspaces on our outcomes, whilst comparing groups-1 and 2 shows the additional effect of education on the play-space intervention. Furthermore, the control group allows us to identify any temporal influences in the rates of characteristics or outcomes.

Data Collection: Baseline and Post-intervention assessments

Data collection will include three rounds of surveys for each mother-child pair:

- Baseline survey before randomisation of groups

- Short-term (3-month) post-intervention follow-up assessments ● Long-term (12-month) follow-up.

These surveys will all include data on our three child health outcome variables (reported diarrhoea, reported injuries, and child development using ASQ3 questionnaire). The baseline data collection survey will include questions about the background characteristics of the mother-child pair, and the follow-up surveys will also include added questions about the acceptability of the intervention (see appendix 4 for more detail).

For our cost-effectiveness analysis, the overall aim is to take a societal perspective of the costs and benefits in delivering the interventions and to the households using them. Costs for developing and delivering the intervention will be collected during the RCT, and costs for mothers during household questionnaires (e.g. cost of soap to clean the play-space). Household costs for episodes of childhood diarrhoea will be asked through questionnaires about travel, consultation, medication and earnings lost from work during follow-ups. (More detail in appendix 4 and 5)

Data Analysis

To check for successful randomisation, we will assess whether background characteristics and outcomes are balanced between the three groups of the RCT at baseline. With successful randomisation, the potential outcomes are homogenous across the three groups without intervention at baseline, so any identified difference in outcomes at the follow-up should be causal.

To find the causal effect of our interventions, we estimate the following regressions:

$$Y_i = \beta_0 + \beta_1 PlaySpace_i * Education_i + \beta_2 PlaySpace_i + x_i'\gamma + u_i \qquad (1)$$

$$Child\ development_i = \alpha_0 + \alpha_1 PlaySpace_i * Education_i + \alpha_2 Playspace_i + x_i'\gamma + u_i \ (2)$$

Where Y_i represents the binary outcome variables $Diarrhoea_i$ and $injury_i$, and $Child\ Development_i$ is modelled as a continuous variable, measured using the ASQ3 outcome measure (see appendix 4). $Playpen_i$ and $Education_i$ are dummy variables equal to 1 if the household receives the treatment and 0 if not, x_i' is a vector of the confounding variables gathered in the baseline survey, and u_i is the error term.

We will use logistic regression to estimate (1) as these are binary outcomes and OLS regression for (2), the child development outcome. These estimates identify the effects of play-spaces: β_2 on diarrhoea and injury rates (in percentage points) and $\alpha_2$on development scores. We expect a negative β_2 and α_2: showing play-spaces are associated with lower diarrhoea, injury rates and child development levels. Since we control for play-pens, β_1 ,α_1

are the additional education effects. This will allow us to analyse whether play-spaces' benefits are significantly improved through education provision.

Follow-up surveys will allow us to identify any attrition: comparing individuals who have dropped out of the study with the baseline statistics will allow us to detect any attrition bias, which we can then control for in our regression.

For the cost-effectiveness analysis, we will use Decision-analytic modelling as described by Siu et al. (2021). This will include an estimation of resource costs for both intervention arms, data on effectiveness from the RCT above, and household and healthcare provider system costs for childhood diarrhoea. The cost associated with a diarrhoeal episode will be attached to the intervention effectiveness estimates as overall savings because we anticipate a reduction in childhood diarrhoea rates. Using these estimates, the Markov model will be used to analyse the longer-term cost-effectiveness of the intervention (See Appendix 5 for further analysis).

Conclusion

Overall, we hope to find a cost-effective solution to the high levels of diarrhoea in children. Whilst our study focuses on diarrhoea, further externalities and spillover effects could arise from our study. Conditional on experiment success, further research into these externalities and their economic implications could be conducted, e.g. injuries and cognitive impacts on children. Furthermore, depending on success, external validity of play-space implementation may be investigated for other regions facing similar issues.

APPENDIX

1.Recruitment procedure:

Before randomisation into groups, we would visit the village head and get written permission to involve the mothers in the village in this intervention and surveys.

Subsequently, we would conduct short house-to-house surveys/census, including GPS of houses, to identify all households with children aged 6-18 months. This list will be our sampling frame.

We will randomly select the mothers from this list based on our sample size requirements. Data collectors will then visit the chosen households for consent and recruitment. At the start of this first home visit, we will ensure the mother-child pair meet all eligibility criteria stated below. Then explain the study verbally in local languages, in case of poor literacy, and provide an information sheet for the mother to keep. The information for consent will explain the intervention options and that we cannot tell them which group they will be in before consent. We will also visit to ask questions about the children and mother and how they manage daily activities. Obtain written or thumbprint consent with a witness in the case of illiteracy.

2.Eligibility Criteria:

Inclusion criteria:

1. Mother-child pairs with the child aged 6-18 months.

Rationale: Teething, toddling children (ages 6-30 months) are at the age to mouth objects and therefore eat soil. Because we conduct a 12-month follow-up, we should recruit younger children so the play-spaces are still in use at 12-months postrecruitment).

2. Living in a selected rural village and not intending to move before the 12-month follow-up survey.

Rationale: Geophagy is a bigger problem in rural areas with more domestic animals, significant compound floors and unpaved boundaries

Exclusion criteria –

1.No domestic animals

Rationale: Since we want to detect diarrhoea and some proportion of pathogen transmission is from domestic animal faeces ingested by toddlers

3.Group Allocations:

Instruction leaflet included with provision of play-space: includes pictures of how to construct the play-space, clean the plastic floor, use in the shade if outside, use toys to stimulate the child, and brief mention of benefits of the play-pen in reducing geophagy and injuries.

4.Data collection:

The household surveys completed by trained data-collectors at baseline and followups will collect all the following characteristics, except for background characteristics that will only be collected at baseline.

Background characteristics of the child, mother and family, such as age and sex of the child, age, education, and employment of mother and father, number of siblings of the child, and household belongings (using Demographic Health Survey questions for The Gambia) made into a score and material of the roof and walls of the house as a measure of household wealth, for example.

Health and other outcomes:

- Diarrhoea - has the child had diarrhoea (as defined by the World Health Organisation) in the last 7 days

- Injury – has the child had any injuries where you have had to get help/advice/treatment from someone else (defined as drowning, burns, injury by animals, scratches/bleeding, a broken bone, head injury by falling or contact with objects, other hurts with physical evidence)

- ASQ3 is a set of questions for each age group that is tested and currently used as a measure of outcomes for children in England. It measures communication skills, gross motor skills, fine motor skills, problem-solving skills, personal–social skills, and all 5 areas of development (Gov.UK, 2022).

- Time saved by Mother over the last 48 hours or 7 days when she could have been relaxing/doing household chores/socialising/working. Measured in approximate time intervals (e.g. do you think you could save time from child care to do other things? If yes, was it <15min, 15-30min, 30-60min, >1hour).

5.Cost-Effectiveness analysis:

Cost of intervention

We will measure the cost of intervention as follows for various players.

- For the cost of production and use of the play-spaces to the health authorities who may want to replicate our work. It is the cost of manufacturing, distributing, peer-educator training and incentives for home visits (assuming they will act as semi-community volunteers and not health staff, thus receiving only incentives and not salary)
- For the families, as play-space and education/peer-support are free, we will ask about extra costs to the family of play-spaces, which is washing soap and is very low-cost.

The cost of diarrhoea to families:

During the follow-ups, we will ask the mothers about the last time the child got diarrhoea and how they got advice or medical help. Some will be visiting hospitals, and others are only getting short advice or will do nothing at home. These will be estimated on average for a case of diarrhoea. We will ask about:

- Consultation costs for advice from any type of healthcare or traditional medicine, travel to see this person or medicine/treatment costs, and time lost from earnings due to these visits.
- The questionnaire will include the following: last time your child had diarrhoea, what did you do, did you ask mother/friend, visit traditional healer, visit the local clinic, far off the hospital, and how much you paid for travel, visit, medicine, time off work and loss of earning.

For health system costs of diarrhoea:

- We will use the data from (Siu et al., 2021), where health service costs in The Gambia (subsidised by government donors) are given to estimate societal costs of average diarrhoea and savings gained through our intervention.

Further cost-effectiveness considerations:

Since there is considerable controversy around the use of cost-effectiveness thresholds in LMIC, then we will compare the cost-effectiveness result with a range of thresholds such as the WHO-CHOICE threshold (Siu et al., 2021), Gambia's GDP levels and an 'opportunity cost' threshold (Siu et al., 2021).

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