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Care for Child Development in rural Malawi: a model feasibility and pilot study

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Evidence demonstrates that encouraging stimulation, early communication, and nutrition improves child development. Detailed feasibility studies in real-world situations in Africa are limited. We piloted Care for Child Development through six health surveillance assistants (HSAs) in group and individual sessions with 60 caregivers and children <2 years and assessed recruitment, frequency, timings, and quality of intervention. We collected baseline/endline anthropometric, child development (MDAT), maternal stress (SRQ), and family care indicators (FCIs) data and determined acceptability through 20 interviews with caregivers and HSAs. HSAs could only provide coverage on 14.2% of eligible children in their areas; 86% of group sessions and a mean of 3.6/12 individual sessions offered to mothers were completed. Pre- and post-assessment of children demonstrated significant changes in MDAT language and social Z-scores and FCIs. Caregivers perceived sessions as beneficial and HSAs good leaders but that they could be provided through other mechanisms. Integrated Care for Child Development programs for 0–2 years old are readily accepted in Malawi, but they are not feasible to conduct universally through HSAs due to limited coverage; other models need to be considered.

Keywords: pilot; feasibility; Care for Child Development; implementation; Africa; early child development

Introduction

Significant impact has been made in reducing child mortality rates globally, but despite this, increasing numbers of children are not thriving, with over 250 million children under 5 not reaching their developmental potential.¹ This can be attributed to chronic malnutrition (stunting), iron deficiency anemia, inadequate developmental stimulation, and poverty. We now have evidence from controlled trials which demonstrate that combined interventions which include support for developmental stimulation for children aged 0–3 years and which also provide advice on feeding, nutrition, and health can have substantial effects on early child development (ECD) and later life-course outcomes such as educational attainment; earnings and mental health, and

that these psychosocial benefits continue into adulthood as do the substantial economic returns.

These combined developmental stimulation, feeding nutrition, and health advice interventions are now promoted by UNICEF, the World Health Organization (WHO), and the World Bank in the Care for Child Development (CCD) intervention package.² For children under 2 years, the health sector has been targeted to implement these programs through extra training modules linked to Integrated Management of Childhood Illness. Studies using this or similar interventions in India,³ Bangladesh,⁴ and Pakistan⁵ using female community health workers have demonstrated clear benefits if CCD is provided through women's groups and during home visits. It is clear that this model works best with supervision and support.⁶ Studies to date

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in African settings have either used high-intensity programs with highly trained workers in home visits (South Africa)⁷ or with high-risk groups (HIV⁺ children) in Uganda.⁸ All research studies have used financial incentives (stipends) with paid research workers implementing the interventions. It is difficult to know whether this will be sustainable in the longer term. With this in mind, there has been an ongoing call from academics and global agencies (WHO, UNICEF, World Bank, and others) to investigate not only the effectiveness of child health interventions, but also to understand approaches to ensure continuity of care in the community under “real life” and implementation of these interventions within health and service systems.⁹ Recently, global experts in child mental health and early childhood development (ECD) have placed emphasis on research into effectiveness of early childhood interventions, task shifting, and the use of integrated services to deliver care in the top global health challenges.¹⁰ Despite this, there are few studies in African settings or elsewhere which have conducted detailed feasibility and pilot studies to understand the implementation of these developmental stimulation interventions in the early years within the existing health system structure. Without this evidence, there is a risk that this investment will be misdirected or ineffective if there is no evidence to understand what makes the intervention effective within the “real life” constraints of the existing community health systems in these contexts.

Malawi has a population of 16 million, of which 80% is rural, with high levels of stunting, poverty, and developmental delay.¹¹ Malawi's Ministry of Health (MoH) has a long standing system of health surveillance assistants (HSAs) who implement routine health care in all localities for community members with no specific service for women and children. The HSAs are a centrally recruited government-paid cadre.¹² HSAs' tasks include community health, family health, environmental health, prevention and control of communicable diseases, and community case management, including HIV, malaria, diarrheal diseases, pneumonia, and undernutrition.¹³ An HSA is expected to serve a population of approximately 1000 people, but the size of their catchment population is often larger. Many HSAs are overstretched and have difficulties in balancing demands placed on them.^{13,14} HSAs have 12 weeks training. Some supervision

by senior HSAs does exist but is not incentivized or competency based. Malawi is one of the first African countries to have ECD support through Community-Based Child Care Centers for 3–5 years old supported by Ministry of Gender, Children, Disability and Social Welfare.^{15,16} This does not support children younger than 3.¹⁷

The aim of this study was therefore to conduct a feasibility study to understand how the WHO UNICEF Care for Child Development intervention would perform when provided in a “real life” situation in Malawi. In this case, we aimed to understand the feasibility through the existing HSA system (the system which reaches the most families at community level) when conducted in both groups and individual sessions in rural and urban settings in Malawi.

Methods

In this study, we used the Medical Research Council (MRC) Framework for complex interventions¹⁷ particularly utilizing the development–intervention–evaluation process to understand the feasibility of the CCD with HSAs in rural and urban Malawian settings.

Our wider study had three phases. First, phase I, the development phase, enabled us to understand the present situation with regard to the evidence base through a literature review and then qualitative work with parents and caregivers to understand the situation with regard to the care, feeding, and stimulation of children under the age of 2 in rural and urban Malawian settings to make sure that we adapted the training materials appropriately. This is published elsewhere (under further review).¹⁸ Phase II consisted of testing the feasibility of delivering the CCD package using methodologies for pilot studies.¹⁹ This enabled us to undertake fidelity measurements of intervention provision with children and mothers in rural and urban settings in Malawi when provided through HSAs in group and individual sessions and also enabled us to gain information about the validity of measures and the numbers needed for expected effect sizes in our study. Phase III aimed to evaluate the acceptability and effect of the intervention with both parents and professionals through qualitative interviews and focus groups as well as analysis of the results of the pilot phase. The latter two phases (phases II and III) are described in this paper and demonstrate a model which can

work to evaluate similar complex interventions in ECD in other locations. The phases of this study are outlined in Figure 1.

Setting for study

The study was undertaken in an urban and a rural setting of Malawi. The rural sites (Nankhumba villages and Kansiya) were in the district of Mangochi. This is an area with mixed fishing and agricultural which has a mixture of Christian and Muslim populations within the community. The urban site was Chilomoni district within Blantyre and included three areas in this district which varied as to how far away from the road they were. This community has a varied population, most who work within the city of Blantyre and are a more mobile population.

Phase I—development phase

Adaptation of the Care for Child Development package for the Malawian context

In order to adapt and create modules for the CCD implementation package for Malawi (Supplementary Fig. S1A and B, online only), we conducted extensive qualitative work through focus groups and interviews with over 180 parents, caregivers, and health workers to understand the contextual situation with regard to the responsive care of children under 2 years in the same rural and urban contexts as the rest of the study. This work is submitted for publication at present (REF). We formulated a core team of reviewers (J.P., M.G., K.C., R.T., and P.C.) and made a decision to adapt training materials from the Caring for the Child's Healthy Growth and Development as our qualitative work identified the importance of linking nutrition and water, sanitation and hygiene advice to developmental stimulation and responsiveness advice. We conducted a stakeholders meeting where the results from the qualitative study were fed back to stakeholders from MoH, Ministry of Gender and Social Welfare, Ministry of Education, the Office of the President of the Cabinet for Nutrition, as well as leads from UNICEF, WHO, and Save the Children. We utilized information from this meeting to formulate our final themes for 12 groups and adapt the training package accordingly. These themes are outlined in the lead themes for the group sessions shown in Supplementary Figure S1A and B (online only). Our core team gained consensus on the structure of the groups and finalized a training workshop plan.

We conducted a training for six HSAs (three rural and three urban) of the adapted package alongside two trainers from Ministry of Health and Nutrition. During the training, we audio-recorded the sessions to gain valuable feedback on the materials and training for future adaptation.

Phase II—piloting phase

Understanding potential coverage of the training

We conducted a census in each area of the study through a house to house survey where all children under the age of 2 years at the time of recruitment who lived in the catchment areas of Nankhumba and Kansiya (Mangochi) and Chilomoni Central, Sigerere or Chibwana (Blantyre) were identified. This provided us with information as to the potential number of children and their families who might be eligible to be provided with the CCD training.

Sampling. A sample size of 60 participants (30 rural and 30 urban) was chosen for piloting as this number would allow enough numbers to pilot the training sufficiently and to aid in power calculations for a larger study in future. After training, recruitment, and prepilot assessment, all six HSAs (one for each 10 participants) were given instructions to “provide at least 2 groups a month (12 groups in 6 months) and 2 visits a month for each participant (120 visits in 6 months)” and were told that they could choose both the location and time of the groups and visits. Therefore, the total number of potential groups and visits which could have been undertaken between all six HSAs in the two locations combined would have been 72 groups and 720 visits. HSAs were encouraged to bring play materials to the groups, were provided with the Child's Healthy Growth and Development training materials, the adapted package of group topics for the 12 groups, and the CCD checklists for completion during each group or individual session.

Recruitment of parents and children from 0 to 2 to the pilot study.

We then utilized a computer generated randomization process for identifying a pilot sample of these children and their parents to take part in the pilot study. Community sensitization was conducted in both sites which involved group workshops with community leaders (religious and otherwise) and chiefs where information about the study was provided. Information leaflets were both

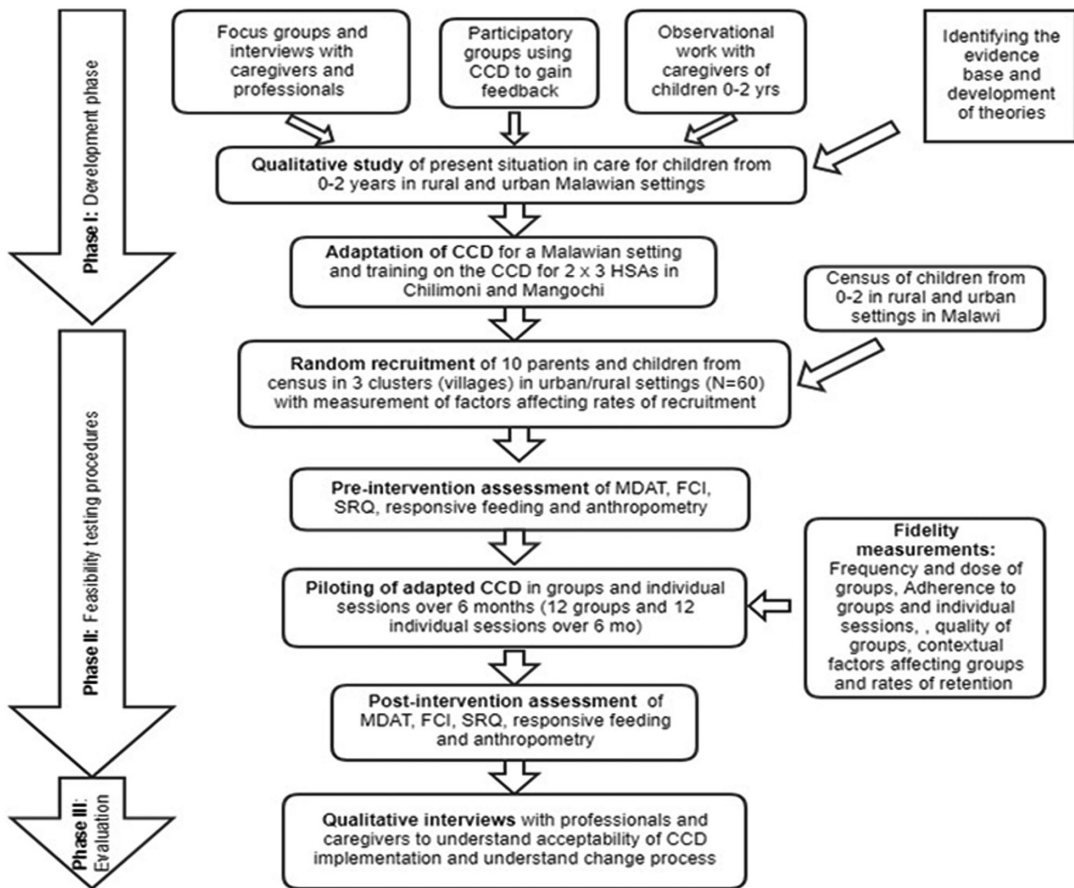


Figure 1. Phases and processes of work undertaken in the Malawi CCD feasibility and pilot study.

provided and read out to all parents who were randomly identified to take part in the study.

Exclusion and inclusion factors. We aimed to include as many children in this study as possible and therefore had limited exclusion factors. These included; any parent who refused to take part in the study and any child who was ill at the time of piloting the intervention.

Pre and postpilot evaluation of children from 0 to 2 years. We measured baseline demographic data using the standard data collection forms for the Demographic and Health Survey (DHS) Malawi 2010 which included information on age and sex of child,²⁰ (educational level, occupation, and socioeconomic status using the World Bank/DHS principal components²¹).

Collection of anthropometric data: All children in the study were measured for length, weight, mid

upper arm circumference, and head circumference using standard anthropometric techniques^{22,23} as recommended by the WHO. The weight of the child was taken using an electronic infant weighing scale (SECA 735). A length was done using a seca 210 measure mat, recorded to the nearest 1 mm and a head circumference used a nonstretchable plastic tape, recorded to the nearest 1 mm.

Collection of child development, family care, maternal stress, and responsive feeding interaction: All children were also assessed using the Malawi Developmental Assessment Tool (MDAT)—a well-validated and sensitive measure of child development for children from 0 to 5 years which is adapted specifically to the rural Malawian context.²⁴ This tool provides information in four domains of development; gross motor, fine motor, language, and social development with cognitive development being assessed across the domains. It has a total of

136 items which are scored against a norm created on over 1400 children in Malawi in 2008 to provide Z-scores for each domain of development.

Family care indicator (FCI)²⁵ is a brief tool for measuring the home situation and amount of stimulation in the home. It is measured through three components; FCI1 (the availability of household playthings), FCI2 (availability of books and magazines around the house), and FCI3 (reported interaction with children). A raw score was created by adding up the positive answers in each of the areas considered. We used the Self-Reporting Questionnaire (SRQ)²⁶ for measuring maternal stress and mental health. The SRQ is a brief measure of psychiatric symptoms designed by the WHO to be used across cultures.²⁷ It has been well validated, translated, and back translated for use in Malawi²⁶ with recent study validating it against depressive episodes in mothers of infants attending for measles vaccination in a hospital setting in Malawi.²⁶ The SRQ is scored out of 20. A cutoff of 7 is used for a “current major depressive episode” and 8 for “any depression” (current major or minor depressive episode). Both the FCI and the SRQ have been validated and adapted for use in Malawi.

Data on responsive caregiver–child feeding interaction were collected as a pilot using a tool validated in South Africa by Tomlinson and Molteno.²⁸ This tool gains observational information through a video recording of a feeding interaction on “eye contact, following cues, showing love, communication, intrusiveness and synchronicity.” This is then scored using a scoring manual with specific explanations for each area. Validation of this tool through face, content, and concurrent validity was conducted during this study, but results will not be reported on in this paper and are the subject of a future paper.

For any child who died during the study, verbal autopsy tools were used to formalize an understanding of the cause of death.²⁹

Measurement of fidelity (frequency, dose, and adherence). We measured fidelity using measures adapted from the recent PEDS trial.⁵ For each session, HSAs filled out a data collection form which provided information on fidelity dosage (location and timings of individual and group sessions, numbers of participants), scheduling of sessions, cancellation of sessions, number of mothers present at the

sessions, and barriers to attendance (adherence), as well as information on other relevant contextual factors that may have affected running or attendance of the session. This information was then given to the research assistants on a monthly basis.

Quality assessment. Two research assistants who were well trained in the CCD package visited two groups and two individual sessions for each of three community healthcare workers in each area to measure fidelity adherence to the CCD curriculum. At these sessions, information was recorded about the quality of the sessions. This included specific information on their general management and knowledge, as well as whether they had done a demonstration, explained the advice, encouraged and praised the mothers and reviewed and checked knowledge at the end of the session.

Phase III—evaluation phase

Caregiver and HSA narratives and supervisory visit

In order to understand whether the CCD intervention could be effective, we undertook further qualitative work to understand the perspectives and views of both the users (caregivers) and service providers (HSAs). The sampling framework for the interviews and focus groups is shown in Supplementary Table S1 (online only). We aimed to gain information from primary caregivers through the use of a semistructured interview topic guide, which covered the barriers and facilitators to taking part in the groups (time, location, environment, community and partner views); satisfaction with the training and the sense of competence of the caregivers who took part. Topics for community healthcare workers also covered satisfaction with training, incentives, other roles, views of the community, and role in early childhood development work. All interviews and focus groups were audio-recorded, translated, and transcribed. The written recorded views of the research assistants who worked as supervisors attending monthly group and individual meetings were also recorded and reviewed.

Data entry. All quantitative data were entered into a Magpi data system³⁰ by a data entry clerk and exported to SPSS version 25 (see Ref. 31) All qualitative data were transcribed in word and then placed in NVIVO-10 (see Ref. 32) for coding of transcripts.

Data analysis. All quantitative data were analyzed using SPSS version 25. The World Bank Wealth Index was created through a multiple assets analysis.³³ Other basic demographic data were analyzed using descriptive analyses. Data on outcomes were analyzed using Wilcoxon Rank Sum or paired *t*-tests.

Ethics. This study was approved by the University of Liverpool Research Ethics Committee (RETH000536) as well as the College of Medicine Research Ethics Committee in Malawi (P.03/12/1193). We gained prior informed consent from the community leaders as well as written consent from each individual who took part prior to any data collection. We provided each individual with an information leaflet relating to the study, which we read out to him or her again prior to consent. Participants signed (or fingerprint stamped with a witness) an individual informed consent form prior to being enrolled in the study.

Phase I results—development phase

Adaptation of the Care for Child Development package for the Malawian context

After our core group meetings and adaptation processes, the structure for each group session was similar to that utilized in the PEDS trial⁵ (Supplementary Fig. 1A and B online). Each group had one of 12 beginning themes (part 1) which was created after the qualitative work outlined in our previous papers. These themes are shown in Supplementary Figure 1B (online). The format and structure of the groups included a thematic opener, a discussion about feeding, play, and hygiene provided by the HSA, and then a chance for a modeling session by one of the mothers in front of the other mothers with facilitation by the HSA. The session then ended with positives and praise, further discussion, and a prayer.

Phase II results—piloting phase

Coverage of the CCD pilot trainings

Within the catchment area of the six community healthcare workers, there was a total population of 11,670 with 420 children (between the ages of 0 and 2 years) eligible for the study. Our random sample of 60 children who were recruited to the pilot study therefore represented only 14.2% (60 of 420) of the population eligible within the catchment area. The HSAs made it clear that they would not have time

to take on more groups than this within their work plans.

Recruitment. 98.3% (59 of 60) of mothers approached randomly agreed to take part in the study. One mother refused to take part following recruitment as she was not happy having a male worker visit her house on a one to one basis due to concerns regarding her husband. One child in Mangochi died after the commencement of the pilot groups and two children in Chilomoni were not traceable for follow up, leaving 56 participants with pre- and postpilot data. A consort diagram is shown in Figure 2.

Pre- and postpilot data. Baseline demographic data (Table 1) indicated the sample had a similar demographic to the overall population (as provided by the Demographic and Health Survey Malawi 2010).²⁰ Percentages of children in each group according to the World Bank wealth index were similar with the exception that the sample had a lower percentage of the most affluent population percentile. There were fewer women working and a higher proportion of parents with completed secondary education in comparison to the DHS population. Forty-seven percent of our sample was male, with similar nutritional characteristics to the general population of children under 5.

Change in child development, family care, maternal stress, and responsive feeding outcomes

Despite the small numbers ($N = 54$) and wide confidence intervals, there were significant changes in pre- and post-MDAT language and social Z-scores over the 6-month period. There were also significant changes in the FCIs both in FCI1—the availability of household playthings and FCI3—the reported interaction with children but not on FCI2 (availability of books and magazines around the house) (Table 2). Maternal stress (SRQ 20) did not show any significant change from the beginning to the end of the study. It may be important to note that our mean score was 4.24 with 12 women scoring over >8 (20%), the threshold indicative of the presence of a common mental disorder such as depression. We do not report on the responsive feeding interaction scale at this time as we are waiting for further validation results prior to doing so in another paper.

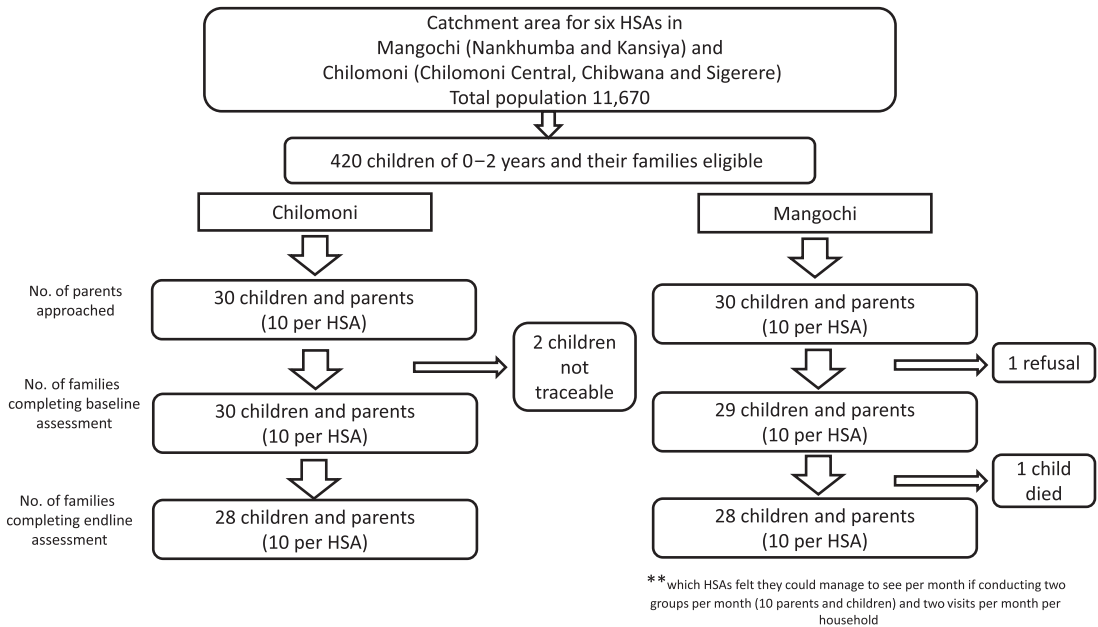


Figure 2. Consort diagram to show flow of participants through the pilot CCD study.

Measurements of fidelity

Frequency and dose. Although there was the potential for the HSAs to conduct a total of 72 group sessions and 720 individual sessions, 62 of 72 (86% of expected) group sessions and an average of 3.6 of 12 (30%) individual sessions were completed in the 6-month period (Table 3). An average group contained 6.3 women (3–10) and lasted 45 min (group) and 30 min for individual sessions. It took an average of 12.5 min to reach the location of the session by foot or bicycle. Locations included local homes, churches, schools, and the chief’s house. Slightly more groups were offered in Mangochi than Chilomoni (Table 3). Barriers to community health-care workers undertaking the intervention included other priorities (e.g., vaccine, child health week, or HIV campaigns), incentives by research studies to do other work or get training (e.g., African medical research foundation), antiretroviral provision spot checks and supervision, and other general responsibilities.

Adherence to sessions. The mean attendance of group sessions by mothers was similar in both locations with mothers attending on average six groups out of 12. A higher percentage of caregivers in the urban setting (Chilomoni) (41.4%) managed to complete over 75% of group sessions offered in

comparison to a rural setting (Mangochi) (16.6%). Percentage of individual sessions completed in both sites was low with approximately one third of caregivers meeting with an HSA for most of the planned intervention sessions and two thirds of caregivers attending for 50% or more of the sessions. Barriers to attendance were multiple but included funerals, need to work and farm (particularly in the rainy season), and need to get governmental provided funds. In each group, the caregivers formed their own committee with a chairman and secretary which helped the groups to continue and form each month.

Quality of visits. The HSAs were good at encouraging and praising caregivers and explaining the advice. The knowledge of the HSA was felt to be good almost all the time; however, one of the HSAs described the perception that they “weren’t fully equipped.” Some commented that they were tired and sped up the sessions to finish as quickly as they could. Many HSAs complained that they felt they should be paid for the extra piece of work and that they should at least be paid for contacting the mothers and engaging with the mothers. HSAs brought their own materials to the group sessions less than half the time. These included cups, spoons, pegs, bottles or tins with beans, cloth dolls, and cars or phones made out of clay.

Table 1. Baseline demographics of 57 participants who completed the Care for Child Development pilot study

	Baseline characteristic N = 57 ^a	Indicator	Study location N (%)			DHS comparison ³²
			Blantyre	Mangochi	Total N (%)	
Family characteristics	SES (wealth index)	Level 2	1 (1.8)	9 (15.7)	10 (17.5)	18.8
		Level 3	4 (7.0)	6 (10.5)	10 (17.5)	19.6
		Level 4	10 (17.5)	1 (1.8)	11 (19.2)	19.6
		Level 5 (richest)	9 (15.7)	0 (0)	9 (15.7)	23.4
		Marital status	Married	23 (40.3)	27 (47.3)	50 (87.7)
	Main carer in house	Mother main carer	27 (47.3)	27 (47.3)	54 (94.7)	
	Mother's age (years)	15–20	6 (10.5)	5 (8.7)	11 (19.2)	–
		21–30	20 (35.1)	15 (26.3)	35 (61.4)	–
		31–40	3 (5.2)	5 (8.7)	8 (14.0)	–
		41+	0	2 (3.5)	2 (3.5)	–
		Mother's education	None	1 (1.8)	0 (0)	1 (1.8)
	Primary		11 (19.2)	19 (33.3)	30 (52.6)	64.8
	Secondary		15 (26.3)	8 (14.0)	23 (40.4)	18.1
	Tertiary		2 (3.5)	0 (0)	2 (3.5)	1.8
	Unknown		0 (0)	1 (1.8)	1 (1.8)	–
	Mother's occupation	Housewife	17 (31.4)	4 (7.0)	21 (36.8)	17.4
		Businesswoman	5 (8.7)	9 (15.7)	14 (24.6)	55.5
		Farmer	1 (1.8)	13 (22.8)	15 (26.3)	N/K
		Student	3 (5.2)	0 (0)	3 (5.2)	N/K
	Child characteristics	Anthropometry	WAZ \leftarrow 2	3 (5.2)	4 (7.0)	7 (12.3)
WAZ \leftarrow 3			0 (0)	2 (3.5)	2 (3.5)	3
LAZ \leftarrow 2			7 (12.2)	4 (7.0)	11 (19.2)	47.1
LAZ \leftarrow 3			4 (7.0)	2 (3.5)	6 (10.5)	19.6
WLZ \leftarrow 2			1 (1.8)	2 (3.5)	3 (5.2)	4
WLZ \leftarrow 3			1 (1.8)	0	1 (1.8)	1.5
WAZ		–0.39 (0.84)	–0.50 (1.37)	–0.45 (1.14)	–1.8	
LAZ		–1.18 (1.4)	–0.31 (1.46)	–0.72 (1.52)	–0.8	
WLZ		0.35 (1.22)	–0.43 (1.22)	–0.09 (1.27)	0.3	

^aTwo mothers did not complete the intervention sessions and are therefore not included in the analysis and are counted as “missing.”

Caregivers consistently brought materials to almost all meetings which included cloth dolls, shaker bottles with groundnuts inside, cups, spoons, and plastic balls.

Phase III results—evaluation phase

In this final phase of work, we undertook qualitative work to further understand the acceptability and feasibility of the intervention. Interviews with caregivers, community healthcare workers, and the research assistants identified a number of core themes, summarized in Table 4. Table 4 outlines some of the quotes which illustrate the main themes that were derived from this work.

Caregiver narratives

We conducted 20 caregiver interviews (10 rural and 10 urban) which were done in caregiver's houses.

Caregiver–child interaction. Caregivers consistently identified examples of the way in which the program had affected their relationship and interactions with the child. Examples of a change in understanding might be,

we would just put children on our backs without even considering that they are people (PC Mangochi);

and an example of a learning point from the groups might be,

Table 2. Table showing changes in Malawi developmental assessment tool, family care inventory, self-reporting questionnaire, responsive feeding interaction measure, and anthropometry

	Preintervention Z-score	Postintervention Z-score	Change in score	95% confidence interval	P value
Malawi developmental assessment tool N = 56					
Gross motor	0.86	1.39	0.53	-1.96 to 0.90	0.45
Fine motor	-0.10	0.79	0.89	-2.4 to 0.64	0.25
Language	-0.02	1.88	1.86	-3.4 to -0.03	0.02
Social	-0.05	0.90	0.94	-1.86 to 0.02	0.04
Family care inventory N = 56					
Availability of play things (FCI1)	3.75	5.27	1.52	2.26-0.78	<0.001
Reported interaction with children (FCI3)	3.88	4.22	0.53	0.97-0.10	0.02
Self-reporting questionnaire (total) N = 56					
	4.24	4.96	0.71	-2.06 to 0.6	0.29
Anthropometry N = 56					
WAZ (overall)	-0.42 (1.48)	-0.91 (1.22)	-0.49	(0.14-0.84)	0.007
LAZ (overall)	-0.68 (1.51)	-1.67 (1.88)	-0.99	(0.48-1.50)	<0.001
WLZ (overall)	-0.06 (1.68)	-0.01	(0.47-0.45)	0.996	

I have learnton how to relate with my child and be attentive towards him/her (PC Chilomoni).

In terms of changes in the child, many caregivers also gave practical examples of the impact of the project on their children. This might include,

I have noticed a change in their children and that they are much more aware (PC Chilomoni),

or the fact that the child has better understanding,

he is now able to know what something is. I am able to send him/her and he/she do exactly that (PC Mangochi).

In terms of the effect of the program on the caregiver, there was more emphasis on this in the urban setting and mothers who did articulate changes within themselves were keen to talk about these and seemed to acknowledge them as important parts of the program. A sense of community support was one of the most central themes to caregivers with many commenting on how the program itself enabled links to be made and created an atmosphere of shared learning and understanding between caregivers. Many mothers explained that they also enjoyed the single (one-to-one) sessions as it gave them a chance to discuss things that they felt they could not reveal in public,

it allowed me to be open (PC Mangochi).

Single (one-to-one) versus group sessions. Many caregivers acknowledged that the single (one-to-

one) sessions were important as they allowed mothers to be more “open and honest” than in the group sessions; however, the importance of meeting in a group was also articulated. One mother mentioned the embarrassment that she had going to a group session,

if we go to the session with a hungry child it wouldn't look good because it would look as if you are not taking proper care of your child.

The group sessions were described as enabling a sense of empowerment and community with caregivers teaching and learning from one another,

we got different views (PC Chilomoni).

This peer support seemed key to caregivers positively appraising the program. According to the participants who were mothers, other family members, such as fathers seemed to have a positive view of the program, though this was often described by participants as occurring after the family member (often the father) was able to see the positive change in the child/mother, rather than from the outset.

Community views. This was a recurrent theme which was expressed by all caregivers. Participants explained that they felt there were some very negative views about the intervention itself (as expressed by the community). This was more evident among participants in the rural site and included comments such as,

Table 3. Table showing numbers of group and individual CCD sessions conducted by HSAs and attended by caregivers in Malawi pilot study

Location		Blantyre			Mangochi			Both locations	<i>P</i> value (CI)	
Group sessions	HSA area N = number of caregivers	HSA 1 N = 10	HSA 2 N = 10	HSA 3 N = 9	HSA 4 N = 10	HSA 5 N = 10	HSA 6 N = 10	All HSAs		
	Maximum offered (out of 12 suggested in 6 months)	9 (75%)	10 (83%)	9 (75%)	13 (108%)	13 (108%)	8 (66%)	62 (86.1%)		
	Total groups offered in each sites in 6 months (max = 36)	28 (77%)			34 (94%)					
	Mean no of groups attended by mothers/6 months (SEM)	6.7 (4.9–8.4)	5.4 (3.7–7.1)	5.3 (3.5–7.2)	8.7 (7–10)	6.2 (4.4–7.9)	3.0 (1.8–4.1)	5.9 (2.8)		
	Mean no of groups (across sites) attended by mothers/6 months (SEM)	5.8 (2.4)			5.9 (3.1)				0.88 (–1.53 to 1.33)	
	Number of mothers completing >75% of sessions offered	3 (30%)	4 (40%)	5 (50%)	2 (20%)	3 (30%)	0 (0%)	17 (28%)		
	Number of mothers completing >75% sessions across sites	12 (41.4%)			5 (16.6%)					
	Number of mothers completing >50% of sessions offered	6 (60%)	4 (40%)	6 (60%)	5 (50%)	6 (60%)	2 (20%)	29 (49%)		
	Total number of mothers completing >75% of sessions across sites	16 (55.2%)			13 (43.3%)					
	Individual sessions	Mean (SEM) number of sessions completed by mothers in 6 months per HSA (potential of 12)	2.4 (1.6–3.1)	1.6 (0.9–2.2)	2.6 (1.6–3.8)	6.9 (5.8–7.9)	4.5 (3.5–5.5)	3.5 (2.1–4.8)	3.6 (2.2)	
		Mean number of sessions completed by mothers in 6 months per area (potential of 12)	2.2 (1.2)			4.9 (2.5)				<0.001 (–3.65 to 1.74)
		Number of mothers completing >75% sessions offered	2 (20%)	4 (40%)	3 (30%)	2 (20%)	6 (60%)	3 (30%)	20 (33.8%)	
		Number of mothers in area completing >75% of sessions offered	9 (31.0%)			11 (36.6%)				
Number of mothers completing >50% sessions offered		5 (50%)	8 (80%)	6 (60%)	8 (80%)	8 (80%)	3 (30%)	36 (61%)		
Number of mothers in area completing 50% of sessions offered		19 (65.5%)			19 (63.3%)					

Table 4. Views of caregivers on acceptability and feasibility of the program

Major theme	Examples of quotes	
	Blantyre	Mangochi
Changes—mother/ child interaction	<i>Taught how to play with our children Making play materials for them I can be following him/her around until he finishes eating</i>	<i>Doing household chores together, the child learns through that I have learnt how to feed the child porridge</i>
Changes—child	<i>My child is now able to eat My child has gained weight</i>	<i>I can see that our children have learnt a lot When I tell her to go get something she responds This program has made my child grow healthy</i>
Changes—mother	<i>I have learnt to interact with people I have learnt the importance of it all</i>	<i>I have learnt about the six groups of food</i>
Sense of community/ peer support	<i>Everyone came with their own views Most felt relaxed and spoke If you had a problem you were able to tell your friends You can help thereby making the community a better place At first they were shy . . . after meeting several times they got used to it</i>	<i>Yes I was relaxed talking We teach each other in groups We can teach others</i>
Group meetings versus single	<i>Single sessions allowed me to be open Group sessions were good because we got different views</i>	<i>I was relaxed both in group and home visits We teach each other in groups Those who feel shy, start to feel relaxed I prefer groups as we teach each other</i>
Fathers views—positive	<i>He said it was good realizing our child would benefit He was ok with it once I explained things</i>	<i>He was happy He was positive My husband welcomed this project he could see the benefit</i>
Community views	<i>During the first days people would say it was a satanic thing Some would say it wasn't important After I explained they were able to understand</i>	<i>We should be able to discuss outside the group to teach others Some people say we are wasting time Some people say they are going to transfuse you blood People were talking about us, perceive us like dogs</i>
Negatives	<i>Meeting when they left their businesses at a standstill</i>	<i>Sometimes I would be away when the HSA came</i>
Changes/suggestions	<i>Ideal to meet during the weekends when there isn't much to do</i>	<i>Being able to demonstrate on our children to see how they are being fed Meeting the group more frequently</i>
HSA as leaders	<i>We the parents would agree to do it I think they had a lot on their plate</i>	<i>Women from our village . . . could be volunteers Sometimes he wasn't visiting so we weren't learning Voluntary people who are willing to work with the HSAs We can take part (in teaching people) as well</i>

people would say it was a satanic thing but i would say no, if the health workers are facilitating it then it's okay, i will continue with my child,

and comments relating to the perceptions of other community members such as,

they treat us like dogs.

Some caregivers reported that once they explained the purpose to other community members, there was some understanding about its importance. In the urban areas, there were some concerns expressed around leaving businesses to come to a group and the need to take preference to be in the field,

it was very difficult especially in the maize planting/harvesting period,

rather than to attend a group session. This highlighted the time pressures faced by caregivers of young infants, particularly where competing demands are important for livelihoods and survival of the wider family.

Community healthcare workers as leaders. When caregivers were interviewed, they provided positive feedback on the leadership of HSAs in some cases citing the benefits of being male HSAs (most common in Malawi),

men are the ones who are good at leading things most of the times (Chilomoni PC IDI).

But many mothers acknowledged that HSAs were busy and not always reliable. Most caregivers suggested either themselves becoming program champions or other mothers in the village on a voluntary basis,

aaah, I think something that directly deals with women should be dealt with women (Chilomoni PC IDI),

but they also recognized the challenges this could present.

HSA narratives

Most HSAs identified the time commitment of the CCD program to be the largest barrier in enabling the program to run well (Table 5). The lack of additional payment for the work involved with the intervention was also identified as a concern by community workers, who identified the possibility of using volunteers to try and spread the workload as an alternative. This was the most negative issue

raised. Most HSAs suggested the use of volunteers to try and spread the workload.

The HSAs also described the timing of the program within the calendar year as to be one of the reasons why the program was less effective to many caregivers who were unable to attend due to other commitments. This was due to the fact that the program ran over the harvesting period (February–May) when caregivers were busy in the field and did not have time to be doing the group work.

Salary and incentives. Many of the HSAs described their unhappiness with the lack of incentives provided in the program. This seemed to be a major issue for all of the workers as the funds provided did not cover beyond expenses and “even then it wasn’t quite enough.” Lack of funding for mobile phone airtime in the urban site and funding for fuel costs in the rural setting appeared to be the financial priorities highlighted by the HSAs.

Explanation of the project to community members and leaders. Community healthcare workers described how important explanation of the project was to both community members and leaders in order for a new program such as this to be implemented and be effective in these remote areas. Many HSAs described the positive changes they heard about or saw in the mother and child,

I have noticed a change in their children and that they are much more aware (HSA, rural site);

A lot of the women have been telling me they see a change in their children (HSA Mangochi).

Views from supervisory visits. Generally, these supervisory visits were positive with praise for the HSA,

the HSA had confidence as he was discussing with the participant, he tried to emphasize the issue of how nutrition, play and stimulation and communication are integrated and how they help in the development of the child in the next two years,

but there were some concerns that the HSAs were sometimes bored of the program:

the HSAs performance is ok though sometimes is kind of reluctant during the work. It felt like he felt like he was just repeating the same things all the time,

or that the HSA had forgotten what he or she should be doing,

Table 5. Views of HSAs on acceptability and feasibility of the program

	Blantyre	Mangochi
Barrier— time/commitment	<i>We have so much work on our hands We have other work to do We also had other jobs on her hands so it was pretty difficult to balance Suggestions—you could also use the community volunteers to work on my behalf when am busy</i>	<i>Time was a barrier as we are also engaged in other work There were no challenges</i>
Barrier—mothers	<i>It was very difficult especially in the maize planting/harvesting period Some women would not make themselves available Initial starting time would have been great because come December we would have finished</i>	<i>Here people are busy with field work Some mothers have gone to the field for farming Some mothers used to come late Most of the programs were done during rainy season so they were farming</i>
Salary	<i>It would all be used for airtime More money for airtime, more toys for the children Just the airtime All the money would end up buying airtime Toys so that women are able to see what we mean</i>	<i>The money was little so it could not even reach home The money was really not enough</i>
Overall positives	<i>Mothers expressed an interest of joining the group again All in all it was good</i>	<i>Yes, I think it was very good</i>
Explaining the project	<i>When we sat down with the mothers they understood the good that would come out The old mother's group testified to the goodness to their fellow women In the beginning such as 'this is all satanic,' but right now things are well</i>	<i>Some people would ask and we would tell them about the project The community – they speculate they will be like Satan is coming The community never thought this project would be possible</i>
Changes in mother/child	<i>Children as well as their mothers have both changes in terms of thinking and behaviour I have noticed a change in their children and that they are much more aware A lot of the women have been telling me they see a change in their children</i>	<i>They can differentiate between green, blue and red cups Yes we saw many difference in both children and mothers from start to end</i>

The performance is alright although sometimes he loses track of the themes and needs to be reminded.

this may indicate potential loss of fidelity with time and the need for ongoing reinforcement of program content.

Discussion

This study demonstrates an example of how beneficial the use of a feasibility and pilot study when conducted in a logical and detailed way can be. In using this detailed approach, we have been able to develop a program that was more specific and tailored to Malawian caregivers and their needs (phase I: development phase), have been able to evaluate

not just the effect sizes of the intervention on our pilot group (for further studies) but also the fidelity of the implementation (phase II: intervention intensity, adherence, recruitment and retention, timings, and place of visits), and then a final phase of study (phase III: evaluative phase) looking at the acceptability and barriers to conducting a program in the longer term. Without this detailed work, we will not be able to scale up a program that will be feasible, sustainable, and acceptable in the longer term.

We have created a program with both group and individual sessions, which we felt could be provided by HSAs. We utilized themes raised in our extensive qualitative work to create a program that would be specific and focused on these themes. There were

Table 6. Approaches to implementation and key lessons learned for future scaling up from Malawi CCD pilot and feasibility study

Approach to implementation	Outcome from CCD feasibility study, Malawi	For future scaling up
Group or individual visit method of implementation?	Group implementation of CCD was feasible, enjoyable, and attendance was over 50%. Many younger mothers, some with depression attended. Individual sessions are more time-consuming although beneficial.	Implementation of CCD through women's groups in the community run through women community leaders.
Content of sessions	Nutrition and developmental stimulation, play, and responsivity were all possible to discuss in the group; however, topics were repetitive.	Additional topics were suggested including women's income generation methods which can be added into the content of sessions.
Implementation of CCD intervention to mothers	Lack of time for HSAs to implement CCD training directly to mothers due to conflicting roles and time commitments: Only 14% of total population of women and children in catchment areas were provided with CCD training when program was included in HSA monthly schedule. Women formed their own committees in groups with lead, communicator, and secretary. Women felt that other women in the community could lead these groups.	Women community leaders can be trained to run their own groups with the creation of their own committees to enable universal coverage of intervention.
Timing and location of implementation of CCD	Commitments from mothers relating to work in the household important to consider. Location was variable but equally feasible.	Groups best organized by mothers at time which suits mothers—usually after work in home done in afternoons. Women to organize location on their own.
Supervision of CCD implementation through women's groups	HSAs seen as respected members of the community and listened to by community members and women. HSAs had time to review groups once a week.	HSAs to supervise women's groups in each village.
Which cadre of worker to supervise CCD work in future	Ministry of Gender and Social Welfare workers less prominent but have specific training and remit in ECD (seen by community leaders and chiefs as those who should lead on ECD) but Ministry of Health HSAs much more common and available.	ECD or HSA workers to supervise women's groups in each village.
Need for community engagement through men/leaders in community	Stigma relating to conducting programs promoting "play" an issue. Mothers seen within themselves as being lazy for not being at home working.	Programs to take place at times which suit mothers. Need for community engagement through supervisors with village health committee and village leadership structures.
How often	HSAs only managed one group per month, whereas women were happy to meet more regularly on their own.	One group per week can be implemented through women leaders but HSA or ECD worker to supervise once a month.

no issues about the content of the sessions when they were conducted, although some community healthcare workers identified that the core content of the CCD package was repetitive to parents when provided twice a month and that the content needed to be developed or changed further over time. In future programs, regular supervisory visits to plan sessions to think through how to bring local agendas into each session to provide some variety to the sessions might be helpful.

In our early census work, we have identified significant challenges with coverage of a universal program of CCD in a real-world setting through HSAs in Malawi. In each district, HSAs are employed to conduct a wide variety of health task and roles for all members of the community.^{13,14,34} In our study, the number of children under the age of 2 in all our areas covered by the six HSAs amounted to 420, roughly seven times the population that the HSAs demonstrated they could manage when asked to conduct groups in real-life settings in Malawi. Our findings indicate that due to the high existing workload of HSAs it is not feasible for them to actually conduct individual CCD visits and groups for every child under age 2 in their catchment area. It is clear that future efforts to scale up a program need to find another cadre of staff who can do the actual individual visits and groups in order to target all children (e.g., take shifting through volunteer caregivers from the community) with HSAs playing a supervisory role. Another option might be to only include certain children who are more at-risk (e.g., have lower nutritional indices and less enabling socioeconomic indices) and should be targeted through the training of HSAs. HSAs certainly may benefit from training; and the learnings from the CCD programs, which promotes strengthening of relationships and building of observational skills linked to maternal child interaction, will be beneficial for their day to day care of the children and families they do see. Both of these options could be piloted in a further study prior to scaling up. It was clear that the HSAs were very busy and lacked enough time to conduct our program. Our fidelity data clearly showed that the HSAs managed approximately 87% of the groups but only 67% of the individual sessions. They had competing interests particularly from other programs that were better incentivized than our program. Another cadre of worker or a volunteer who is supervised by an HSA

or an ECD program lead may enable better cover and time for the program.

While we had excellent recruitment of participants within our study, problems with retention and adherence to groups developed as the study progressed. The mothers created times of day for the program where they felt they could best manage it (after conducting housework and other responsibilities) in a location that worked best for them and which the HSA could attend easily. Despite this, many caregivers managed only to attend half or fewer of the sessions due to competing interests, in particular harvesting, attending funerals, and caring for other relatives.

Although our pilot study had only 59 participants, we have demonstrated that our outcome measures demonstrated significant changes in language development on the MDAT as well as significant changes on the FCIs. Both these measures were feasible to use as an outcome measure and showed good validity in this setting. With this small sample size, we have not adjusted for covariables such as socioeconomic status, education, and frequency of group or individual intervention. We identified no significant change in the SRQ although 20% of caregivers screened positive for depression (SRQ cutoff >8). While participatory women's groups in low- and middle-income countries, such as India, have been associated with some improvement in depressive symptomatology, the intervention may not have been specific enough to target the mental health needs of this subgroup of caregivers, which warrants further investigation.³⁵

Our study has highlighted the need to adapt the implementation of the CCD program to the Malawi context, on the basis of our findings during the feasibility (phase II) and evaluation (phase III) studies. Although we conducted community sensitization at the beginning and end of the study with chiefs and leaders in all villages where the CCD study took place, we did not continue to conduct regular community groups with community members and fathers during the implementation phase of the study. The feedback we received from caregivers regarding community perceptions of the program indicates that further scaling up requires more assertive engagement with community leadership and more frequent communication to improve the provision of information and facilitate community understanding of the intervention. This may

Box 1.**Key messages**

- Few studies have undertaken detailed mixed methods research to understand the barriers and facilitators to enabling parents and caregivers to benefit from programs that encourage child stimulation, early responsive communication, and nutrition and are very limited particularly in African settings.
- Often studies do not undertake research to identify how early child development stimulation programs can be provided in a sustainable way through existing health or social welfare systems.
- Without this understanding, it is not possible to integrate programs which will be sustainable and acceptable in resource-limited settings.

What this paper adds

- Programs that encourage child stimulation, early responsive communication, and nutrition in a very resource-poor setting in Malawi are acceptable both by parents and health surveillance assistants.
- Measurements using culturally valid simple tools for assessing early child development alongside family care indicators can show sensitivity to change and can be used in scaled up programs.
- The burden on time for health surveillance assistants to undertake this program is high and other cadres of workers supported through health surveillance assistants may enable sustainable systems.

improve acceptability and adherence to future interventions.

We highlight the lessons learned from the CCD pilot and feasibility study and the approaches to implementation that may enhance the program in the future (Table 6). The feasibility study demonstrated the added advantage of utilizing a group method, alongside individual intervention, and highlighted alternative providers such as local women leaders in the community. This could enable greater flexibility in timing and location of interventions that can be provided by a community healthcare worker and improve uptake and participation in the community. Further assessment of the appropriate cadre of worker to supervise such a community-led intervention is required, particularly whether this would be best suited to an ECD worker or senior community healthcare worker. Other suggestions to improve the intervention package included incorporating income-generating activities (possibly micro-finance) through and within the group. This may assist with addressing the competing demands that caregivers face, and improve other aspects of family and community welfare and functioning, but requires careful further investigation.

Our study is one of the first to provide a detailed approach for understanding the feasibility of the

CCD in a real-world setting in Africa. The strength of the study is the mixed methods approaches that were taken. This was shaped by maintaining a clear process for undertaking the study through the MRC framework for complex interventions. We undertook extensive early qualitative work to adapt the training package, piloted the tool, used detailed processes to understand fidelity of the implementation, and conducted assessments of acceptability of the program. The study only reports on the planned piloting of the CCD package with 60 families in rural and urban settings in Malawi, a process we felt was important prior to undertaking a larger study. The numbers in this study provide us with information for a future larger trial; however, larger numbers would have provided better information, particularly with regard to responses from the intervention. At this stage, we did not conduct a randomized trial with a control group. Future studies would benefit from this type of design, likely conducted as a step-wedge waitlist-type model. Our study has demonstrated the difficulties in providing the CCD package through HSAs. A study to undertake the same detailed research procedures but with another type of worker would have been incredibly beneficial to conduct simultaneously. This will be needed prior to any future scaling up of our program.

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Supporting information

Additional supporting information may be found in the online version of this article.

Figure S1. Structure of group sessions (A) and themes for part 1 of each group session (B) in the Malawian version of the CCD.

Table S1. Sampling framework for focus groups and semistructured interviews with caregivers and health workers to understand acceptability of the CCD pilot in Malawi.

Competing interests

The authors declare no competing interests.

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