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Use of an adapted participatory learning and action cycle to increase knowledge and uptake of child vaccination in internally displaced persons camps (IVACS): A cluster-randomised controlled trial

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ABSTRACT

Background: Vaccination is a key public health intervention that can reduce excess mortality in humanitarian contexts. Vaccine hesitancy is thought to be a significant problem requiring demand side interventions. Participatory Learning and Action (PLA) approaches have proven effective in reducing perinatal mortality in low income settings and we aimed to apply an adapted approach in Somalia.

Methods: A randomised cluster trial was implemented in camps for internally displaced people near Mogadishu, from June to October 2021. An adapted PLA approach (hPLA) was used in partnership with indigenous 'Abaay-Abaay' women's social groups. Trained facilitators ran 6 meeting cycles that addressed topics of child health and vaccination, analysed challenges, and planned and implemented potential solutions. Solutions included a stakeholder exchange meeting involving Abaay-Abaay group members and services providers from humanitarian organisations. Data was collected at baseline and after completion of the 3 month intervention cycle.

Results: Overall, 64.6% of mothers were group members at baseline and this increased in both arms during the intervention (p = 0.016). Maternal preference for getting young children vaccinated was >95% at baseline and did not change. The hPLA intervention improved the adjusted maternal/caregiver knowledge score by 7.9 points (maximum possible score 21) compared to the control (95% CI 6.93, 8.85; p < 0.0001). Coverage of both measles vaccination (MCV1) (aOR 2.43 95% CI 1.96, 3.01; p < 0.001) and completion of the pentavalent vaccination series (aOR 2.45 95% CI 1.27, 4.74; p = 0.008) also improved. However, adherence to timely vaccination did not (aOR 1.12 95% CI 0.39, 3.26; p = 0.828). Possession of a home-based, child health record card increased in the intervention arm from 18 to 35% (aOR 2.86 95% CI 1.35, 6.06; p = 0.006).

Conclusion: A hPLA approach, run in partnership with indigenous social groups, can achieve important changes in public health knowledge and practice in a humanitarian context. Further work to scale up the approach and address other vaccines and population groups is warranted.

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1. Introduction

Each year immunization averts an estimated 2.5 million deaths among children under five years old. Weak health systems are a

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major constraint on the effectiveness of immunization programmes and these challenges may be exacerbated in fragile states and humanitarian contexts [1,2]. In addition to these supply side constraints, improving demand for vaccination services is seen as a critical issue. Vaccine hesitancy was listed by WHO as one of ten major threats to global health in 2019 [3]. However, the determinants of the beliefs and behaviours related to vaccination are complex and context specific [4,5].

Vaccine-preventable diseases are prevalent in Somalia and under-five child mortality is high, at 117 per 1,000 live births [6]. Measles is a leading cause of death in children under the age of five

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and large-scale outbreaks caused high levels of excess mortality during both the 2011 famine and the 2017 food crisis. Despite this, only about half of children are immunized against the six major childhood diseases [7]. Nationally, measles vaccination coverage remains low and was only 24% in a recent survey of IDP populations in Mogadishu [8].

Somalia has been chronically affected by conflict since 1991, together with recurrent natural disasters such as droughts [9–11]. Internally displaced persons (IDP) are the population group most frequently affected by acute malnutrition and disease outbreaks, as they often live in *peri*-urban camps that lack access to essential services. Studies have also indicated a low knowledge of health and nutrition issues in IDP and a range of factors leading to vaccine hesitancy in the broader population [12,13].

The women's group Participatory Learning and Action approach is based on the ideas of Paulo Freire and the importance of social empowerment to address health issues. To achieve this, teachers and learners engage in a dialogue, exchanging ideas and experiences, and implementing a cycle of learning, action, and reflection. PLA interventions have been effective in improving maternal and newborn health in a variety of countries and, more recently, have been used to reduce the risk of type 2 diabetes in Bangladesh [14,15]. The mechanisms and factors behind successful implementation of this approach have been described in developmental contexts in Asia and Africa [16–18]. However, the involvement of stakeholders, and the political and security context require particular consideration when implementing social interventions in a conflict setting.

The PLA approach can be implemented either with new groups, specifically formed for that purpose, or with pre-existing endogenous social groups. Abaay-Abaay groups typically comprise 10– 20 members and are also known as Abay Siti. They are traditional female social groups that emerged in the 1880s [19]. They are found in many parts of Somalia and usually meet every week or month. Anecdotal reports, and our own formative research, indicate that the groups are commonly found in stressed and displaced populations, including most IDP camps in Mogadishu, and in this study, we chose to implement the PLA approach in partnership with the pre-existing Abaay-Abaay groups.

The 'Improving vaccination awareness & coverage in Somalia' (IVACS) study aimed to assess whether an hPLA intervention, implemented in partnership with endogenous women's social groups, could improve the uptake of vaccination services for children living in IDP camps, by reducing hesitancy and barriers to access. We tested the hypotheses that an hPLA intervention would improve maternal knowledge, vaccination coverage, and attitudes to vaccination.

2. Methods

2.1. Setting

The trial took place in IDP camps within the Afgooye Corridor, in *peri*-urban Mogadishu, Somalia. This area contains the majority of IDP camps in Mogadishu, which are semi-permanent and the cumulative result of multiple protracted crises. The IDP camps are privately-run settlements, often managed by informal settlement managers or 'gate keepers'. The camps are often over-crowded, may lack basic sanitation and health services, and residents risk recurrent evictions [20]. People living in the camps are mainly dependent on humanitarian assistance and casual labour. Action Against Hunger has been working in Somalia since 1992 and has been implementing integrated humanitarian assistance programmes in the Afgooye Corridor for the past 28 years [21].

2.2. Intervention design

The intervention involved the implementation of an adapted Participatory Learning and Action (PLA) cycle in partnership with indigenous community groups. Abaay-Abaay groups (AAG) are traditional female social groups that are found in many parts of Somalia and usually meet every week or month. The groups typically have 10-20 members and meeting activities include sharing popcorn, roasted coffee beans, drinking tea and/or coffee and discussing local issues, and singing traditional religious songs (Digri). Women pay cash or in-kind for the meeting organization. Groups are also commonly found in stressed and displaced populations, including most IDP camps in Mogadishu. The majority of members are from the same clan, village, or district and live within the same IDP camp or group of camps. Groups are led by the Khalifada (lead woman), who is usually elected by the group members based on attributes including her perceived leadership ability, and ability to provide exemplary childcare.

During the trial preparations we identified and mapped camps in the areas of the Afgooye Corridor where Action Against Hunger is operational. We found 12 camps where Abaay-Abaay group leaders were resident and interviewed the Khalifada within these camps. All of them agreed to participate in the study and to invite the facilitator to the meetings if their camp was randomly selected to be in the intervention arm.

Before the intervention started, we adapted the PLA manual developed by Women and Children First (UK) for use with Abaay-Abaay groups in IDP camps in southern Somalia. Adaptation to this humanitarian emergency context involved reducing the number of group meetings from eleven to eight and reducing the number of stakeholder meetings to only one. These adaptations were designed to ensure the approach could be implemented within the short timelines and security constraints that are often associated with humanitarian response programmes. We labelled the adapted PLA approach hPLA. The adaptation also included the addition of a final, non-facilitated, meeting to assess if AAG members would sustain interest in child vaccination and/or related topics after the end of the facilitated PLA cycles. We also developed localized picture cards for common childhood health problems in IDP camps. Finally, we adapted the reporting tools such as the group register, the meeting reporting forms and monthly reporting tools.

The group Facilitators were two locally recruited women who had completed university education, and were recruited by the study team following assessment of their communication skills, motivation, familiarity with the study areas, and language skills. They received a four day training about the PLA approach, group facilitation, and the common vaccine presentable childhood diseases, their prevention and control, vaccination schedule, types of routines vaccines and benefits of vaccination. Each facilitator was responsible for running two to three PLA group session each week.

The IVACS hPLA intervention entailed weekly facilitated AAG meetings for a period of two months (from 27/07/2021 to 29/09/2021). An average of 38 members attended each meeting, led by an external facilitator who was recruited to guide participants through a four-phase PLA cycle focused on identification, prevention and control of child health problems, and evaluation of the group's activities. All the groups were pre-existing and open to all community members and women of reproductive age and adolescent girls; those who were pregnant or had children were particularly encouraged to attend. There were five Abaay-Abaay groups, one in each of the five intervention camps. In total, there were 40 group meetings facilitated by two female facilitators across the 5 intervention camps.

In phase one of the PLA intervention cycle (see supplementary materials, Fig. 1), AAG members identified 9–16 child health problems and then used a voting system to prioritize three of them. In all camps, measles and pneumonia were selected as the first two, followed by pertussis, scabies, malnutrition, skin diseases, and cholera. In phase two, AAG members identified disease prevention and management practices, and barriers to implementing such practices. Popular strategies included awareness raising, mobilizing mothers during vaccination days, helping working mothers to take their children to vaccination centres, and environmental cleaning.

After phase two, there was a stakeholders' meeting where the research team facilitated a meeting between AAG member and the humanitarian agencies in the area who were providing vaccination services. To try and ensure decision makers were present, middle-management personnel who did not work directly in the health facilities were invited and all agencies sent health officers. Camp leaders, fathers, religious leaders, and other women who were not part of the routine AAG were also invited to attend. Two such meetings were held; one for a group of two camps and one for a groups of 3 camps that were close to each other. In these meetings, AAG members presented the progress of their PLA meetings to the stakeholders and shared the challenges that they were facing in health seeking, which included long distances to health facilities, long waiting times at facilities, irregular opening of vaccine vials, frequent stock-outs, and other issues. One of the agencies (Action Against Hunger) that was running mobile teams in the Khada area offered to extend their mobile teams to the intervention camps as a solution to their challenges.

In phase three, AAG members planned and implemented solutions and strategies, that had been developed in phase two. Facilitators also visited selected households to check if women were Vaccine xxx (xxxx) xxx

receiving any messages and if they received the right messages. If facilitators felt that some women didn't receive any information and/or didn't retain the information given, they requested volunteer mothers to go back for more sessions. This solution implementation phase lasted for two weeks. In addition, in this phase, mobile teams from the agency that offered to extend their mobile teams during the stakeholders' meetings started visiting the camps and vaccinating children up to the age of 23 months with all the routine vaccines. Due to national policy constraints, only measles vaccine was given to children who were older than 23 months but younger than 5 years.

In phase four, groups reflected on their progress in addressing common childhood health problems. All five groups in the intervention camps evaluated strategies through self-reflection. These meetings were facilitated by one of the study facilitators using a self-evaluation tool. Feedback was also provided to the group about how things have changed as a result of their interest and solution implementation. Lastly, non-facilitated meetings were attended to assess if groups sustained interest in child vaccination and/or related topics after the end of the facilitated PLA cycles.

During group discussions, facilitators took extensive notes and captured a summary of the discussion points. They also recorded attendance on paper forms and presented the reports to the research officer each week. The research officer supported the facilitators and provided structured supervision. She conducted observation of facilitators at these meetings, using a checklist, to explore fidelity to the participatory method. She used the structured observations to give facilitators scores out of 30 on whether or not the facilitation process was clear, there was enough time allocated for the session, participants were interested, there was enthusiasm for the next meeting, and the Khalifada was happy

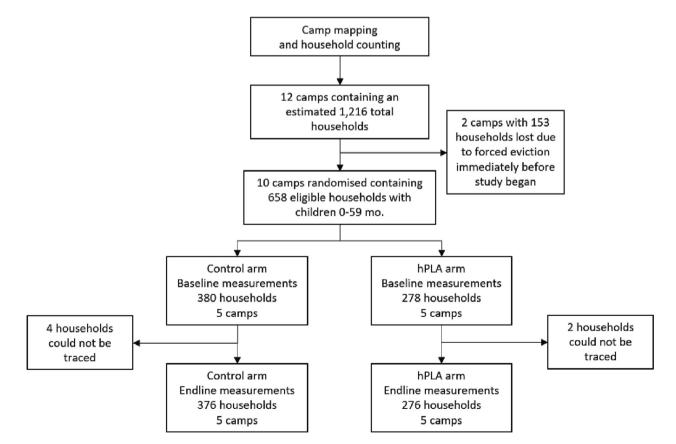


Fig. 1. Study flow chart for households.

with how the meeting went. The level of participant interest was evaluated qualitatively by observing side-talk, attention, and participation in discussions.

The five camps allocated to the control group received the usual standard of health care. Community health workers also routinely carried out outreach programs where they encouraged families to take their children for vaccinations. In the control camps, women continued with their usual AAG meetings. There was no facilitation by study staff and to avoid any possible observer effect the meetings were not observed. However, after completion of the endline data collection, the research officer visited the control camps and provided feedback about the study findings.

2.3. Trial design

We implemented a cluster-randomised controlled trial with IDP camps as the cluster units. We initially mapped the location of 187 potential clusters in the last quarter of 2020. We used three criteria to select clusters for inclusion in the trial: an active Abaay-Abaay group should be functioning in the camp; the group leader (Khalifada) should be resident in the camp; the selected camps should be at least 0.5 km away from any other camp included in the trial.

We planned to include 12 clusters in the study with an average of 65 children aged 0–59 months per cluster. However, immediately before the study was due to begin two of the selected camps were forcibly evicted. To map additional areas and locate new camps for inclusion was not thought to be feasible within the available budget and timeline. It was therefore decided to proceed with the trial using the remaining 10 camps.

We randomly allocated half of the 10 clusters to the hPLA intervention (see Fig. 1). The PI performed cluster randomisation in London using random numbers generated in Excel. As with most interventions of this nature, participants could not be 'blinded' to allocation status. Within each cluster, all households with children aged <5 years were included in the study (n = 658); together with all the children aged <5 years (n = 1269) and their mothers/caregivers that were members of these households (n = 663) (Fig. 2). The cohort was closed so that only the households and individuals enrolled at baseline were followed up at endline, 3 months later.

2.4. Sample size

The sample size required to test for a minimum increase of 20 percentage points in measles vaccination coverage was assessed using clustersampsi in Stata v16 (StataCorp. 2015. Release 14. College Station, TX: StataCorp LP). Based on data collected during previous intervention trials in the area, we expected to see a baseline measles vaccination coverage of around 60% [22]. We also assumed an average population of 65 children (aged 0–59 months) per cluster, an alpha risk of 0.05, a power of 0.8, and an ICC of 0.04. We found that we would need to sample 6 clusters (camps) per arm. These were expected to contain a total of approximately 780 households, with equal numbers in each arm. As described above, two cluster were lost immediately prior to starting the trial and the study proceeded with only 5 clusters per arm.

2.5. Data collection

We collected information at the household and individual level at baseline in June/July 2021 (see Table 1), and at endline in October 2021. All data was collected using a structured questionnaire, translated into Somali, on mobile Android devices running Open Data Kit (ODK). Completed questionnaires were uploaded to the OnaData servers, and the data was compiled as .csv files. Prior to baseline data collection, we implemented a three-day training session for enumerators and supervisors and prior to endline we ran a two-day refresher course. During these training sessions, we piloted and revised the questionnaires. All teams were supervised in the field during data collection. During each round of data collection, if we could not reach a household after repeated attempts or any of its members were absent, we enquired about the reasons for this absence from family or neighbours.

2.6. Household characteristics

We collected data on the numbers of household members, the sex of the household head, the time since they became internally displaced, and when they moved to their current camp of residence.

Using a questionnaire, we obtained data on the household's main water source, if they treated the water before drinking, and how they disposed of child stools. An inventory of household assets was obtained using an 8-item checklist and an asset score was calculated for each household (possible range 0-8). The coping strategies used by each household was assessed using the reduced strategies index (rCSI). The rCSI is a simple tool applied in different contexts that assesses the frequency, in days within a 7-day period, and the severity of five coping strategies commonly used by households, when they cannot access enough food [23]. The five coping strategies are: consuming less preferred foods, borrowing food, reducing meals, reducing portion sizes, and restricting adult's food consumption to preserve children's food consumption. We summed the frequency responses to these strategies to create an index where higher scores indicate greater food insecurity. The possible range of the rCSI was 0-35. Rations of prepared food were distributed in this setting, so we also asked how many times, within a 7-day period, the household relied on these wet rations.

2.7. Mother/Caregiver characteristics and knowledge on health and nutrition

We asked mothers/caregivers their age in completed years, their level of education, if they could read or not, which languages they spoke, and if they slept under a mosquito net during the previous the past night. We also asked about their area of origin and their clan. We assessed knowledge of child health topics using a list of 12 questions. The knowledge score was calculated for each caregiver using the scoring scheme shown in **Table A1**. We asked about membership of Abaay-Abaay and Ayuuto (microcredit) groups and the number of meetings they had attended during the last 30 days. We also asked if the caregiver had received any vaccinations as a child or during pregnancy, and if they would like their own child to receive vaccinations against diseases such as measles.

2.8. Child characteristics

When possible, we ascertained the children's date of birth from health record cards. Where this was not available, we determined the month and year of birth using a calendar of local events. Age was determined at baseline only and was incremented by 3 months to give the estimated age at endline.

We collected data on vaccination coverage, based on the Somalia Expanded Programme on Immunisation (EPI) schedule (see **Table A2**), by checking the child's health card at baseline and endline, or by mothers/caregivers recall if no health card was available or there was no entry for a particular vaccine [24]. 'Penta series completion' was defined as a child aged from 12 to 27 mo. who had received all 3 doses of the pentavalent vaccine. 'Timely vaccination' was calculated for all children aged 0–59 months based on whether they had received all the vaccines that they were eligible to receive according to their age and the national immunization schedule. We also asked mother/caregivers whether the child

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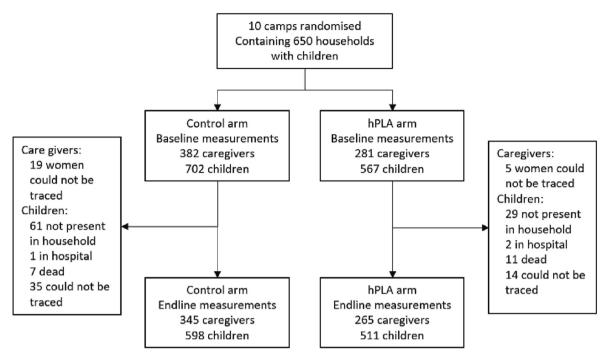


Fig. 2. Study flowchart for caregivers and children.

had slept under a mosquito net the previous night, whether they

had been unwell in the last four weeks, and if care was sought for serious conditions.

Table 1

Baseline characteristics.

Household characteristics	Control (n = 3	80)	hPLA (n = 278		
	Mean/%	95% CI	Mean/%	95% CI	P-value
Household size (n)	6.7	6.17, 7.18	6.5	5.88, 7.03	0.520
Female head of household (%)	7.9	2.70, 20.91	22.7	4.49, 64.64	0.339
Time as IDP (years)	8.01	2.66, 13.36	4.42	3.10, 5.75	0.175
Time in current camp of residence (mo.)	15.9	9.39, 22.50	17.9	11.13, 24.61	0.654
Household uses tube well or piped water (%)	100.0	_	99.6	97.00, 99.96	0.318
Household assets score (possible range 0-8)	2.38	1.38, 3.38	2.74	2.42, 3.05	0.458
Consumption of wet rations in last 7 days (%)	12.7	2.71, 41.68	21.2	5.04, 57.78	0.551
Reduced Coping Strategies Index (rCSI) score	11.49	9.80, 13.19	12.10	9.14, 15.07	0.694
Mother/Caregiver characteristics	Control (n = 3	82)	hPLA (n = 281		
	Mean/%	95% CI	Mean/%	95% CI	P-value
Age (years)	31.3	27.8, 34.7	29.4	27.6, 31.3	0.312
Educational achievement (%)					
No formal education	94.5	91.35, 96.55	90.8	87.58, 93.17	0.050
Primary education	5.24	3.29, 8.23	6.41	2.84, 13.82	0.650
Secondary or above	0.26	0.03, 2.21	1.10	1.18, 6.74	0.048
Clan (%)					
Darood	0.52	0.17, 1.65	0.71	0.22, 2.32	0.692
Digil and Mirifle	59.16	35.58, 79.17	64.06	39.18, 83.14	0.745
Dir	4.45	2.27, 8.53	4.27	0.61, 24.43	0.963
Hawiye	14.40	3.06, 47.29	9.61	3.90, 21.76	0.638
0.51	21.47	8.61, 44.22	21.35	9.64, 40.86	0.992
Received vaccinations as a child (%)	26.70	12.91, 47.24	36.65	19.94, 57.34	0.414
Received a vaccination during last pregnancy (%)	75.39	65.50, 83.18	87.54	84.79, 89.86	0.016
Children characteristics (aged 0–59 months)	Control (n = 7	02)	hPLA (n = 567		
	Mean/%	95% CI	Mean/%	95% CI	P-value
Age (months)	26.3	24.0, 28.6	27.2	26.3, 28.2	0.424
<12 months (%)	21.4	15.5, 28.7	20.5	18.1, 23.1	0.777
12–23 months (%)	19.8	15.2, 25.5	23.3	17.8, 29.9	0.348
24–59 months (%)	58.8	50.2, 67.0	56.3	52.2, 60.3	0.552
Male (%)	51.0	46.9, 55.1	52.7	46.6, 58.8	0.608
Slept under a mosquito net last night (%)	5.0	2.7, 9.1	15.5	5.7, 35.6	0.141
Had health problem in last 4-weeks (%)	10.1	4.9, 19.7	13.2	4.0, 35.7	0.678

¹ 0.5 is a classification of ethnic groups that is widely used in Somalia. It includes a number of marginalised and minority clans, including the Bantu Somalis.

2.9. Data management and analysis

Completed questionnaires were uploaded to OnaData servers and the compiled data was subsequently downloaded from the server as.csv files and cleaned using Excel 2019 Power Query. Data was analysed and stored on encrypted and password protected devices. We undertook intention to treat data analysis using Stata v17. Prevalence and mean estimates at baseline were calculated accounting for the cluster design using the Stata svy commands. For outcome variables we assessed impact using mixed effects, multilevel regression models: linear, or logistic, depending on whether the outcome variables were continuous or categorical. Models included cluster as a random-effect, and dummy variables denoted the time-point (baseline or endline) and intervention as fixed-effects in the model. All models included baseline data to account for any observed differences at baseline and were adjusted for age, sex, education, and previous experience of vaccination, as appropriate. We used robust variance for calculation of standard errors. Mean and prevalence estimates, adjusted for the model covariates, were obtained using the margins post-estimation command. Study documents and data will be retained for 10 years as per institutional guidelines.

2.10. Outcomes

The primary outcomes of the trial were: measles vaccination coverage, defined as the proportion of children aged 9–59 mo. who had received MCV1; Penta series completion, defined as the proportion of children aged 12–27 mo. that had received all 3 doses of Penta vaccine; Timely Vaccination, defined as the proportion of children, aged <60 mo. at baseline, who had received all their vaccinations according to the EPI schedule and their age (**Table A2**); mother/caregiver's knowledge of child health; and preference for getting their children vaccinated. Following trial registration with ISRCTN, the name of the 'EPI vaccination coverage' outcome was changed to 'Timely Vaccination' to align better with terminology used in the literature, and 'Penta series completion' was added as an additional indicator of vaccination coverage.

The secondary outcomes of the trial were: child morbidity and mortality, possession of a home-based health record card, number of Abaay-Abaay groups successfully established and level of participation, safe conduct of group activities measured by direct observation; acceptability and utilisation of PLA training materials; completion of learning cycles and topic coverage by groups measured by direct observation; and any adverse events associated with group membership. In the study protocol we had also planned to conduct verbal autopsies for deceased children but due to delays in initiating the study caused by COVID-19 restrictions it was not possible to conduct these interviews within the available timescale. Following trial registration, the 'possession of a health record card' indicator was added as an additional secondary outcome.

2.11. Ethics approval and trial registration

The Ministry of Health & Human Services of the Federal Republic of Somalia (reference: MOH&HS/DGO/0381/feb/2021) and the Research Ethics Committee of UCL (project ID: 4684/003) granted ethical approval. The study was registered on 3rd August 2021 with ISRCTN (ISRCTN83172390). Informed verbal consent was obtained from camp leaders in all IDP camps before starting data collection. In addition, following a detailed explanation of the study objectives and data collection process, informed verbal and written consent was obtained from caregivers at the household. Study participants were informed about their right to withdraw from the study and that participation or withdrawal from the study would not affect their entitlement to humanitarian assistance. Confidentiality and data security of the respondents was ensured by use of password protected encrypted devices.

3. Results

3.1. Participant flow

Figs. 1 and 2 show the household, caregiver, and child participant flow for the study. Overall, there was a very good follow-up of households (99%) and a good follow-up of caregivers (92%). For children, a sample of 1,269 children were included in the study at baseline and follow-up was 85% in the control and 90% in the intervention arm. Unfortunately, a total of 16 children died during the trial period, 10 boys and 6 girls. The number of deaths in the control and hPLA arms were comparable (7 and 9 deaths, respectively) and the overall death rate was 0.22 deaths/100 childmonths. The observed mortality rate was similar to that previously reported in this area outside of acute emergencies [22,25]. Other causes of loss to follow up included children being away from the household at the time of the interview and those that could not be traced.

3.2. Baseline characteristics

Table 1 shows baseline characteristics of households, mothers/caregivers and children. Most households reported being male headed and the average household size was 7. Almost all households reported access to piped water. Households reported a high consumption of wet food rations from humanitarian organisations during the previous seven days. Household asset scores and the rCSI were well balanced between camps. We found no significant differences in any of the household characteristics between study arms.

The mothers/caregivers from the sample were on average 30 years of age and over 90% of them had received no formal education. Mother/caregivers in the intervention arm were more likely to have received secondary or higher education although only 1% had benefitted. About one third recalled receiving vaccinations as a child and about 8 out of ten had been vaccinated during pregnancy, with a higher proportion in the intervention arm.

Children were on average 27 months old and there were slightly more males than females. One in ten children reported sleeping under a mosquito net the previous night, and a similar proportion reported having been ill in the previous 4-week period. There was no significant difference in baseline child characteristics between study arms.

3.3. Implementation of the intervention

The planned hPLA intervention was successfully implemented in the 5 intervention camps and direct observation of group meetings revealed the training materials were acceptable and well received. However, it should be noted that the original plan to train and support the Khalifada to implement the hPLA meeting cycle was changed due to the low literacy level that was reported during the interviews conducted prior to trial commencement. Instead, external facilitators were recruited and trained to facilitate meetings after being invited to attend by the Khalifada.

Table 2 show the participants exposure to the Abaay group intervention. In both control and intervention camps membership of Abaay-Abaay groups increased significantly during the trial, with a larger increase in the intervention arm. However, the frequency that members attended meetings did not change in either arm, ranging from 0 up to 10 meetings in the previous month.

Table 2

Participant group membership and exposure to the intervention.

		Prevalence or count (95% CI)								
Trial arm		Baseline		Endline		Change	95% CI	p-value		
Member of Abaay-Abaay group $(\%)^1$	Control	43.98	(24.0, 66.1)	64.64	(36.0, 85.6)	20.7	(4.9, 36.4)	0.016		
	Intervention	63.70	(44.5, 79.4)	95.09	(75.9, 99.2)	31.4	(15.8, 47.0)	0.001		
Meetings attended in last 30 days (n)	Control	2.9	(2.61, 3.14)	3.3	(2.83, 3.83)	0.46	(-0.18, 1.09)	0.139		
	Intervention	3.0	(2.36, 3.65)	3.4	(2.84, 3.99)	0.41	(-0.59, 1.40)	0.379		

¹ Abaay-Abaay groups run in the control camps were not facilitated by research staff and did not utilise the hPLA approach.

3.4. Primary outcomes

Table 3 shows the impact of the intervention on the primary outcomes of the study. Maternal/Caregiver knowledge improved significantly in the intervention arm of the trial, the score doubling from 8 to 16 points. Educational status, having received a vaccination (both as a child and during pregnancy), and age were all positively associated with a higher maternal knowledge score at baseline and were therefore included as covariates. They remained as significant exposures in the final model.

The proportion of children vaccinated in each study arm at baseline and endline is shown in Table 3, after adjustment for the model covariates. The hPLA intervention significantly improved measles (MCV1) vaccination coverage and Penta series completion, which increased by 19 and 20 percentage points compared to the baseline values with an adjusted odds ratio of 2.4 for both vaccines. However, there was no impact on achieving timely vaccination. Disaggregation of coverage by vaccine (**Table A3**) revealed that there was a particularly low coverage of OPV0 vaccination (39 and 50% at endline), which contributed to the low timely vaccination proportion of 40% observed by the end of the trial.

Inconsistent responses about children's vaccination status were detected during data cleaning and defined as a positive report, by verbal recall or record card, of vaccination with a particular antigen at baseline followed by a negative report at endline. The results of the consistency analysis for each vaccine is provided in Table A4. Inconsistent responses varied by vaccine from 7% of participants for Penta 1 up to 32% with OPV0. The most common type of inconsistent report was a positive verbal recall at baseline followed by a negative verbal recall at endline, indicating unreliable recall. For example, for Penta 1 77% of the 90 consistency errors were of this

type. The proportion of inconsistent responses were higher in older children. To reduce the risk of bias, records with inconsistent vaccination responses were excluded from the main analysis reported in Table 3. A secondary analysis was also conducted with inconsistent answers included and the significance and direction of all the outcomes remained unchanged, although the magnitude of the coefficients was altered.

Caregivers had a surprisingly high baseline preference for getting a young child vaccinated against diseases such as measles (>95% in both arms). While this positive preference increased by 4 percentage points in the intervention arm the difference was not significant.

Home-based child health record cards were provided by the organisations running the vaccination services during the trial. Possession of a card increased significantly, rising by 17 percentage points in the intervention arm.

4. Discussion

4.1. Summary of results

Our results show that an adapted hPLA method, when implemented in partnership with into pre-existing social groups, was effective at increasing maternal knowledge and improving child vaccination coverage within a 3-month period. The speed of the intervention effect makes it feasible to consider hPLA as an intervention suitable for use in humanitarian emergencies. To the best of our knowledge, this was the first study to demonstrate that a PLA intervention can increase routine vaccination in an IDP context.

The importance of group participation in PLA approaches was demonstrated in a review by Prost et al., where a threshold partic-

Table 3

Intervention effects on primary and secondary outcomes.

		Adjusted prevalence or mean score (95% CI)								Adjusted Regression Model		
Trial arm		Control				hPLA						
		Baseline	Endline		Baseline		Endline		aOR or Score	(95% CI)	P-value	
Primary outcomes												
Caregiver knowledge score ¹	7.79	(6.66, 8.92)	8.02	(6.76, 9.27)	8.24	(7.33, 9.14)	16.36	(15.73, 17.00)	7.89	(6.93, 8.85)	<0.0001	
Measles vaccination (%) ²	63.6	(52.4, 75.0)	69.8	(59.2, 75.5)	67.9	(60.3, 75.5)	86.6	(80.5, 92.7)	2.43	(1.96, 3.01)	<0.0001	
Penta series completion $(\%)^3$	62.2	(54.2, 73.0)	68.0	(57.7, 78.3)	65.4	(54.4, 76.4)	85.4	(76.7, 94.0)	2.45	(1.27, 4.74)	0.008	
Timely EPI vaccination (%) ⁴	39.7	(28.1, 51.4)	37.5	(29.0, 46.0)	39.7	(29.0, 46.0)	40.0	(15.1, 64.9)	1.12	(0.39, 3.26)	0.828	
Vaccination preference (%) ⁵	95.8	(91.4, 100)	96.4	(93.6, 99.1)	95.2	(91.3, 99.1)	99.4	(98.4, 100)	2.30	(-0.33, 4.93)	0.086	
Secondary outcome												
Child health record card (%) ⁴	18.9	(8.9, 28.8)	21.3	(18.5, 24.1)	18.0	(10.7, 25.3)	35.3	(28.6, 42.0)	2.86	(1.35, 6.06)	0.006	

In all analyses, except caregiver knowledge and vaccination preference, results are adjusted for child age and sex, and the baseline.

value of the outcome variable. For caregiver knowledge and vaccination preference results were adjusted for age, educational status, previous vaccination of the caregiver, and baseline responses.

¹ We assessed impact in mothers/caregivers using linear regression and we report the adjusted regression coefficient. Possible scores ranged from 0 to 21 (see Table A1). ² We assessed impact in children aged 9–59 months using logistic regression and we report the adjusted odds ratio.

³ Impact was assessed in children aged 12–27 months using logistic regression and we report the adjusted odds ratio.

⁴ We assessed impact in children aged 0–59 months using logistic regression and we report the adjusted odds ratio.

⁵ We assessed impact in mothers/caregivers using logistic regression and we report the adjusted odds ratio.

ipation of 30% of pregnant mothers was required to acheive impact [14]. In this study we found high initial levels of Abaay-Abaay group membership, and this increased by 31 percentage points in the intervention arm. The high rates of participation are likely to have contributed to the success of the intervention, and argue in favour of utilising indigenous social groups where these are known to be active and popular.

Another important factor was the flexibility and responsive nature of the health service suppliers. Humanitarian emergencies are typically characterised by high levels of need but may also, in some situations, be associated with relatively high levels of resource inputs from international donors when compared to nonemergency developmental contexts in low income countries. Within the 10 IDP camps included in the trial there were 3 international and 2 local NGOs supplying health services. These organisations were very open to responding to requests from the Abaay-Abaav groups to attend the stakeholder meetings and, subsequently, to respond to the groups requests by extending the scope of their mobile vaccination teams. The presence and willingness of health actors to respond to the group requests was perceived as important in achieving a rapid and successful intervention. So, while the hPLA intervention was designed to work via increasing demand it also indirectly led to important changes in the supply of services. Such a change in service supply may not always be possible in other contexts.

4.2. Comparison with other studies

Previous PLA trials have shown that the approach can have positive impacts on a range of public health priority issues including maternal and perinatal mortality, and type 2 diabetes [14,15]. However, few PLA studies have included vaccination coverage as a main outcome and in this study in one of the first to report a significant impact on this indicator. Other SBCC approaches include traditional didactic health promotion activities, multi-media campaigns, social media, and mHealth interventions. mHealth interventions have been demonstrated to have potential to improve multiple health indicators in low income countries while the potential of social media campaigns, especially when combined with behaviour change theory has recently been reviewed [26-28]. However, all of these approaches have limitations. Combining the hPLA approach with a conditional cash distribution might have additive benefits, although careful design would be required to ensure that the cash distribution did not adversely impact on the social cohesion and functioning of the Abaay-Abaay groups.

Different vaccination coverage indicators are reported in different studies [29]. Here, we chose to use 'measles vaccination coverage' in children above 9 months, due to the importance of measles infections for child mortality in this and other emergency and displacement contexts, and its use as an indicator of an adequate humanitarian response [25,30]. We included 'Penta series completion' to indicate the overall functioning of routine EPI vaccination and allow comparison with the global DPT3 coverage indicator used by WHO [2,30]. Lastly, we measured 'Timely vaccination' to provide information on the ability of the EPI system to provide age appropriate vaccination.

Analysis by vaccine and child age revealed that delivery of OPV0 was very low, and this accounted for the lack of improvement in the Timely Vaccination indicator despite the large improvements in age appropriate coverage of other vaccines. A lack of improvement in OPV0 coverage has also been reported in a CCT trial in Nigeria [31]. Qualitative data (to be reported elsewhere) suggest that OPV0 was likely to be missed out as infants were frequently offered BCG, OPV1, and Penta 1 on their first to a health facility, rather than BCG and OPV0. This is because many mothers stay at home after delivery until the 45th day, a period locally known as

Umul. This suggests that further work on staff training and support is required as well as a review of the EPI schedule.

Achieving full vaccination is challenging in this context and this is not made easier by the existence of government policy that does not allow catch up vaccinations to be started in children over 24 months of age unless they had already received part of the immunisation series, a particular limitation in a highly mobile IDP population [24]. The current policy is less age inclusive than the WHO recommendations for catch up vaccination [32]. These state that restrictive target age groups or upper age limits should be removed from national policies. Evidence-based approaches to identify and remove barriers to vaccination are recommended as part of the Immunization 2030 global strategy [33].

4.3. Strengths and limitations

The partnership between an NGO that had been operational in the area for many years and an academic institution with a strong track record in research in fragile contexts, was important in ensuring the successful completion of the trial in this insecure context. Due to COVID-19 restrictions, it was not possible for the researchers to visit the field sites but regular video call and use of video conferencing during the team training sessions helped maintain effective interaction between the academic researchers and the field team. When a member of the field team tested positive for COVID-19 the study activities were postponed for 10 days but were able to resume following this pause.

In the Somalia context, issuing and retention of home-based health record cards is intermittent and variable, with different types of record card, or no record card, being issued by different health service providers and the quality of data recording on the cards was also observed to be inconsistent. As record cards and participant recall were used to measure vaccination coverage there was a risk of recall and ascertainment bias.

Increased possession of home-based health record cards during the endline data collection interviews also meant that a greater proportion of responses about vaccination status were derived from examination of record cards, rather than participant recall, at this time point. This led in a few cases (1.3%) to the data collection teams recording a negative vaccination variable from the card at endline in contrast to a positive recall answer being given during the baseline. However, errors in verbal recall were much more common. To reduce the risk of measurement bias, any records with a positive vaccination recall recorded at baseline and a negative record card entry at endline were deleted from the primary analysis. However, inclusion or exclusion of these records did not change the significance or direction of the reported results, although the size of the coefficients did change. These results from this subanalysis indicate the importance of home-based written records to provide accurate data on vaccinations.

Lastly, due to time and access constraints it was not possible to involve community participants in the development and iterative testing of the PLA materials prior to their use in the group meetings. This may have led to their design being sub-optimal and have reduced the potential effectiveness of the intervention.

5. Conclusion

Our results show that an adapted PLA approach, run in partnership with local, indigenous social groups, can help achieve important changes in public health knowledge and practice in a protracted humanitarian context. The approach shows promise for adaptation to additional public health priorities and population target groups. Further work to scale up the approach and to address other vaccines and population groups, is warranted.

Data availability

Data will be made available on request.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Trial Registration

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Appendix A. Supplementary material

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