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IVACS: Improving vaccination awareness & coverage in Somalia

Submission date
26/07/2021

Recruitment status
No longer recruiting

Registration date
03/08/2021

Overall study status
Completed

Last Edited
23/10/2023

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Childhood vaccination coverage in Somalia is relatively low, resulting in unnecessary illness and deaths. The aim of the study is to improve awareness, knowledge, and uptake of the available vaccination services. To do this we are exploring the use of a Participatory Learning and Action (PLA) approach with indigenous women's groups known as Abaay-Abaay. Using a series of facilitated meetings we will assess if this approach can lead to improved caregivers' knowledge and increase vaccination coverage in this humanitarian context.

Who can participate?
All children under five and their caregivers, who are living in the selected camps for displaced people near to Mogadishu will be invited to participate.

What does the study involve?
We will compare the camps receiving the PLA intervention with those that do not. Participants in all study camps will be asked to take part in two questionnaire interviews, one at baseline and one at endline. Women who attend Abaay-Abaay groups in the intervention arm camps will be asked to take part in a series of eight facilitated meetings during which child health issues and the role of vaccinations will be discussed, priority problems identified, potential solutions found, and group led interventions planned, implemented, and self-evaluated. Women attending Abaay-Abaay groups in the control camps will not be exposed to any interventions.

What are the possible benefits and risks of participating?
Participation in the Abaay-Abaay groups is entirely voluntary and a long established social custom on Somalia. There are no particular risks in participating in a group receiving the PLA intervention other than it may take time away from discussing other topics that the group would have discussed if there was no intervention. However, if groups decide to implement interventions to improve access to vaccination services there is a risk that other community members may not approve of their actions.

Where is the study run from?
The study is run by University College London (UK), in collaboration with Action Against Hunger (Somalia).

When is the study starting and how long is it expected to run for?
August 2019 to November 2021

Who is funding the study?
The Bill and Melinda Gates Foundation (USA)

Who is the main contact?
Andrew Seal MSc PhD, a.seal@ucl.ac.uk

Contact information

Type(s)
Scientific

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Study information

Scientific Title
Improving Vaccination Awareness & Coverage in Somalia

Acronym
IVACS

Study objectives
Community women's Abaay-Abaay (Sister-Sister) groups can successfully adopt an adapted Participatory Learning and Action (PLA) approach, spatially-distanced if necessary, to improve caregivers' knowledge and increase vaccination coverage, in humanitarian contexts in southern Somalia.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Approved 25/02/2021, Somali Federal Republic Ministry of Health and Human Services (PO Box 22, Mogadishu, Somalia; no telephone number provided; dg@moh.gov.so), ref: MOH&HS /DGO/0381/feb/2021
2. Approved 07/06/2021, UCL Research Ethics Committee (Office of the Vice Provost Research, 2 Taviton Street, London, UK; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: 4684/003

Primary study design
Interventional

Study design
Interventional cluster randomized trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Improvement in routine vaccination coverage for children.

Interventions
Participatory interventions with women's groups using a Participatory Learning and Action (PLA) approach have shown positive impacts on maternal and child health outcomes in numerous settings. The women's group PLA approach is based on the ideas of Paulo Freire and draws on the principle that sustainable social change is possible if teachers and learners engage in a dialogue, exchanging ideas and experiences, and implementing a cycle of learning, action, and reflection. We intend to adapt this approach to make it suitable for use in populations affected by humanitarian crisis in conflict settings, enabling them to better understand and make optimal use of the available health services, in particular childhood vaccination.

We aim to implement a PLA intervention by working with indigenous Abaay-Abaay groups. The groups typically comprise 10-20 members and are traditional female social groups that are found throughout Somalia and usually meet every week or month. The groups are also commonly found in stressed and displaced populations, including most IDP camps in Mogadishu.

The intervention will be randomly allocated to half the camps. Camps will be mapped using GPS handsets and their locations visualised using Google Earth Pro. They will then be listed in descending order of distance to the local health facilities and the first camp in the list allocated to intervention or control using a random number generator formula in Excel. Alternate camps in the list will then be allocated to the same arm.

In the intervention camps trained Facilitators will run a series of eight meetings with the Abaay-Abaay groups, identifying and learning about child health problems, identifying possible solutions, planning and implementing the solutions, and then evaluating how the solutions worked. Prior to the meetings starting a facilitation manual and supporting visual aids (picture cards identifying child health problems such as symptoms of infection) will be developed. The manual will be based on that developed by Women and Children First (WCF) and adapted to the local context. The meetings will be observed by a member of the research team and notes taken on the meeting processes using an observation checklist.

The control camps will receive no intervention and their Abaay-Abaay groups, child health services, and any current BCC activities will proceed as usual. There will be no direct observation

of the control camp meetings to avoid any possible ‘observer effect’. Participation in meetings in all camps will be assessed using the endline questionnaire.

Intervention Type
Behavioural

Primary outcome(s)
1. Measles vaccination coverage - % of children 9 - <59 months of age who received the measles vaccine, measured by novel questionnaire at baseline and end-line
2. EPI vaccination coverage - % of children 0 - <59 months of age who received all vaccines required by the national vaccination protocol, measured by novel questionnaire at baseline and end-line
3. Knowledge of vaccination and vaccination timings, measured by novel questionnaire at baseline and end-line
4. Attitudes to vaccination, vaccination coverage, measured by novel questionnaire at baseline and end-line

Key secondary outcome(s)
1. Under-five morbidity measured using questionnaire recall at baseline and endline
2. Incidence of measles measured using symptom recall at baseline and endline
3. Under-five death rate measured using enumeration of household members at baseline and endline
4. Causes of death ascertained using Verbal Autopsy (VA) interview following a reported death

Process indicators:
5. Number of Abaay-Abaay groups successfully established is measured by direct observation
6. Safe conduct of group activities is measured by direct observation
7. Prevalence of participation in an Abaay-Abaay group by age and clan measured by questionnaire at baseline and endline
8. Acceptability and utilisation of PLA training materials by group leaders (Khalifada) is measured by direct observation
9. Completion of learning cycles and topic coverage by groups is measured by direct observation
10. Any adverse events associated with group membership or activities is measured by direct observation and open ended interviews

Completion date
30/11/2021

Eligibility

Key inclusion criteria
Children aged 0 - 59 months and their primary caregiver

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group

Mixed

Sex
All

Total final enrolment
1269

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
29/06/2021

Date of final enrolment
17/07/2021

Locations

Countries of recruitment
Somalia

Study participating centre
Camps for Internally Displaced
Khada District
Afgooye Corridor
Mogadishu
Somalia
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Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (a.seal@ucl.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/03/2023	24/03/2023	Yes	No
Results article	Barriers to childhood vaccination uptake among Internally Displaced Populations (IDPs)	17/10/2023	23/10/2023	Yes	No