**Clustered randomized control trial intervention on U5 children diarrhea hotspot areas in southwestern Ethiopia**

By;

Bezuayehu Alemayehu[[1]](#footnote-2)\*, Argaw Ambelu1, Birhanu Teshome Ayele[[2]](#footnote-3)

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# Statement of compliance

The study will be conducted in accordance with Jimma University Institutional Review Board (IRB) ethical approvals. The Principal Investigators will assure that no deviation from, or changes to the protocol will take place without previous agreement from (IRB) ethical clearance. If there is any significant change on the protocol, there will be immediate contact to IRB for any modifications that affects the trials.

Summary

Introduction: Under-five children's diarrhea is a major cause of morbidity all over the world, mainly in developing countries. About 2.4 billion of acute diarrhea episodes are occurring across the globe including South Asia and Sub-Saharan African countries. Around 22% of diarrhea prevailed in Ethiopia. Particularly, southwestern Ethiopia has accounted for 18.3% of diarrhea due to individual and community-level risk factors like poor handwashing practice and unimproved water source for drinking. This interventional study aim to evaluate the effectiveness of handwashing with soap at six critical times and *Wuha Agar* (chemical solution used to treat water) in home-based water treatment to reduce diarrhea in southwestern Ethiopia.

Methods: Cluster randomized control with factorial design will be conducted in North Bench district, southwestern Ethiopia, from May to October 30/ 2020. Thirty-six clusters have been calculated and equally allocated, nine clusters for handwashing, home-based water treatment, and combination intervention will be equally allocated to each groups having twenty households per cluster with a total of 720 households with under five children will be followed up to six months based on implementation modality. Baseline data will be collected at the first two weeks from 36 clusters. The baseline survey will be done after obtaining oral informed consent from mothers or caregivers next to ethical clearance.

Mothers/caregivers satisfying the eligibility criteria will be the study participants. Data will be processed and entered in Epi data 4.4 and then imported into Stata 14 software for analysis. The incidences of diarrhea from both groups will be recorded in every two weeks and analyzed by using generalized estimated equation models.

# Background

Globally under five children diarrhea(U5 diarrhea) remain a major public health threat with nearly 1.7 billion cases occurring annually in all age groups and the second for 578,000 deaths among children under five years in 2013 (Achieng & Foyeke, 2007; Asamoah*etal.,* 2016). In the world, a child dies every 60 seconds of diarrhea, six million children who do not live beyond the age of five years (UNICEF, 2016) due to several determinants (Genser *et al.,* 2008). Globally, 90% of U5 diarrhea has been linked to poor water, sanitation, and hygiene provision, mainly about 88% of deaths was occurred in developing countries (Bill & Foundation, 2017).

U5 diarrhea remains a major public health problem in East African nations(Shirley *et al*,. 2013), particularly in Ethiopia the prevalence accounts about 22.6% in the different regions with a median of 45%(Bambrick *et al.,* 2015). Similarly, in northwest parts of Ethiopia, annual incidence rate during the study period was 155.3 per 1,000 populations at risk with variation greatly across the study districts(Azage, Kumie, Worku, & Bagtzoglou, 2015).The study conducted in sheko district, Bench Maji Zone, southwest Ethiopia indicated that socio economic and environmental factors contributed U5 diarrhea(Gebru *et al.,* 2014). The prevalence of U5 diarrhea in Bench Maji Zone were 18.3 %, that is affected by individual and community level factors mainly not washing hands during critical times were 4.6 times risky for U5 diarrhea (Alemayehu, *et al*., 2020).

However, many cluster randomized control trial study were conducted to prevent the U5 diarrhea like in Pakistan on the effectiveness of hand washing promotion on childhood diarrhea in high risk community was decrease the incidence of diarrhea by 39% (Painter, Billhimer, Hoekstra, & Children, 2004). Systematic review and Meta-analysis pooled analysis result WASH interventions show diarrhea risk reductions between 27% and 53% in under five children (Darvesh & Vaivada, 2017). The study conducted in Nigeria reported that the risk of U5 diarrhea significantly higher among children whose mothers did not hand washing with soap before food preparation (OR=3.0, p<0.05), before feeding their children (OR=3.0, p<0.05) and after leaving the toilet (OR=4.7, p<0.05). Poor water handling (OR=2.0, CI=1.2-3.5), presence of clogged drainage near the house (OR=2.1, CI=1.2-3.7) and breeding places for flies (OR=2.7, CI=1.6-4.7) will be mentioned as factors significantly associated with under five children diarrhea(Oloruntoba etal., 2014).

However, study showed at Bangladesh the effect of hand washing at recommended times with water alone and with soap on child under five children diarrhea suggested that hand washing before preparing food is a particularly important opportunity to prevent childhood under five children diarrhea. Hand wash with water alone can significantly reduce childhood under five children diarrhea(Luby*etal.,* 2011). A study in Pakistan found that hand washing in the household reduced the incidence of U5(Painter et al., 2004). A systematic review from 17 studies on effect of hand washing with soap concluded that relative risk of U5 diarrhea associated with not hand wash, implying that hand washing could reduce the risk by 47% (Curtis & Cairncross, 2003). Whereas, in Salvador, Brazil, U5 diarrhea and observed hygiene behavior found that the prevalence of diarrhea among unhygienic behavior was recorded was 2.2 times that among children in the “mainly hygienic” group.

A cluster-randomized, community-based trial of hand washing promotion in Karachi, Pakistan reported that five years after receiving hand washing promotion, intervention households was more likely to have soap at the household hand washing station, know key times to WASH hands and report purchasing more soap than controls, suggesting habituation of improved hand washing practices in the population(Ayers, 2014).

Another study conducted at Dabat district northwestern Gondar, revealed that SODIS as water treatment for household decreased 40% diarrhea incidence(Bitew *et al.*, 2018). Similarly at Jigjig district eastern Ethiopia, community based cluster randomized control trial on hand washing with soap and WASH education have shown 35% reduction of U5 diarrhea incidences(Abdiwahab Hashi, Abera Kumie, 2017) .

Nevertheless, some studies have been carried out on the prevention of U5 diarrhea with different strategies. In the case of Bench Maji zone on hand washing with soap at critical time and home-based water treatment, there is limited intervention research in spite of no washing hand at critical time contributing 4.6 time and unimproved water source 2.53 time risky of diarrhea for under five children (Alemayehu et al., 2020).

# Study objective

The objective of this study is to evaluate the effectiveness of hand washing with soap at six critical time and household chlorinationfor water treatment to reduceU5 diarrhea in southwestern Ethiopia from May to October 30/ 2020.

# Study area and period

The trial will be done in the district of North Bench, Bench Maji Zone, southwestern Ethiopia, which is located 550 km from the capital city of Addis Ababa. The research will be carried out from May to October 30/ 2020.The estimated population is 148, 285, of which 71,177 men and 77,108 women and 23,147 children under five. The district has 24 kebeles with 29,610 households and an average family size of 4.14(source: Bench Maji zone health department, 2020)

# Randomization type

Community based cluster with factorial design will be used to conduct an interventional study in North Bench district, southwestern Ethiopia. The clusters will be selected randomly for trial based on the established criteria.

The sample size has been determined based on the method developed by Hayes and Bennett(Bennett, 2014) and using the following assumptions: 6.3 episodes/100 person week observation among control group from a previous similar trials ( Hashi *etal.,* 2017) , 80% statistical power, a 95% confidence interval, considering both type I and type II errors. As per the guidelines of cluster-randomized trials in health service research, intra-cluster correlation coefficient (ICC) is an appropriate way to estimate cluster variability and 0.02 will be maintained. Thirteen pair clusters will be expected to detect forty percent (40%) difference in episodes between the intervention and control groups including design effects of 1.38 by applying the formula 1+(m-1) ICC, where m is the number of households in each clusters, and including 20 households per clusters that will be maintained based on family health folder management system(Bitew et al., 2018). Finally, 36 clusters having 720 households have been calculated and equally allocate with ratio of 1:1 for each arm. The study has four arms such as clusters used only handwashing with soap at critical time, only Wuha Agar provided for home based water treatment, both hand washing with soap at six critical times and Wuha Agar treatment and control, which have no any intervention activity.

# Subject selection

Baseline characteristics of households (HH) with under-five children will be assessed before conducting RCT, including HH characteristics (socioeconomic and WASH status), child status (age, gender, vaccine status, time for supplementary feeding) and household information on Corona virus (COVID-19).

Oral informed consent will be obtained from mother/caregivers of the selected child. A household will be considered eligible for the study if the following criteria are met:

1. At least one child aged 0–59 months living in the home
2. Not being a model household,(households that successfully implement all 16 packages of the Health Extension Program (HEP) are officially certified as a Model Health Extension Household.
3. Mothers/caregivers of under-five children living in the study area for at least four months and have no plan of migrating during the study period.
4. The children will be exclude, when they are seriously sick by other disease at the time of study and will be referred to near health facility
5. The Communities using only untreated drinking-water sources
6. Unavailability of drinking water-quality management and diarrhea interventions
programs in the community

# Randomization and masking

The study’s intervention aim does not notified for field workers and the study participant (control and intervention), the cluster will be made geographically distinct from each other during randomization and also the dispersed nature of the cluster makes it possible to minimize information contamination. The lottery methods will be used to assign randomly to intervention and control groups in the presence of community representative, chairman of the kebele and coordinator from health Office health.

# Intervention approaches

Interventions will be given after preparing a protocol of activity designed to prevent diarrhea at the HH level. The intervention activity will be a key message that will be distributed by delegated field workers to eligible HHs every week for the next four months following a practical demonstration and delivering key health message at individual HH level.

After an active demonstration, plain soap and Wuha agar will be provided for assign eligible HHs. Impression materials (leaflets) will be prepared with key message in Amharic states critical HW time and amount of chlorine solution for water treatment. There will be pictorial representation of the critical time and water treatment for those unable to read printing materials. The message will be enforced every week of stay, and the families will be supplied with one bar soap and Wuha agar for respective house hold. While, there is no intervention for the control groups to minimize the incidence of diarrhea. The field workers will collect, record the incidence, manage the case for the consecutive four months, and report every two weeks.

# Intervention description

Hand washing with soap and water

**Treatment A: Hand washing with soap at six critical times only**

Handwashing messages

1. Wash your hands with given soap before meal preparation
2. Wash your hands with given soap before eating food
3. Wash your hands with a given soap after child washing
4. Wash your children’s hands with the soap (provided) after defecation
5. wash your hands with given soap after toilet use
6. wash your hand with given soap after contact any dirty materials

**Repeat the above six key messages through demonstration**

Provide the clusters or HH the plain soap with strict recommendation to use for only hand washing at six critical times.

**Treatment B: Home-based water treatment only**

 Home-based water treatment message

* Treat drinking water with Wuha Agar following the following steps

**Demonstration of home based water treatment with Wuha Agar**

1. Add one cup of Wuha Agar in to twenty liter (Jerican) of raw drinking water
2. Shake well the *jerican*
3. Drink the water at least after thirty (30) minutes of treatment
4. Never drink before 30 minutes
5. Collect all bottles after you have completely finished the chemical used for treatment
6. Never share the Wuha Agar with any other households

**Treatment C: Hand washing with soap at six critical times and home-based water treatment**

1. Provide soap and Wuha Agar for the clusters.
2. Follow the procedures of handwashing and water treatment

**Control group: no any treatment**

# Data collection and outcome assessment

**Data collection**

* One field worker will be assigned to each cluster after a baseline data collection for case identification and to check the proper use of soap and chemical as per the intervention approaches.
* After a baseline data collection, enroll the eligible clusters and follow for the next six months.
* Observe the proper use of the intervention and record data on FOLLOW UP format every week.
* Record childhood diarrhea episodes from intervention receiving groups (those assigned to follow intervention clusters)
* Record childhood diarrhea episodes from control groups (those assigned to follow control clusters).
* The questionnaire will initially prepare with English and then will be translated in to local Amharic.

**Definition or meaning of diarrhea in this approaches**

* Diarrhea episodes will be reported based on the recommended standard diarrhea concept that three or more loose or watery stools are present per day stool observed in under five children.
* The primary care takers providers will be advice to report the onset of diarrhea within two weeks for field workers.

# Supervision approaches

Selections of field workers

* Field workers will be selected based on their willingness to participate for next six months of cluster supervision.
* Two days training with practical approaches will be given for effective supervision including ethical issues

# Duties of field workers

* Raise awareness for assigned HH every week for six months (health education messages and demonstration )
* Provide information message on preventing diarrhea by demonstrating six critical hand washing time and treat drinking water with Wuha agar one cup per 20 liters of water.
* Ensure the effective practices of handwashing at six critical times and home based water treatment as per intervention approaches
* Distribute leaflet depicting six critical handwashing time with soap and Wuha agar application steps for the intervention groups
* Record the diarrhea incidence among under five children every two weeks for 6 months

# Follow up and data management

The questionnaire will initially prepare with English language and then, to test accuracy, It will be translated in to local (Amharic) language and then returned to English by language Experts.

Furthermore, field workers will be selected on the basis of their expertise and willingness to participate data collector. Two days training will be given on the structure, process and presentation of data. During data collection the supervisors will be monitor the accuracy, consistency of the data.

# Statistical analysis method

Upon closing the trial, data will be cross cheeked for its completeness and consistence. Data will be double entering in to EPI data version 3.02. Intention-to-treat analysis will be used to compare the incidence of diarrhea among intervention and control arms. The rate of diarrhea (per 100 person-weeks) in children under-five years of age will be measured for the intervention and control communities. Comparison of episodes of diarrhea from both groups will be compared and analyzed by Generalize estimate model on stata14.0 software.

# Ethical consideration

Ethical clearance will be taken from Institution Review Board (IRB), Jimma University and then, summit to Bench Maji zone health department and North Bench district health office for actual implementations of trials.

# Finding dissemination and publication plan

The finding of this result will be dispatches to all concerning body such as Jimma university public health faculty post graduate programs coordinating office, and Bench Maji Zone and North Bench district Health department. The finding will be published in peer viewed reputable journal.

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**Attachment**

**A. Subject information and intervention period**

First, I want to thank you for giving your time to undergo this conversation for the study from May to October 30/ 2020. Having saying this I will give you enough information about the study that I’m going to do and please listen with full attention. Finally, if there is any question/ ambiguity you can ask and get information.

**Study:** Childhood diarrhea is the leading causes of morbidity and mortality among children under 5 years of age in the Sub Saharan Africa including Ethiopia. The disease can be caused by a variety of infectious microorganisms and various factors such as water, hygiene and sanitation.

**Subject’s role**

If you are voluntary to participate in this study, you are required to give us about your household WASH and child diarrhea status. In addition, you will give other socio demographic information that is related with the study.

**Subject’s right**

Study participants have the right to know their result, and if they are not interested, they can withdraw from the study at any time.

**Subject’s benefit**

Participating in this study does not give any other unique benefit for study participants. However, the results of this study would provide evidence for prevention of childhood diarrhea.

**Harm**

Study participants do not get any harm by participating in this study.

**Confidentiality**

All the data obtained from the participants will be kept strictly confidential by using only code numbers and locking the data. No one will have access to the non-coded data except the principal investigator.

**B. Informed consent**

My name is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_a member of data collectors on community based cluster randomized control trial study conducted on childhood diarrhea in North Bench district, southwestern Ethiopia. The research is under study by PhD students at Jimma University, Department of Environmental Health Science and Technology. Currently, I am collecting information on associated factors of child hood diarrhea. I will visit and ask certain questions if you are voluntary to provide information. No financial payments will be given to you for participating in this study.

The questions usually take about 20 to 30 minutes. All of the answers you give will be confidential and will not be shared with anyone. You can withdraw from the study at any time but I hope you will agree to answer these questions since your views are important. If I ask you question that you do not want to answer, just let me know and I will go on to the next question or you can stop the interview at any time.

Do you have any questions? a. Yes b. No (stop interview if no)

May I begin the interview now? If yes continue!

Signature of interviewer-----------------------------------date-------------------------------------------

C**:** Baseline data survey questionnaires

Annex II**.** Baseline data collection format

Part I: Socio-demography profile of the household House No\_\_\_\_\_\_\_\_\_\_ date \_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| Sn | Description of question  | Response  | skip |
|  | Primary Mother/caregiver of child | Mother /caregiver |  |
|  | The gender ofcaregiver | M \_\_\_ b F\_\_\_ |  |
|  | The current age of mother/caregiver by complete year | \_\_\_\_\_\_\_\_\_\_\_\_ |  |
|  | The current educational level of mother/caregiver? | \_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
|  | Marital status of mother/caregiver? |  |  |
|  | The current educational level of father? | \_\_\_\_\_\_\_\_\_\_\_\_ |  |
|  | The current occupation of mother/caregiver? | \_\_\_\_\_\_\_\_\_\_\_\_ |  |
|  | The current occupation of father? | \_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
|  | The responsibility of mother/caregiver of child in the household | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
|  | The current area of residence of mother/caregiver | Urban \_\_\_ Rural\_\_\_ |  |
|  | Family members in household | M.\_\_\_ F.\_\_\_\_ T.\_\_\_ |  |
|  | The sources of family income? (If more than one answer, list them) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
|  | Were affected by diarrhea in last two weeks? | Yes No |  |
|  | If yes,Qs 013, their gender and age  | Gender\_\_\_\_\_ Age\_\_\_ |  |

**Part Two: Water supply and management conditions of the household**

|  |  |  |  |
| --- | --- | --- | --- |
| Sn.  | Description of question  | Response  | Skip |
|  | The sources of household water | Pipe Protected wellProtected spring Unprotected wellUnprotected springRiver Other, specify |  |
|  | Do you get water all the year? | Yes No |  |
|  | If no Q 16 , for how money days? |  |  |
|  | How many minutes it takes to fetch water? | \_\_\_\_\_\_\_\_\_\_minutes |  |
|  | What materials do you use for storing water at home? | Jerkan Pot Plastic bucket Tanker Other specify\_\_\_\_\_\_\_\_ |  |
|  | How many times do you wash water storage materials at home? | \_\_\_\_\_\_\_\_ |  |
|  | Is there coverage for water storages? | Yes No  |  |
|  | How many litters of water do you use for individuals (cooking; drinking; washing) per day? | \_\_\_\_\_\_\_\_\_\_litters  |  |
|  | How do you draw water at home? | By immersing inside By pouring Directly from pipe Other specify \_\_\_\_\_\_\_ |  |
|  | Do you treat water at home? | Yes No |  |
|  | If yes for Q024, what are materials or chemicals do you used for treating water at home? | Chlorination Wuha- agar BoilingFiltering specify \_\_\_\_\_\_\_\_ |  |
|  | Where do you dispose wastewater? | On open field Soak pitCesspoolOthers, specify\_\_\_\_\_\_\_ |  |
|  | Where do you dispose solid waste?(more than one response) | On open field  pitburnOthers, specify\_\_\_\_\_\_\_ |  |

**Part Three: Sanitation status of household (Observational)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| S/N | Description of question  | Response  | Skip |  |
|  | Is there a latrine? | Yes No |  |  |
|  | If yes for Q028, what types of latrine do you use? | pit latrine VIP latrine Water carriage pit latrine.other specify\_\_\_\_\_\_\_ |  |  |
|  | If yes for Q028, are they Functional? |  Yes No |  |  |
|  | Is there hand-washing facility? |  Yes No |  |  |
|  | If yes for Q031, what type of detergent they use for hand hygiene? | SoapAshSoap and AshWater onlyOther ,specify\_\_\_\_\_\_ |  |  |
|  | What is the distance of latrine from water source in meter? | \_\_\_\_\_\_\_\_ |  |  |
|  | What is the distance latrine from home in meter? |  |  |  |
|  | If No for Q028, where do you use for latrine? | Open field Communal PublicOthers,e.specify\_\_\_\_\_\_ |  |  |
|  | Is there shelf for food utensils? | Yes No |  |  |
|  | When did health worker visit your home? | \_\_\_\_\_\_\_weekly/monthly  |  |  |

**Part four: Under five children in the house**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Sn | Description of question  | Response  | Skip |  |
|  | How many under five children do you have? | \_\_\_\_\_\_\_\_\_ |  |  |
|  | What is the gender of the child? | M\_\_\_\_ F\_\_\_\_T\_\_\_\_ |  |  |
|  | Age of the child in months respectively  | \_\_\_\_\_\_\_,\_\_\_\_\_\_\_ |  |  |
|  | Is their child affected by diarrhea in last two weeks? | Yes No |  |  |
|  | If yes for Q041, what is their gender? | M\_\_\_\_\_ F\_\_\_\_\_ |  |  |
|  | If yes Q041, what the age in months? | \_\_\_\_\_\_ |  |  |
|  | If yes for Q041, what is the frequency of diarrhea? per/day | \_\_\_\_\_\_\_ |  |  |
|  | If yes for Q041, what is the duration of diarrhea? | \_\_\_\_\_\_\_ |  |  |
|  | If yes for Q041, what is the type of diarrhea? |  Watery bloody  not know |  |  |
|  | Is the child vaccinated for Rotavirus? | Yes No |  |  |
|  | If yes Q047, type of vaccinated?  | Rota 1 Rota 2 |  |  |
|  | Has the child fed supplementary foods? | Yes No |  |  |
|  | If yes for Q046, at what age has the child started in month? | \_\_\_\_\_\_\_\_\_\_\_ |  |  |
|  | Do you know benefit of Exclusive feeding? | Yes No |  |  |
|  | Do you heard about diarrhea? | Yes No |  |  |

**Part Five: Hand washing behaviors of caregiver/mother**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Do you think hand washing can prevent diarrhea? | Yes No |  |  |
|  | Do you wash your hand after toilet?  | Yes No |  |  |
|  | Do you wash your hand after cleaning baby’s feces?  | Yes No |  |  |
|  | Do you wash your hand after contact with dirty matter?  | Yes No |  |  |
|  | Do you wash your hand before feeding child?  | Yes No |  |  |
|  | Do you wash your hand before preparing food?  | Yes No |  |  |
|  | Do you wash your hand before eating food?  | Yes No |  |  |

Part six COVID 19 related (put the (√) if their answer correctly)

|  |  |  |  |
| --- | --- | --- | --- |
| 060 | Please list the main clinical symptoms of COVID 19 ? | 1.Fever\_\_\_\_2.fatigue\_\_\_\_3.dry cough\_\_\_\_ 4.myalgia\_\_\_\_\_, 5.breathing difficulty\_\_\_\_\_ |  |
| 061 | List the transmission ways of COVID19virus? | 1. Breathing, sneeze, cough \_\_\_\_\_\_2. Physical contact\_\_ 3. Hand shake\_\_\_ 4. specify if any \_\_\_\_  |  |
| 062 | Prevention methods of COVID19 | 1.wash hand with soap\_\_\_\_2.avoid crowd \_\_\_3.keep physical distance \_\_\_\_\_\_4.spesify if any\_\_\_\_\_\_\_ |  |
| 063 | Do COVID 19 virus affect all age group |  1.Yes 2.No |  |
| 063 | It is necessary for children and young adults to take preventive measures for COVID19 infection | 1.Yes 2.No |  |
| 064 | Can you list what have you done to prevent COVID19 infection  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

**C. Follow up format for treatment groups**

**Clusters number: -------------Treatment type: -----------------Month------------Visiting round (circle it): One Two**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Household Characteristics  | Child characteristics   | Diarrhea Incidence   | adherence | Compliance  |
| Household name  | HH ID | Age in months | Gender  | Yes | No | Yes | No | Yes | No |
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**Supervisors**

**Name: --------------------------------------------------Mobile number: -----------------------------------Sign-----------------------------------------**

**Follow up format for control group**

**Clusters: -------------------------------Month---------------------------- Visit round: One Two**

|  |  |  |
| --- | --- | --- |
| Household Characteristics  | Child characteristics   | Diarrhea Incidence   |
| Household name  | HH ID | Age in months | Gender  | Yes | No |
|  |  |  |  |  |  |
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**Supervisors**

**Name: --------------------------------------------------Mobile number: -----------------------------------Sign-----------------------------------------**

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Map of the intervention areas

1. Department of Environmental Health Science and Technology, Jimma University, Jimma, Ethiopia [↑](#footnote-ref-2)
2. Division of Epidemiology and Biostatistics, Faculty of Medicine and Health Sciences, Stellenbosch University, Stellenbosch, South Africa

These authors contributed equally to this research. Correspondence and requests for materials should be addressed to B.A. (email: bezua@ymail.com) [↑](#footnote-ref-3)