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Evaluation of a behavioral intervention to improve child feces management practices in Odisha, India

Submission date
10/02/2020

Recruitment status
No longer recruiting

Registration date
18/02/2020

Overall study status
Completed

Last Edited
29/08/2024

Condition category
Other

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

Plain English summary of protocol

Current plain English summary as of 30/04/2021:
Background and study aims
While child feces are likely a significant source of fecal exposure, the latest National Family Health Survey (2015-2016) reported only 36% of Indian households safely dispose of their child's feces into a latrine, with the State of Odisha having the lowest rate at 13%. Emory University conducted an evaluation of a community-based water and sanitation infrastructure program, implemented by the Odisha-based NGO Gram Vikas, and found that while the program led to substantial increases in latrine coverage and use, the practice of safe disposal of child feces continued to be a challenge. Research is needed to better understand what works and what doesn't when it comes to influencing caregivers to adopt safe child feces management (CFM) practices that can reduce household fecal exposure and ultimately improve health. The primary aim of this study is to evaluate a behavioral intervention aimed at increasing safe CFM practices among caregivers of children aged under 5. The key behaviors of interest are safe disposal of child feces into the household latrine and teaching young children how to use the latrine on their own so they establish the habit of latrine use rather than open defecation. Emory University and Gram Vikas joined together to collaborate on this study with Emory University as the research partner and Gram Vikas as the implementing partner.

Who can participate?
The study will be carried out in 74 rural villages in Ganjam and Gajapati districts that previously participated in Gram Vikas's community-based water and sanitation infrastructure program (known as MANTRA). Eligible participants will be households that have a latrine and at least one child less than 5 years old. The study will focus on the CFM practices of the primary caregiver of the child but the intervention will target all caregivers of the child including fathers and grandmothers.

What does the study involve?
The study involves both the design and evaluation of a novel CFM intervention with four key phases: baseline data collection, intervention design, intervention implementation, and endline data collection.

Baseline: a baseline survey will be carried out across the 74 trial villages before implementation of the CFM intervention. The primary respondent for the survey will be the primary caregiver of the child aged under 5. The survey will include questions about household demographics, household water and sanitation, CFM practices, RANAS behavioral factors, perceived stress, and received social support. The survey will also include a structured spot check of the household's water and sanitation facilities. A sub-set of households will be approached for hand-rinse and drinking water samples to assess household-level fecal contamination. Once baseline data collection is complete, the villages will be randomly allocated to the intervention or control group.

Intervention design: Emory and Gram Vikas will co-design the novel CFM intervention following the RANAS (Risks, Attitudes, Norms, Abilities, Self-Regulation) approach to behavior change, which utilizes results from the baseline data collection to identify the most important behavioral factors to address in the intervention activities. User-centered design will also be applied to develop hardware that aids caregivers in practicing safe disposal and latrine training.

Implementation: After the behavior change activities of the intervention are fully designed, Gram Vikas will implement across all intervention villages. During implementation, Gram Vikas will also distribute assistive CFM hardware (wash basins, buckets with lids, latrine training mats) that was previously developed in a formative research phase using a user-centered design approach. A process evaluation will also be carried out to document whether or not the intervention was implemented with fidelity.

Endline: Finally, endline data collection will take place across the 74 trial villages approximately 3 to 5 months post intervention delivery. The endline survey will be similar to the baseline survey but with additional questions about the intervention activities, such as respondent attendance. Note that this study is taking place during the COVID-19 pandemic and as such, the study may experience unexpected delays that may prevent endline data collection from taking place at the anticipated time after intervention delivery.

What are the possible benefits and risks of participating?
The researchers believe there are no risks to caregivers and households participating in the study. Possible benefits to participation may include a change in CFM practices with a subsequent reduction in household fecal contamination and improved health outcomes for household members. However, the researchers are not measuring health impacts in this study. Findings from this study may also help inform Gram Vikas’s future CFM programming in MANTRA villages.

Where is the study run from?
The study is based out of Gram Vikas’s Mohuda Campus in Berhampur, Odisha as it is located within a few hours’ drive of all enrolled study villages.

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

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

Who is the main contact?
1. Prof. Thomas Clasen (PI)

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2. Gloria D. Sclar (Research Manager)
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Previous plain English summary:
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While child feces are likely a significant source of fecal exposure, the latest National Family Health Survey (2015-2016) reported only 36% of Indian households safely dispose of their child's feces into a latrine, with the State of Odisha having the lowest rate at 13%. Emory University conducted an evaluation of a community-based water and sanitation infrastructure program, implemented by the Odisha-based NGO Gram Vikas, and found that while the program led to substantial increases in latrine coverage and use, the practice of safe disposal of child feces continued to be a challenge. Research is needed to better understand what works and what doesn't when it comes to influencing caregivers to adopt safe child feces management (CFM) practices that can reduce household fecal exposure and ultimately improve health. The primary aim of this study is to evaluate a behavioral intervention aimed at increasing safe CFM practices among caregivers of children aged under 5. The key behaviors of interest are safe disposal of child feces into the household latrine and teaching young children how to use the latrine on their own so they establish the habit of latrine use rather than open defecation. Emory University and Gram Vikas joined together to collaborate on this study with Emory University as the research partner and Gram Vikas as the implementing partner.

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The study involves both the design and evaluation of a novel CFM intervention with four key phases: baseline data collection, intervention design, intervention implementation, and endline data collection.
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Intervention design: Emory and Gram Vikas will co-design the novel CFM intervention following the RANAS (Risks, Attitudes, Norms, Abilities, Self-Regulation) approach to behavior change, which utilizes results from the baseline data collection to identify the most important behavioral factors to address in the intervention activities. User-centered design will also be applied to develop hardware that aids caregivers in practicing safe disposal and latrine training.
Implementation: After the behavior change activities of the intervention are fully designed, Gram Vikas will implement across all intervention villages. During implementation, Gram Vikas will also distribute assistive CFM hardware, such as latrine training mats, that was previously developed in a formative research phase using a user-centered design approach. A process

evaluation will also be carried out to document whether or not the intervention was implemented with fidelity.
Endline: Finally, endline data collection will take place across the 74 trial villages approximately 1 year after baseline. The endline survey will be similar to the baseline survey but with additional questions about the intervention activities, such as respondent attendance and satisfaction.

What are the possible benefits and risks of participating?
The researchers believe there are no risks to caregivers and households participating in the study. Possible benefits to participation may include a change in CFM practices with a subsequent reduction in household fecal contamination and improved health outcomes for household members. However, the researchers are not measuring health impacts in this study. Findings from this study may also help inform Gram Vikas's future CFM programming in MANTRA villages.

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April 2019 to March 2021

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

Who is the main contact?
1. Prof. Thomas Clasen (PI)
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2. Gloria D. Sclar (Research Manager)
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Implementing and evaluating behavioral interventions on safe child feces management practices among rural villages in Ganjam and Gajapati districts, Odisha, India

Study objectives
It is hypothesized that the practice of safe disposal of child feces among primary caregivers of children less than 5 years old residing in communities that received the intervention will be higher compared to primary caregivers of children less than 5 years old residing in communities that did not receive the intervention (i.e. control).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 21/10/2019, Emory University Institutional Review Board (Emory University Institutional Review Board, 1599 Clifton Road, 5th floor, Atlanta, GA 30322, USA; Tel: +1 (0)404 712 0720; Email: irb@emory.edu), ref: IRB00115339
2. Approved 22/05/2019, Xavier University Bhubaneswar's Independent Ethics Committee

(Xavier Institute of Management, Xavier Square, Bhubaneswar – 751013, India; Tel: +91 (0) 6747764880; Email: peppin@xub.edu.in), ref: 220519

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Child feces management behaviors of primary caregivers of children less than 5 years old

Interventions
Current interventions as of 30/04/2021:
A baseline survey will be carried out across the 74 trial villages prior to implementation of the CFM intervention. The respondent for the survey will be the primary caregiver of the child aged <5 years. Once baseline data collection is complete, the villages will be assigned to intervention or control arm using stratified block randomization and no masking The treatment arm will receive a novel CFM behavioral intervention designed using the Risks, Attitudes, Norms, Abilities, Self-Regulation (RANAS) approach to behavior change (Mosler, 2012) and will also receive assistive hardware (wash basins, buckets with lids, and/or latrine training mat) developed through a user-centered design approach. The behavioral intervention will primarily aim to motivate caregivers to safely dispose of their child's feces into the latrine and/or to teach their child how to use the latrine themselves (i.e. toilet training). The behavioral intervention will be implemented by the NGO Gram Vikas in clusters (i.e. villages) allocated to the intervention arm. The control arm will not receive the intervention.

The CFM intervention includes six behavior change strategies (i.e. program activities):
1. Hardware and Action Knowledge Opening Meeting: The meeting starts with a discussion on typical CFM practices and why they are unsafe, followed by a video that tells the story of two mothers; one mother safely manages her child’s feces and another does not, illustrating messages related to health risks, costs and benefits, and the needs at different child development stages. The Gram Vikas mobilizer then uses a banner with illustrations to explain how to use the CFM hardware to safely dispose of children’s feces or teach them how to use the latrine. Volunteers are called upon to demonstrate the new information and then certain hardware is distributed to each caregiver depending on her child’s age (wash basin and bucket with lid for 0 to <7 months old; latrine training mat with tray for 7 to <48 months old). The meeting closes with a group commitment to use the new hardware and practice safe disposal

and/or child latrine training.
2. Building Self-Efficacy and Goal Setting Household Visits: The Gram Vikas mobilizer then visits each caregiver at her home and consults with them on their new practice, tailored to safe disposal and/or latrine training. During the visit the caregiver demonstrates her current practice, discusses any challenges she is facing and creates a barrier plan or is given tips, and creates a 'goal tracker' to monitor her progress in reaching the behavior change goal. The visit ends with the Gram Vikas mobilizer inviting other household members to express their approval of safe disposal/latrine training and to explain how they will support the caregiver. The second household visit is similar to the first but involves checking on the 'goal tracker' and having the caregiver positively self-reflect on her change.
3. Caregiver Support Group Meeting: Facilitated group meeting is held in-between the household visits to allow caregivers to reflect on their progress, re-commit to their goal of practicing safe disposal/latrine training, and provide strategies to fellow caregivers on how to address common challenges and offer words of encouragement to each other.
4. Celebrating 'Safe CFM Families' Closing Meeting: The final activity is a celebratory meeting that invites caregivers, their family members, and important village stakeholders (i.e. Anganwadi worker, VWSC members) to come together and share their experiences with adopting the safe CFM practices and its importance. The village stakeholders then give each caregiver a certificate to acknowledge her and her household's achievement.

Previous interventions:
A baseline survey will be carried out across the 74 trial villages prior to implementation of the CFM intervention. The primary respondent for the survey will be the primary caregiver of the child less than 5. The survey will include questions about household demographics, household water and sanitation, CFM practices, RANAS behavioral factors, perceived stress, and perceived social support. The survey will also include a structured spot check of the household's water and sanitation facilities. A sub-set of households will be approached for hand-rinse and drinking water samples to assess household-level fecal contamination. Once baseline data collection is complete, the villages will be assigned to intervention or control arm using stratified block randomization and no masking.

The treatment arm will receive a novel behavioral intervention designed using the Risks, Attitudes, Norms, Abilities, Self-Regulation (RANAS) approach to behavior change (Mosler, 2012) and will also receive assistive hardware, such as potties or latrine training mats, developed through a user-centered design approach. The behavioral intervention will primarily aim to motivate caregivers to safely dispose of their child's feces into the latrine and/or to teach their child how to use the latrine themselves. The behavioral intervention will be implemented by the NGO Gram Vikas in clusters (i.e. villages) allocated to the intervention arm. During implementation, a process evaluation will be carried out to document whether or not the intervention was implemented with fidelity.

The control arm will not receive the intervention.

*The behavioral intervention is currently being designed using the RANAS behavior change approach and as such, details of the exact intervention activities/components will be updated when complete.

Finally, an endline survey will be carried out across the 74 trial villages approximately 1 year after the baseline survey.

Intervention Type
Behavioural

Primary outcome measure

Current primary outcome measure as of 30/04/2021:
The primary outcome is safe disposal of child feces into the household latrine the last time the child defecated, which includes both the child using the latrine themselves or the caregiver disposing of the child's feces into the latrine. This is a behavioral outcome that will be self-reported by the primary caregiver of the child less than 5 years old (or by a secondary caregiver if the primary caregiver is not available). The primary outcome will be measured between December 2019 to February 2020, prior to exposure to the intervention, and again approximately 3 to 5 months post intervention delivery.

Previous primary outcome measure:
The safe disposal of child feces into the household latrine the last time the child defecated, which includes both the child using the latrine themselves or the caregiver disposing of the child' s feces into the latrine. This is a behavioral outcome that will be self-reported by the primary caregiver of the child less than 5 years old (or by a secondary caregiver if the primary caregiver is not available). The primary outcome will be measured between December 2019 to February 2020, prior to exposure to the intervention, and approximately 1 year later after this baseline measurement.

Secondary outcome measures

Current secondary outcome measures as of 30/04/2021:
Measured between December 2019 to February 2020, prior to exposure to the intervention, and approximately 3 to 5 months post intervention delivery:
1. Child latrine training measured through self-report by the caregiver using a structured survey
2. Latrine use of children up to age 10 years old measured through self-report by the caregiver using a structured survey
3. RANAS behavioral factors measured through self-report by the caregiver using a structured survey
4. Received social support measured through self-report by the caregiver using a structured survey
5. Fecal contamination of the household environment, measured using different environmental sampling techniques such as hand-rinses and drinking water samples analyzed for levels of E. coli

Previous secondary outcome measures:
Measured between December 2019 to February 2020, prior to exposure to the intervention, and approximately 1 year later after this baseline measurement:
1. Child latrine training measured through self-report by the caregiver using a structured survey
2. Latrine use of children up to age 10 years old measured through self-report by the caregiver using a structured survey
3. RANAS behavioral factors measured through self-report by the caregiver using a structured survey
4. Perceived social support measured through self-report by the caregiver using a structured survey
5. Fecal contamination of the household environment, measured using different environmental sampling techniques such as hand-rinses and drinking water samples analyzed for levels of E. coli

Overall study start date

01/04/2019

Completion date

30/12/2021

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 30/04/2021:
Participant-level inclusion criteria:
1. Woman or man of at least 18 years of age
2. Primary caregiver of at least one child less than 5 years old (for baseline survey this is children less than 5 at the time of survey data collection while for the endline survey this is children who were less than 5 at the time of intervention delivery). If primary caregiver is not available then a secondary caregiver of the child is also eligible for inclusion
3. Household has a latrine
N.B. The study will also engage a sub-set of children ages 0 to 5 years old from eligible households in a hand rinse sample. Participants less than 18 years old will not be engaged in any other research activities, however.

Village-level inclusion criteria:
1. Completed Gram Vikas MANTRA program (a community-based water and sanitation infrastructure program)
2. At least 75% of households in the village have access to a latrine
3. Community water supply system (i.e. water tank) is functional
4. Village size is between 35 to 250 households
5. Village has an Anganwadi Center (government-run daycare and preschool center)
6. Gram Vikas has no significant programming planned for the village during the study period
7. Village was not part of formative research phase of the study

Previous participant inclusion criteria:
Participant-level inclusion criteria:
1. Woman or man of at least 18 years of age
2. Primary caregiver of at least one child less than 5 years old (child age based on age at time of baseline recruitment). If primary caregiver is not available then a secondary caregiver of the child is also eligible for inclusion
2. Household has a latrine
N.B. The study will also engage a sub-set of children ages 0 to 5 years old from eligible households in a hand rinse sample. Participants less than 18 years old will not be engaged in any other research activities, however.

Village-level inclusion criteria:
1. Completed Gram Vikas MANTRA program (a community-based water and sanitation infrastructure program)
2. At least 75% of households in the village have access to a latrine
3. Community water supply system (i.e. water tank) is functional
4. Village size is between 35 to 250 households with at least 5 eligible households (i.e. have a latrine and at least one child less than 5 years old)
5. Village has an Anganwadi Center
6. Village was not engaged during formative research activities
7. Predominant language of village is Oriya
8. Gram Vikas has no significant programming planned for the village in 2020

Participant type(s)

Mixed

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
Anticipate around 850 participants across 74 clusters with an average of about 11 participants per cluster. All households that meet the participant inclusion criteria will be approached for recruitment and thus, the exact number of participants enrolled in each cluster is not yet known.

Key exclusion criteria
Participant exclusion criteria:
1. Less than 18 years old (except for the hand rinse sample which will engage children ages 0 to 5 years old)
2. Not a primary or secondary caregiver of a child less than 5 years old
3. Household does not have a latrine

Date of first enrolment
02/12/2019

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
India

Study participating centre
Gram Vikas
Mohuda Village
Brahmapur, Odisha
India
760002

Sponsor information

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University/education

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Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, 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

Publication and dissemination plan
Current publication and dissemination plan as of 30/04/2021:
The researchers aim to submit a study protocol for publication. They anticipate reporting the trial results by December 2021, which will include results from an intention-to-treat analysis showing whether or not intervention status was associated with a change in the primary outcome (safe disposal of child feces). They anticipate publishing the trial results in a peer-reviewed journal by end of 2021 and presenting the trial results at relevant conferences.

Intention to publish date

30/12/2021

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

Previous publication and dissemination plan:
The researchers aim to submit a study protocol for publication. They anticipate reporting the trial results by August 2021, which will include results from a multivariate analysis showing whether or not intervention status was associated with a change in the primary outcome (safe disposal of child feces). They anticipate publishing the trial results in a peer-reviewed journal by end of 2021 and presenting the trial results at relevant conferences.

IPD sharing statement
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Study design and rationale	15/01/2022	17/01/2022	Yes	No
Results article		27/08/2024	29/08/2024	Yes	No